THEME 17

CHARACTERISTICS OF DIETARY SUPPLEMENTS, ANALYSIS OF INDIVIDUAL DIETARY SUPPLEMENT INGREDIENTS, SAFETY DETERMINATION AND APPLICATION

Motivational statement

Nutrition is one of the main factors of living conditions that shape human health and quality of life. Recently, a new field of knowledge has emerged – pharmaconutritionology, which is the borderline between nutrition science and pharmacology. The outstanding Russian scientist academician A.A. Pokrovsky noted that "... food should be considered not only as a source of energy and plastic substances, but also as a very complex pharmacological complex."

Studies of nutrition, energy consumption and population health, conducted in many countries of the world, have shown a significant change in the structure of human nutrition over the past 100 years. At the same time, the consumption of essential nutrients, especially micronutrients and biologically active food components, decreased.

The diet is usually characterized by excessive consumption of animal fats and easily digestible carbohydrates, and at the same time, for the majority of the population, the diet is significantly deficient in the content of polyunsaturated fatty acids (omega-3 and omega-6); soluble and insoluble dietary fiber (pectin, gums, mucus, cellulose, etc.); vitamins; a wide range of vitamin-like substances of natural origin (L — carnitine, ubiquinone, choline, lipoic acid, etc.); macronutrients (calcium, etc.); trace elements (iodine, iron, selenium, zinc, etc.).

The search for alternative solutions to this crucial problem has led scientists to the idea of the need to develop technologies for obtaining complexes of dietary supplements from natural sources in essentially chemically pure form.

Dietary supplements are compositions of natural or identical to natural biologically active substances intended for intake with food or for introduction into food products to enrich the diet with food or biologically active substances and their complexes.

Taking into account all the above, it should be noted that the mass introduction of dietary supplements to food allows us to solve the problem of providing the population with the scarcest nutrients that will help increase the resistance of the human body to adverse environmental conditions, improve the quality of life of patients, reduce the risk of the most common diseases, and as a result significantly improve the health indicators of the nation in as a whole.

The objective: to form students' understanding of nutrition as an environmental factor and its impact on humans. To familiarize students with the concept of dietary supplements, classification, functions, role for the human body, with the basic regulatory framework governing the circulation of dietary supplements.

Questions for discussion

- 1. General characteristics of dietary supplements.
- 2. Classification of dietary supplements.
- 3. The role of dietary supplements in human nutrition.
- 4. Differences between dietary supplements and medications.
- 5. Functional role of nutraceuticals.
- 6. Physiological significance of parapharmaceuticals.
- 7. Functional role of eubiotics.
- 8. Regulatory issues of turnover of dietary supplements, their safety.
- 9. Features of the sale of dietary supplements in Russia.
- 10. Procedure for establishing the safety of food additives.

Independent work of students

- 1.Situational problems. Reference material, tables and recommended literature may be used. The situational problems should be reported in writing.
 - 2. Discussion report prepared by the students on an individual task of a teacher.

Task 1. Fill out the table with information about dietary supplements available in retail (obtain from your teacher). Analyze the relationship between the functional purpose of dietary supplements and micronutrients (minors) contained in them. Compare daily dose micronutrients and minors (recommended by manufacturers) adequate with standards their consumption, using MP 2.3.1.1915-04 "RECOMMENDED LEVELS CONSUMPTION OF **FOOD** AND **BIOLOGICALLY ACTIVE** SUBSTANCES" https://ohranatruda.ru/upload/iblock/5e9/4293846547.pdf.

Table 1

Tradin	Dietary	Terms	Functional	Daily	Content
g	supplement	and	new		micronutrient
brand		condition	appointment		s (minor) in

(Name)	Manufacture	S	dietary	dosag	daily
	r	storage,	supplement,	e	allowance
		number	contraindicatio		dosage
		SGR	n		

Conclusion			and
recommendati	ons:		

An example of a table to fill out based on information from labels and annotations of dietary supplements

Tradin	Dietary	Terms and	Functional	Daily	Content
g	supplement	conditions	new	dosag	micronutrie
brand	Manufactur	storage, number	appointment	e	nts (minor)
(Name	er	SGR	dietary		in
)			supplement,		daily
			contraindicati		allowance
			on		dosage
Allico	INAT-	At a temperature not	Maintenance	2	Allicin, 5
r	PHARMA	above +30°C in dry	functions	tablet	mg
	PHARMA	place, guaranteed	cordially-	S	
		shelf life 24	vascular	150	
		months from the	systems,	mg	
		date	normalization		
		manufacturing,	lipid		
		SGR	exchange		
		77.99.10916.B.00			
		371.			
		08.03			

Task 2.	Solvi	ng situ	ational pr	ofes	siona	lly oriented	l proble	m №			
 											
										 	
			Answer			questions.	Select	one	or	more	answer
										 	
											

Reference material

Dietary supplements are natural (identical to natural) biologically active substances intended for consumption along with food or for inclusion in food products.

Adequate level of consumption - the level of daily consumption of food and biologically active substances, established on the basis of calculated or experimentally determined values, or estimates of consumption of food and biologically active substances by a group/groups of practically healthy people (using epidemiological methods), for which this consumption (with taking into account health indicators) is considered adequate (used in cases where the recommended amount (norm) of consumption of food and biologically active substances cannot be determined).

Dietary supplements are used as an additional source of food and biologically active substances to optimize carbohydrate, fat, protein, vitamin and other types of metabolism in various functional states, to normalize and/or improve the functional state of organs and systems of the human body, incl. products that have restorative,

mild diuretic, tonic, sedative and other types of effects in various functional conditions, to reduce the risk of diseases, as well as to normalize the microflora of the gastrointestinal tract, as enterosorbents.

Dietary supplements must meet the quality requirements established by regulatory documents in terms of organoleptic, physicochemical, microbiological, radiological and other indicators for the permissible content of chemical, radiological, biological objects, prohibited components and their compounds, microorganisms and other biological agents that pose a danger to human health.

In biologically active food additives, the content of the main active ingredients is regulated. However, unlike medicines, Russia does not provide for mandatory certification or declaration (quality testing by independent laboratories) of each batch of dietary supplements. The quality of dietary supplements is checked almost only during production, which is often taken advantage of by unscrupulous manufacturers, violating technology and recipes. In addition, clinical studies of the use and effect of dietary supplements are not mandatory. All of the above, together with unreliable (and often aggressive) advertising, creates fertile ground for fraud and deception in the production and sales of dietary supplements.

In the Russian Federation, examination of documentation, medical and biological assessment, sanitary-chemical, microbiological and other necessary studies of dietary supplements, as well as, if necessary, making a decision on their clinical testing, are entrusted to the Center for Hygienic Certification of Food Products of the Department of Sanitary and Epidemiological Surveillance of the Ministry of Health of the Russian Federation, which is located on the basis of the Institute of Nutrition of the Russian Academy of Medical Sciences. In some cases, this work is carried out jointly with other authorized institutions.

Dietary supplements are included in the "List of products subject to state registration with the Federal Service for Surveillance on Consumer Rights Protection and Human Welfare."

The right to produce, use, sell dietary supplements on the territory of the Russian Federation, as well as import dietary supplements, is given by the Certificate of State Registration (SGR).

For dietary supplements that have passed state registration in accordance with the Resolution of the Chief State Doctor of the Russian Federation "On state registration of biologically active food additives" No. 21 dated September 15, 1997, a federal register of biologically active additives (BAA) is maintained. Information about dietary supplements, agreed with Rospotrebnadzor, is open and is kept up to date on its Search server on the official website of Rospotrebnadzor http://fp.crc.ru.

The registration certificate contains information about the name of the dietary supplement, the manufacturer and recipient of the certificate for the dietary

supplement, their addresses, the certificate number and the date of its issue, the scope of the dietary supplement, the composition and hygienic characteristics of the dietary supplement.

The production, circulation and sale of dietary supplements in the Russian Federation is regulated by SanPiN 2.3.2.1290-03 "Hygienic requirements for the organization of production and circulation of biologically active food additives (BAA)".

The SGR is valid for the entire period of production of dietary supplements, i.e. is actually an indefinite document.

Before the introduction of the state registration procedure, dietary supplements underwent a sanitary and epidemiological examination, the results of which were included in the sanitary and epidemiological report (SEZ) or registration certificate (RU). These documents were valid for 3-5 years, after which a reexamination was necessary. All SEZ and RU, the terms of which have not yet expired, continue to be valid together with the SGR for newer dietary supplements. Information about the majority of existing SEZs and RUs is also included in the database of the Rospotrebnadzor Search Server.

Information on the packaging of dietary supplements should contain:

- names of dietary supplements, and in particular:
- manufacturer's trademark (if available);
- designations of regulatory or technical documentation, the mandatory requirements of which must be met by dietary supplements (for dietary supplements of domestic production and CIS countries);
- composition of dietary supplements, indicating the ingredient composition in order corresponding to their decrease in weight or percentage terms;
 - information about the main consumer properties of dietary supplements;
- information on the weight or volume of dietary supplements in a unit of consumer packaging and the weight or volume of a unit of product;
 - information about contraindications for use in certain types of diseases;
 - indication that the dietary supplement is not a medicine;
- date of manufacture, warranty expiration date or deadline for the sale of products;
 - storage conditions;
- information on state registration of dietary supplements indicating the number and date;

• location, name of the manufacturer (seller) and location and telephone number of the organization authorized by the manufacturer (seller) to accept claims from consumers.

Retail trade in dietary supplements is carried out through pharmacies (pharmacies, pharmacy stores, pharmacy kiosks, etc.), specialized stores selling dietary products, food stores (special departments, sections, kiosks).

The sale of biologically active additives is not allowed:

- 1) Who have not passed state registration;
- 2) Do not have documents confirming their safety;
- 3) Expired;
- 4) In the absence of appropriate conditions for implementation;
- 5) Without label;
- 6) In the case when the information on the label does not correspond to the information agreed upon during state registration;
- 7) In the absence of information on the label, applied in accordance with the requirements of current legislation;
 - 8) Without packaging or if its integrity is damaged;
 - 9) With obvious signs of poor quality.

To extend the shelf life of products and give them a marketable appearance, food additives are used.

In accordance with SanPiN 2.3.2.1290-03 "Hygienic requirements for the organization of production and circulation of biologically active food additives (BAA)", retail trade of dietary supplements can only be carried out through pharmacies (pharmacies, pharmacy stores, pharmacy kiosks and others), specialized stores sale of dietary products, food stores (special departments, sections, kiosks).

Classification of dietary supplements

There are various classifications of dietary supplements depending on their composition, functional activity, effects, etc.

Based on their composition, dietary supplements are divided into the following groups: **nutraceuticals, parapharmaceuticals and eubiotics**.

Nutraceuticals are biologically active food additives used to correct the chemical composition of human food.

Nutraceuticals are essential nutrients or their close precursors. This group of dietary supplements can rightfully be classified as food, since in most cases it is represented by well-studied natural components, the physiological need and biological role of which have been established.

Nutraceuticals include: vitamins, provitamins, macro-microelements, polyunsaturated fatty acids, amino acids, carbohydrates, dietary fiber.

Sources of amino acids: are produced in most cases in the form of easily digestible, ready-made dry carbohydrate-protein-fat-mineral-vitamin mixtures, which contain a high amount of milk, egg, and soy proteins with a digestibility of 97%. Their main function is to additionally enrich the traditional diet with essential amino acids (methionine, lysine). They are often used by athletes to accelerate the growth of muscle mass, and are used for diseases of the liver and blood vessels.

Sources of fatty acids, fat-soluble vitamins and lipids: The Russian population is deficient in linolenic and eicosapentaenoic acids (polyunsaturated fatty acids), and their role in the body is extremely high. For example, in the construction of cell membranes. Natural sources of such acids are soybean and flaxseed oil. To compensate for their deficiency, various supplements are also produced. Supplements containing phospholipids are produced to increase the activity of antioxidant systems. In the prevention of cardiovascular diseases, it is recommended to use supplements containing fat-soluble vitamins.

Sources of carbohydrates: used mainly by patients with diabetes. Such dietary supplements contain fructose, inulin, xylitol and other sweeteners. They enhance metabolism, improve glucose tolerance and insulin sensitivity. Currently, various supplements containing inulin based on the juice of vegetables, fruits and berries have been developed.

Sources of fiber: these include pectin, bran, vegetable fiber, cellulose. Available in the form of mixtures. The gel-forming properties of pectin make it possible to use it as an enveloping agent in the treatment of gastrointestinal diseases. It is obtained from: citrus fruits, apples, beets, sunflowers, watermelon, pumpkin, grapes, cotton, etc. Sources of water-soluble vitamins: The most effective forms of these vitamins are powdered vitamin drinks.

Sources of minerals: in recent years, complex supplements containing macro- and microelements with anti-carcinogenic effects have been developed. At the same time, they try to make them as easily and quickly digestible as possible.

Parapharmaceuticals are biologically active food additives used for prevention, auxiliary therapy and support within the physiological boundaries of the functional activity of organs and systems.

These are, as a rule, products containing minor food components - bioflavonoids, organic acids, glycosides, biogenic amines, regulatory oligopeptides, polysaccharides, oligosugars, etc.

Eubiotics (**probiotics**) are biologically active food additives, which contain live microorganisms and (or) their metabolites, which have a normalizing effect on the composition and biological activity of the microflora of the digestive tract.

In turn, they are divided into 3 groups: probiotics, synbiotics, prebiotics.

Probiotics are drugs of microbial origin, while prebiotics are non-bacterial in nature.

Synbiotics are drugs obtained by rationally combining pro- and prebiotics.

The most common probiotics are bifidobacteria and lactobacilli. They are used to prepare various food products such as yogurt, kefir, bifidoc, ice cream or even candy. Probiotics are used to prevent microbial imbalance in the body, as well as for intestinal inflammation, gastritis, acute intestinal infections, etc.

Prebiotics include various carbohydrates. For example, inulin, lactosulu, galacto-, fructo-, oligosaccharides. Despite the fact that prebiotics are not digested or absorbed in the upper parts of the digestive tract, they are capable of causing active growth and reproduction of bifidobacteria and lactobacilli.

The difference between dietary supplements and medications

It should be especially noted that the mechanisms for implementing the therapeutic and prophylactic effects of pharmacological drugs and dietary supplements are significantly different. The only exception is, perhaps, the treatment with dietary supplements of classical deficiency conditions, such as scurvy or beriberi. In other cases, the main principles of the treatment and prophylactic action of dietary supplements and pharmacological drugs differ significantly.

Dietary supplements	Medicines					
Specificity of action						
Regulation of a very wide range of biochemical reactions and physiological functions. A specific action is always accompanied by nonspecific effects, reactions that are beneficial to health.	action. Nonspecific effects most often manifest themselves as toxic or side					
Physiological action						
The therapeutic effect is realized through physiological evolutionarily fixed mechanisms.						
Toxicity and adverse reactions						
For most micronutrients there is no toxic dose because they have been	Many medications are characterized by toxic reactions and complications					

are natural components of food.	due to the very narrow interval between therapeutic and toxic doses.			
Speed of ach	ieving effect			
Speed of defi	ic ving circut			
Achieving a positive and sustainable	The effect is quick but short-lived.			
effect is usually slow.				
Interaction wi	th other drugs			
Interaction with other micronutrients	Interactions with other			
in most cases is characterized by	pharmaceuticals are often			
synergy and complementarity of	characterized by antagonism,			
beneficial effects and the elimination	neutralization of the therapeutic			
of possible undesirable reactions.	effect, or aggravation of toxic			
	reactions.			

Principles of using dietary supplements

The use of additives is based on some principles:

- 1. The principle of functionality and consistency. That is, the impact must be complex, since the functioning of organs in the body is directly related to nutrition.
- 2. The principle of phasing. At different stages of the disease, it is advisable to select different supplements. For example, in the first stages it is necessary to urgently eliminate the symptoms of the disease, and at the end of treatment, eliminate the toxic effect of taking medications.
- 3. The principle of adequacy. It is necessary to prescribe dietary supplements, taking into account the nature of the disease and the characteristics of its course.
- 4. Syndromic principle. The prescription of biological additives should be made taking into account those symptoms that are pronounced. The principle of optimality. When treating or preventing diseases, the dosage must be selected individually.
- 5. Combination principle. Dietary supplements can be combined with food and other medications.

Analyzing all the principles, we can say about dietary supplements that this is a product that must be used in combination with other therapy during illness. It is impossible to cure with supplements alone.

There are a number of recommendations for the use of dietary supplements:

 \checkmark it is better to start using the supplement in small quantities in order to assess

the body's response to this product;

- ✓ for best absorption of the supplement, manufacturers recommend taking it with food. However, dietary supplements that contain potassium must be consumed between meals to avoid a decrease in the concentration of hydrochloric acid in the stomach;
- ✓ in the first half of the day they take supplements that increase the tone of the body so that excessive activity does not interfere with falling asleep;
- ✓ eubiotics containing live microorganisms are stored strictly in the refrigerator so that bacteria do not have the opportunity to rapidly grow and reproduce, which leads to spoilage of the additive;
- ✓ you should not independently increase the portions of dietary supplements consumed, except in cases where this is recommended by a doctor;
- ✓ taking several dietary supplements at once without consulting a doctor can lead to negative consequences; Dietary supplements are stored in a dark, dry place, protected from direct sunlight.