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REGULATIONS ON FUNCTIONAL PRODUCTS IN DIFFERENT COUNTRIES

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Abstract

The paper presents a comparison of standards for the manufacture of functional products in the world, provides normative documents for the countries presented in the article. Regulatory principles relating to functional foods in general also apply to functional dairy products. In addition, in the case of probiotic products with laws and regulations regarding the use of yeasts, or intentionally added live microbial cultures used in the food production process, should also be taken into account. Such practices vary considerably from country to country, but in general the human status of probiotics is very unclear, while microbiological feed additives are subject to detailed regulation in the EU.

Keywords: functional food products, bifidobacteria, lactobacilli, plant fillers, biological value. prebiotics, probiotics, bifidobacteria, lactobacilli, fruit and berry enrichments, thickeners, fermented sour milk desserts.

In recent years, there has been a steady increase in the consumption of functional products. Their popularity is due to the variety of taste, composition, consistency, which meets the needs of a wide range of consumers. Ingredients that give products functional properties meet the following requirements: have a positive effect on nutrition and health, are safe in terms of a balanced diet, have accurate physico-chemical parameters, should not reduce the nutritional value of products, taken orally as food, have the appearance ordinary food, be natural [7].

The Ministry of Health of Ukraine notes that the Law "On Food Safety and Quality" regulates the production and circulation of food, including for special functional nutrition.

Functional food product - is a food product that contains as a component of drugs and herbal components that are used to prevent or mitigate the course of human disease [2]. According to some authors, almost 25% of food products in the EU belong to functional foods [6]. Traditional fermented milk products, which include bifidobacteria, which dominate in the normal intestinal microflora of a healthy body, can also be included in functional foods. Bifidobacteria regulate the qualitative and quantitative composition of the normal intestinal microflora, inhibit the growth and prevent the reproduction of pathogenic, putrefactive and gas-forming microflora, restore the damaged structure of the intestinal mucosa. Along with other representatives of the normal intestinal microflora, bifidobacteria are involved in digestion and absorption, synthesis of B vitamins, vitamin K, folic and nicotinic acids, promote the synthesis of essential amino acids, better absorption of vitamin D and calcium salts, which stimulate the activity of immune protective functions of the body [4]. The standard defines a functional food product as a product intended for systematic consumption in the diets of all age groups of a healthy population. It reduces the risk of eating disorders, maintains and improves health due to the presence of physiologically functional foods.

According to the famous German scientist Prof. KO Honickel, the functional product is:

a food product (not an additive, pill or powder) derived from natural ingredients;

a product included in a person's daily diet;

a product that regulates certain processes in the body.

Some scientists consider functional products that are created by man in order to give them certain properties aimed at maintaining health.

The functional mainly include products:

enriched (with the addition of vitamins, micronutrients, dietary fiber, etc.);

from which compounds not recommended by doctors (trace elements, glycosides, lactose, etc.) were removed;

in which some substances are removed and replaced by other components.

Traditionally they are divided into:

dietary, aimed at the treatment of food-dependent diseases;

prophylactic purposes (cardiovascular, obesity, etc.);

specialized, aimed at one function (for athletes);

enriched (added or substituted micronutrients);

An effective way to normalize the imbalance of the intestinal microflora is the creation of symbiotics (a complex of pro- and prebiotics) and the manufacture of products based on them, which will stimulate the development of its own intestinal microflora and increase the body's defenses [8].

Functional products do not exist as a legal term in either the US or the EU. Nutrition can be considered functional if it is satisfactorily shown to have a beneficial effect on one or more target functions in the body, in addition to adequate nutritional properties, so that it is either related to improving health and well-being and reducing the risk of disease. Functional foods should remain foods and they should demonstrate their effects in amounts that can usually be expected from eating in

the diet: they are not pills or capsules, but part of normal food.

Functional food can be a natural food, to which was added a component, or a food product from which the component was removed by technological or biotechnological method. It is also food.

The nature of one or more components have been changed, or any combination is possible. Functional food can be functional for all members of the population, or for certain groups of the population, which can be determined, for example, by age or by genetic constitution.

In Japan, the Ministry of Health and Welfare introduced in 1991 the concept of foods for specific medical uses or foods that are intended for consumption as part of a regular diet, and to promote the development and maintenance of health by regulating the body's functions , as well as protection against a number of conditions and diseases, including cardiovascular disease, hypertension, diabetes and osteoporosis [1].

Despite a slightly different wording in different definitions, the general principles of functional foods are intended for consumption in normal amounts and have a beneficial effect, unrelated food effects, are common and can also be applied to functional dairy products.

Functional products, similar to dietary supplements, perform the following functions:

compensate for deficiencies of biologically active components in the body;

support the normal functional activity of organs and systems;

reduce the risk of various diseases, create a dietary background;

support the beneficial microflora in the human body and the normal functioning of the gastrointestinal tract.

The EU Food Act defines a functional product as follows: "Functional food is any modified food or food ingredient that may have a beneficial effect on human health in addition to the traditional nutrients it contains." According to some sources, the European market for functional products in 2003 was estimated at $ 3.3 billion, of which functional dairy products accounted for 65%, bakery products - 9, various pastes, soft cheeses, jams and other types 23, drinks that have a positive effect on human health (vitaminized and therapeutic for athletes, the elderly, pregnant women, etc.) - 3%. In the United States in 2003, revenue from the sale of functional foods to the population amounted to 44.1 billion dollars.

The main function of food can be considered to strengthen human health. According to the Federal Food and Necessity Act (LMBG, Germany), foods are substances that are mainly consciously and unconsciously consumed by a person in unaltered culinary or processed form to meet his food needs and / or taste habits. Most foods can combine both food and flavor, and some can be purely food or purely flavoring.

Despite the fact that food has always performed the function of providing human nutrition, the concept of "functional foods" has been introduced, which due to the presence of certain additives that have a positive (beneficial) effect on human health, are able to fill the nutrient deficiency [2].

The concept of functional foods appeared in Japan for the popular products there "Tokutci Hohenyo Shokuhin" and meant: foods that, along with nutritional and physiological value, bring therapeutic benefits.

The functionality of the products is quite noticeable since the early 80's, when the European market was introduced foods enriched with vitamins and iodine (multivit amine juices, iodized sausages and confectionery). With the advent of probiotic dairy products (1995) in the minds of people fixed the concept of "functional foods". At the same time, in the industrial sector of beverages, the direction of ZFS has become established, ie the enrichment of fruit juices, refreshing and dairy drinks with vitamins, micronutrients and minerals. Recently, the group of functional foods also includes jams, confectionery, bakery, sausages (Table 1).

Table 1

ACTIONS of additives and groups of products in which they are made

Product group	Additives	Functional action	Food products
ACE group	Vitamin A (β-carotene)	Cell protection, disease prevention	Drinks, jams, confectionery and frozen foods
	Vitamin C	Cell protection, disease prevention	Tea, ice cream, dairy products
	Vitamin E	Cell protection, disease prevention	Soups
ALL-group +	Vitamin B	Improving concentration, activity	Drinks, confectionery
	Vitamin C	Cell protection	Refreshing drinks
	Vitamin E	Cell protection	Refreshing drinks
	Vitamin D	Improves calcium absorption	Refreshing drinks, dairy and confectionery
Probiotics	Probiotic lactic acid bacteria	Positive effect on the intestinal flora, strengthening	Dairy products, cheeses, cereals, sausages, fruit juices, milk drinks
		Improving the immune system	
Prebiotics	Ballast substances, inulin, oligofructose, fiber	Improving the activity of intestinal flora and digestion	Yogurts, cereals, confectionery, fruit juices, dairy drinks
Minerals	Calcium	Protection against osteoporosis	Confectionery, mineral water

	Magnesium	The structure of the muscles that are exposed to the load	Refreshing drinks
	Potassium	Increased activity, protection of nerves	Refreshing drinks
Trace elements	Iron	Hematopoiesis	Refreshing drinks
	Iodine	Improving the thyroid gland	Table salt, confectionery, ready and frozen foods, sausages
	Selenium	Cell protection	
Fatty acids omega-3	DNA = docosahexaenoic acid, EPA = eicosapentaenoic acid, highly unsaturated fatty acids	Protective effect on the cardiovascular system, improving blood circulation properties	Eggs, soft drinks, confectionery, sausages
Secondary plant substances	Lycopene	Protection of cells, anti-cancer effect	Dough products
	Lutein	Cell protection, anti-cancer effect	Refreshing drinks
	Flavonoids, green tea extract	Cell protection, anti-cancer effect	Refreshing drinks, tea, muesli, confectionery products, pastes for sandwiches
	Phytosterols	Positive effect on blood cholesterol	

In Germany, functional products are evaluated differently. Due to the fact that they belong to food products, their production is subject to the law of the LMBG, according to which the advertising of such products on the basis of therapeutic action is prohibited. If

new products are coming into circulation, safety for consumer health must be confirmed. Their positive effect has not been determined either, as this would require testing each individual product for its therapeutic value.

The attitude to functional products in the Scandinavian countries is ambiguous. Finland is considered "Silicon Valley" in terms of functional products; Sweden, Norway and Denmark are cautious in their assessments.

A study conducted by the IDA Center at the Business School in Ophus on the different attitudes towards functional foods to consumers in Denmark, Finland and the United States found that Finnish consumers perceive functional foods better than Danish and American consumers.

Many health promotion companies have been set up in Finland. Among such products are the following [3].

Xylitol is considered to be the first functional food ingredient in Finland that has been scientifically proven to have a health effect. For example, it is used as a sweetener in toothpaste and chewing gum.

The Finnish dairy company Valio was the first to research and launch probiotics.

Benecol is a very valuable ingredient of Finnish origin for the production of functional products. It is added to vegetable margarine because it lowers cholesterol.

Among other products, Pan Salt - has a beneficial effect on blood pressure, Multi-Bene - is suitable for lowering blood pressure and inhibits the development of some forms of cancer, used in dairy products for people who are lactose intolerant. Therefore, Finland is considered in all respects a world leader in the development and sale of functional foods.

In other Scandinavian countries, labels have limited use of information on the effects of relevant additives on human health.

In Sweden, there is a "Center for Improvement and Innovation in Functional Products". The country is also working to establish a National Center for Clinical Research on Food for Their Health Impacts, and the Swiss Nutrition Fund is developing a program to monitor "specific information" about the health effects of products supplied by functional food manufacturers.

In Norway, consumers know very little about functional foods, and Danish consumers are more wary of them.

Provisions on functional foods should specifically focus on safety, efficacy and claims related to the proposed benefits. While the general principle that all foods should be safe applies to naturally functional foods, specific safety aspects associated with a particular functional component or modification may need to be addressed. The benefits must be clearly demonstrated and must be communicated to consumers in such a way that claims do not blur the distinction between food and medicine - a difference that is widely considered necessary by law enforcement officials. The following examples of chapters implementing these general principles within different legal and regulatory traditions are outlined.

Functional foods can be divided into the following groups:

—Products enriched with the appropriate content of macro- and micronutrients;

—Dietary and medical direction - aimed at eliminating food-related human diseases;

—Therapeutic and prophylactic purposes - aimed at the prevention of common diseases;

—Specialized - narrowly focused on the relevant functions of the body (radioprotective, detoxifying, immunomodulatory and other actions or nutrition in extreme conditions);

—Baby and gerontological nutrition.

Functional products are quite common in many countries around the world. In some European countries, government subsidies are provided for the enrichment of food with vitamins and micronutrients. In Japan, the active study of pro- and prebiotics began in the 80's. Now this country ranks first in life expectancy, which experts associate with the use of probiotic and prebiotic products. The market for functional products in Japan reached about 6.8 billion dollars. USA.

Consumption of functional products of mass consumption, including those enriched with essential micronutrients, is considered to be one of the most effective and economically justified ways to correct the existing deficiency of essential substances. The problem of micronutrient deficiency can be solved by developing and including in the diet of functional products, including those enriched with essential nutrients and dietary supplements. It is important to carry out a comprehensive commodity assessment of foods enriched with micronutrients.

Japan Researchers distinguish three main groups of properties of functional products:

—High nutritional value;

— Pleasant organoleptic properties;

—Positive functional action.

Information on functional products that are developed and used in Japan are presented in table. 2.

Table 2

Functional foods in Japan

FOSHU products	Functional ingredient
Improve bowel function and prevent, diseases of the gastrointestinal tract	Oligosaccharides, fiber. Lactic acid bacteria
Lower cholesterol	Soy proteins. Chitosan
Reduce the content of neutral fats	Diacylglycine
Hypoglycemic	Dextrins, wheat albumins
Improve the absorption of minerals	Phosphopeptides, oligosaccharides

As noted above, functional US foods are not recognized as special, but belong to the federal food. Other relevant legislation includes nutrition, labeling systems and dietary supplements, which are mainly certain contraindications that may be attached to foods. The Food and Drug Administration plays a key role in assessing the evidence for health claims, although other US government bodies or the National Academy of Sciences may also provide authoritative conclusions about the health effects of food [4].

Japan is probably the only country where there is a formalized procedure for approving functional foods. The 1991 FOSHU system was revised in 2001 by MHLW by introducing a new category: "Food for Health", which is divided into two subcategories: namely, food with nutritional functions. Until 1991, only ordinary foods were not eligible for status FOSHU, but subsequently dietary supplements (in the form of tablets and capsules) were also included in the system (it should be noted that they are not functional products according to the European definition of FUFOSE.) In 2005, the FOSHU category was also divided into three subsystems: , standardized by FOSHU and Qualified FOSHU.

In order to obtain FOSHU status, the applicant must identify the main functional ingredient (s), determine the mechanism of action (standardized FOSHU), and specify how the product will help to improve the diet. Product safety can be demonstrated in a variety of ways, based on a history of safe use or toxicological studies. The effectiveness of the product must be demonstrated through clinical trials. Standardized FOSHU products require a statistical significance of P-value <0.05 compared to control in a clinical trial for effect (s) to demonstrate. In qualified FOSHU, the mechanism of action of the functional component may be unknown, and the P-value for statistical significance may be <0.1. If the mechanism of action is known, non-randomized controlled clinical trials are also acceptable for qualified FOSHU status.

There is no specific legislation in the EU on functional foods other than the Common Food Law 178/2002 EC. This provision sets out the general principles and requirements of food law, including food safety, and establishes the European Food Safety Authority (EFSA). Regarding aspects of safety and efficacy of functional foods (and feeds), specific EU rules and directives on novel foods, genetically modified foods and feeds, and feed additives are relevant [5].

New food regulation

The Novel Food Regulation (EC 258/97) defines foodstuffs or food ingredients that were not consumed significantly in the EU until 1997 as a novel and are assessed for safety before they can be placed on the market. Genetically modified or genetically modified foods have subsequently been removed from the scope of Novel food regulation and subject to certain rules on genetically modified foods and feeds.

According to the ordinance, the new food should not pose a danger or mislead the consumer or be nutritionally different from the usual analogue that it is going to replace that there may be a shortage of food. These aspects are taken into account when evaluating new foods destined for EU markets.

The evaluation procedure starts in the Member State where the applicant first wants to introduce a new food product. The application is sent to the competent authority of the country that carries out the initial evaluation of the product within 90 days. This assessment, together with the details of the application, shall be communicated to the Commission and to the other Member States. Member States have 60 days for a question, comment or object. Disagreements are discussed in the Standing Committee on the Food Chain

and Animal Health (PCCC), which represents the Member States and decides by a qualified majority. In addition, the scientific opinion of the European Food Safety Authority (EFSA) is regularly required.

In case the SCRC cannot make a decision, the application is submitted to the Council of Ministers. If the Council of Ministers is unable to act or does not obtain a qualified majority on the matter within three months, the final decision shall be moved to the Commission.

Although a functional food is not necessarily a new food, several functional products (mostly foods, including dairy products containing cholesterol-lowering phytosterols or -stanols) have been approved according to the procedures outlined in the new food regulations.

Regulation on genetically modified food and feed Regulation 1829/2003 of the EU on genetically modified food and feed sets out procedures for dealing with genetically modified (GM) products.

Again, the applicant shall submit an application to the competent authority of the Member State in which the product was originally intended to enter the market. The competent authority shall send the application and supporting data to EFSA within 14 days, which will also inform the Commission and the other Member States. EFSA is expected to formulate an opinion within six months and submit it to the applicant, the Commission and the Member States. The final decision shall be made in accordance with the procedure laid down in the preceding paragraph.

To date, no GM-functional foods have been submitted for evaluation, although the possibility of this, albeit with this in mind, consumers' views on genetically modified foods in the EU certainly exist.

Regulations on feed additives

Although there are no specific rules at EU level for functional foods, the situation is quite different with microbiological feed additives, which in most cases can also be classified as animal probiotics. Since many species of microorganisms, as well as strains used in animal nutrition, also occur in conventional and functional foods, the feed provision may also have some bearing on functional foods, in particular in the case of possible harmonization of legislation on microorganisms in the food chain. These aspects have recently been considered and discussed by Wessels et al., Von Wright and Anadon et al.

Appropriate regulation of the definition of the authorization procedure for feed additives 1831/2003 EU on additives for use in animal nutrition. The applicant submits an application to the commission, which will inform the Member States and send the material to EFSA. EFSA will also receive the relevant information specified in Article 7 of the Regulation directly from the applicant at the time of application. EFSA will give its opinion within six months of receipt of the valid application and its intermediary to the Commission, the Member States and the applicant. The Commission shall develop a draft decision within three months of receiving the opinion. This draft decision is subject to a Committee procedure similar to that used with new products or genetically modified foods.

Specific requirements for the approval of microbiological feed additives are defined in the opinion of the former Scientific Committee on Animal Nutrition (SCAN). Opinion Scan 2001 "Guidelines for the Evaluation of Additives, Part II: Enzymes and Microorganisms are still largely in place, although new guidelines are currently being developed.

In accordance with the basic principles, the effectiveness of the additive must be demonstrated in at least three field tests by assessing the relevant zootechnical parameters. Safety requirements for microorganisms are quite strict, requiring:

• Tolerance studies in target species using, if possible, at least ten times the overdose of the supplement and delayed from one month (young, fast-growing animals) to three months according to the target animal category.

Operator safety studies, including eye and skin irritation and possibly also increased skin sensitivity. In general, all microbiological additives are considered as potential respiratory sensitizers and protective measures are recommended.

• genotoxicity studies (bacterial reverse mutation test and a wide selection of mammalian in vitro clastogenic test tubes) and a 90-day rodent feeding study. These studies are designed to protect the interests of consumers in order to exclude the possibility of unknown or undetected harmful microbial metabolites in the feed, which could create a consumer risk if it accumulates in products of animal origin.

In addition to these general requirements, the Scanner has published separate opinions addressing the specific problems associated with Bacillus bacteria species used as probiotics in animals, as well as the risk of transmissible antibiotic resistance genes in microorganisms used as feed additives.

Safety of Bacillus Bacteria in Animal Nutrition, 2000 deals with the risk of toxigenic Bacillus species entering the food chain. Bacillus species intended as feed additives should be tested for the production of enterotoxins or emetic toxin. The procedure includes the exact taxonomic characteristics of the strain, PCR tests for known enterotoxin genes and cytotoxicity for the final exclusion of enterotoxin or emetic toxin.

SCAN's views on the presence of antibiotic-resistant transmissible genes: "Criteria for the Evaluation of Antibiotic-Resistant Microorganisms" 2001 and 2002 were subsequently updated with the document "Prisoners of the FEEDAP Group of Experts or the veterinary value of 'EFSA. In these views, some control points for MIC values for 13 clinically important antibiotics are presented. The genetic background of resistances exceeding these breakpoints must be clarified and confirmed to be internal, physiological or mutational, but not transmitted, prior to authorization. This requirement has apparently led to similar problems on antibiotic resistances in starters as well as probiotics used in human food. There is currently a European Sixth Framework Research Program for the Evaluation and Critical Assessment of Resistance to Antibiotic Transmission in the Food Chain (ACE-ART), which covers these issues.

Food claims have received considerable attention from lawmakers. One of the central principles was that a clear distinction between food and medicine should be maintained. This principle is quite convincingly formulated in Directive 2000/13 / EC, which categorically prohibits claims to "attribute to any food the property of preventing or treating human disease or refer to such properties. This principle makes the marketing of functional foods quite difficult, as it prevents the communication to the general public, even from a scientific point of view, of reliable medical information that contributes to the effects of functional foods or food ingredients.

Claims that are generally allowed to varying degrees are nutrition requirements and functional requirements. The functional requirement usually consists of two parts, one of which states the presence or concentration of a particular ingredient in the product, and the other its physiological role. Particularly relevant for functional foods are functional requirements, which relate to the special beneficial effects of the food component over the diet, as well as reducing the risk of disease. The latter suggest that the food component reduces the main risk factor in the development of human diseases.

Relevant laws in the United States on nutrition, denoting both the Education and Dietary Supplements, Health and Education Act. Allowed health claims or health-related claims include nutrient claims content, structure and functional requirements (functional requirements), dietary requirements guide, qualified health requirements transport relationships between components in diet and developmental risk diseases (approved by the FDA and supported by the weight of reliable available scientific data) and health requirements confirm the relationship between the components in the diet and the risk of disease or health (approved by the FDA and supported by a significant scientific agreement). The Significant Scientific Agreement (SSA) is a standard largely determined by the FDA. So far, 12 RSU on the relationship between the dietary component and health disease exist, namely:

1. calcium and osteoporosis
2. dietary lipids and cancer
3. sodium and hypertension
4. Saturated fats and cholesterol and the risk of coronary heart disease
5. fiber containing cereals, fruits and vegetables and cancer
6. Fruits, vegetables and cereals that contain fiber, especially soluble fiber, and the risk of coronary heart disease
7. fruits and vegetables and cancer
8. folic acid and neural tube defects
9. Carbohydrate sweeteners and tooth decay
10. soluble fiber from certain foods and the risk of coronary heart disease
11. soy protein and the risk of coronary heart disease
12. plant sterol / stanol esters and the risk of coronary heart disease

Qualified health claims have been introduced because the burden of proof to obtain an SSA level is considered quite difficult to achieve. Of qualified medical requirements, the relationship between the food component and the disease should not be as strong as to achieve SSA. Therefore, FDA operators that can be used as claims are also conservatively and carefully worded. As an example, the FDA has formulated a requirement for green tea and cancer:

Based on a FDA review of whole-body strength of publicly available scientific evidence for the requirement for green tea and a reduced risk of breast cancer, the FDA ranks this evidence as the lowest level for qualified health requirements. For the reasons outlined above, the FDA concludes that it is very unlikely that green tea reduces the risk of breast cancer.

In Japan, certain health requirements are allowed for FOSHU products. For example, functional components such as oligonucleotides, lactobacilli and bifidobacteria, Psyllium husks, digestible dextrin, wheat bran, low molecular weight sodium alginate and partially hydrolyzed guar gum may be associated with requirements such as: In addition, requirements to reduce the risk of disease are allowed for FOSHU products rich in calcium or folic acid.

Nutritional function claims are permitted for FNFC foods containing permitted vitamins and minerals. Labels should clearly indicate the recommended dosage and warn that excessive use of the product does not cure the disease or improve health.

In the EU, a proposal for regulation in the field of nutrition and health claims was in preparation, and was adopted on 20 December 2006 (Regulation 1924/2006 / EC). It entered into force on 1 July 2007. establishes the principle of pre-marketing authorization, especially with risk lawsuits related to the development and health of children. In these cases, applications submitted through national competent authorities shall be evaluated by EFSA and approved using the Standing Committee procedure.

Profits have been defined as ‘‘mono- or mixed cultures of living micro¬organisms which, in relation to humans or animals, have a beneficial effect on the host organism by improving the properties of the microflora. According to a later definition in the report of the FAO / WHO working group to develop guidelines for the evaluation of probiotics in food: Probiotics are living microorganisms that, when administered in sufficient quantities, are beneficial to health [10].

As viable microorganisms deliberately entering the food chain they are reminiscent of many traditional snack foods that have been used in a variety of foods since ancient times. The use of starters is an age-old practice, and no special attention has been paid to their safety aspects in human food. Thus, they received relatively little attention from lawmakers. Therefore, there is little experience in experimentally evaluating the safety of food microorganisms, probiotics or starters. As noted on pages 268-70, the situation is very different from micro-organisms intended as feed additives in the EU, which require detailed case studies on safety. Even with animal profits, however, much of the formal safety

testing of the device (eg, genotoxicity tests) is not often required in practice due to methodological difficulties.

Possible income provisions, therefore, also have implications for the status of conventional starters and conversely, in the case of harmonization of case law on microorganisms intentionally added to the food chain is done. In the following sections of this and there are situations concerning the regulatory status of starters, profits and other food microorganisms are briefly discussed.

Existing yeasts are generally classified as food ingredients, processing aids or ingredients (Feord, 2002). In Europe currently only Denmark and France have an official notification or system approval for new strains intended for use in food. French recommendations based on the decision tree approach also recommend toxicological studies (including animal studies) if there is a need to ensure no risk [9].

While the regulatory framework for food microorganisms is not well defined in the EU, in the US the microorganism used in food can be classified either as an additive, in which case it must be approved by the FDA, or it can be considered generally safe (GRAS). The product may have GRAS status or have a history of safe use in food dating before it is released on January 2, 1958 or it has been declared safe by qualified professionals under the intended use. The responsibility for providing expert opinions on the safety of the substance or microorganism lies solely with the applicant; The FDA will only either accept or reject them. GRA status is also usually applied only to the special use of the microorganism (ie bifidobacteria Lactis BB12 and thermophilic streptococcus in infant formula).

When SCAN principles were formulated for the evaluation of microorganisms used as feed additives, no exceptions were made for species and strains that have a history of human use. It was soon recognized that this led to an abnormal situation where the strain was exposed to a much stricter safety assessment if it was intended as a feed additive than if it had been used as a food starter or human probiotic. The large number of species and strains that are already used in food production further makes their safety strain evaluation by deformation virtually impossible. Therefore, a paper outlining the position "Safety assessment and regulatory aspects of micro-oranisms in feed and food applications" was published in SCAN in 2002. This paper suggested that specific microorganisms with a history of safe use or otherwise found This list will be based on the "Qualified Presumption of Safety (QUF)" - a presumption defined as a belief or assumption based on reasonable evidence and qualified to address certain restrictions on application '. The basic idea is that for a microorganism and having the status of QPs, safety assessments should focus only on those aspects that are relevant to the organism (eg, the possible presence of markers of antibiotic resistance) and not on the global strain safety assessment.

The QPS concept was further developed in 2003 with the participation of members from several EU Scientific Committees (SCAN, Scientific Committee on Food, Scientific Committee on Plants), which prepared a working paper on a common approach to safety assessment of microorganisms used in food and feed / food production ". This document was the subject of public consultation [6].

Following the establishment of the EFSA Scientific Colloquium on the subject, it was organized in Brussels in late 2004. The CPF Concept was generally seen as a good way to introduce useful elements of the GRAS system without compromising safety aspects. Therefore, EFSA has established a working group to provide a proposal for a list of microorganisms that can be considered for CPT. This work is currently under development.

Conclusions and future trends

The regulatory aspects that apply to functional dairy products are pretty much the same as functional foods in general. Functional products, with the exception of Japan, are not officially recognized in food law as a separate legal entity, and therefore provisions on critical aspects, safety and efficacy are largely absent. It can be assumed that this situation will change and formal criteria will be established for addressing functional foods at both the national and international levels.

The question of what permitted medical requirements are, of course, important both in terms of product development and the marketing of functional foods. Again, perhaps Japan currently has the most consistent policy on health claims that can be accepted. In the US and especially in the EU, health requirements are still under development. While the distinction between food and medicine should be free, a more relaxed policy of enhanced function requirements and reduced disease risk will encourage the further development of functional foods.

Specific issues on probiotic dairy products and safety assessment of probiotic strains are related to the development of regulations concerning the general use of microorganisms in food, whether conventional starters or profits. The GRA system and ultimately the European QPS approach would allow the use of traditional safe starters and profits without much safety assessment focusing on limited resources where they are needed, namely situations where a completely new microorganism is intentionally introduced into the food chain.

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EXPERIMENTAL STUDY OF VIBRATION ACCELERATIONS IN AXIAL DIRECTION ON MODERNIZED TRAVEL WHEELS

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Abstract

The article discusses experimental studies of axial vibration accelerations that occur in the axle of the traveling wheels when the cargo carriage of the overhead crane moves. To compare the results of experimental studies, double-ribbed running wheels with a cylindrical rim were selected. These wheels are used on almost all overhead cranes. Also, wheels of a new modernized design were manufactured for experimental research.

Keywords: traveling wheel, vibration acceleration, modernized wheel, overhead crane.

The most common hoisting machines in the manufacturing process are overhead cranes. Ensuring their reliable and trouble-free operation at the present time is a very urgent task [1, 2].

The durability of an overhead crane depends on the durability of its metal structure, which perceives significant variable loads [3, 4].

The operating cycles of an overhead crane cause rapidly changing load processes not only in time, but also in magnitude [5]. This requires a fairly accurate determination of all force factors that arise during the operation of an overhead crane, both static and dynamic [6].

The main loads arising in the metal structure of an overhead crane appear during the lifting and lowering of the load and the operation of the mechanisms for the movement of the freight carriage and the bridge [7, 8].

Many works have been devoted to assessing the influence of parameters of movement mechanisms on dynamic loads in metal structures [9, 10].

We proposed a new design of a traveling crane wheel with an elastic insert [11, 12], which made it possible to significantly reduce the dynamic loads during the operation of the movement mechanism [13].

The dynamic model of an overhead crane is considered in [14]. The authors determined the linear oscillations of the model. There is also a description of the vibration of the load and the trolley during the movement of the crane. The friction forces in the system are estimated. An assessment is given of the influence of the load shift during the action of the resistance forces when the crane is moving. But the work does not consider the dynamic loads in the metal structure of the crane during movement.

The possibility of modernizing the mechanism of movement of the cargo carriage of an overhead crane by replacing a three-stage vertical cylindrical gearbox with a two-stage and separately removed gear transmission is considered in [15]. In this case, the running wheel is mounted on the shaft of the bogie wheelset. The authors argue that such a block diagram will reduce energy losses and increase reliability. But at the same time, it was not investigated how much the dynamic loads decrease.

This gives grounds to assert that it is advisable to conduct a study to improve the operational reliability and durability of the running wheel through the use of elastic inserts.

The aim of the study is to substantiate the feasibility of modernizing the design of the running wheel on the basis of vibration signs arising in the running wheel.

To achieve the goal, the following tasks were set:

- conduct an experimental study of the formation of vibration accelerations in the axial direction in wheels of standard design;

- conduct an experimental study of the formation of vibration accelerations in the axial direction in the wheels of the modernized design.

To measure vibration accelerations arising during testing of the bridge crane trolley, the «Ultra-B-I» complex. The software included in the measuring complex allows real-time plotting of vibration accelerations versus time, as well as determining the spectral composition of the signal.

The research was carried out on an operating overhead crane. The vibration measuring complex was located directly on the bridge crane. The sensors were installed at the control points of the crane trolley. With the help of wires placed on the crane beam, they were