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Presenting the checks of dietary supplements by NFCSO

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SUMMARY

The interest in various dietary supplements, which are considered to be beneficial for human physiological effects, has been growing steadily for years, so the importance of their food safety is increasing due to increasing consumption. Their production and distribution are bound for notification by the law. In the current legislative environment, these products are in the category of foods, and their control is, the responsibility of the food safety authority, among others. In my manuscript, I present the most important results of the inspections carried out by the NFCSO and the Pangea Action carried out internationally in 2018. Inspections were carried out partly by the NFCSO on the basis of own control and monitoring plans, and partly on notifications of public interest. The results of several investigations were published on the website of NFCSO.

Introduction

According to ESZCSM decree 37/2004. (IV. 26.) **[1]**, dietary supplements belong to the category of foods. Based on the definitions of the decree, this group includes foods that contain nutrients or other substances having nutritional or physiological effects in a concentrated form, individually or in combination. These products are marketed in a pre-dispensed or dispensable form, such as capsules, pastilles, pills, powders in packets, ampoules, drop bottles or other similar forms suitable for dispensing small amounts.

Discussion

Dietary supplements should not be confused with ancillary medical devices or therapeutic equipment, or herbal teas that are regulated by completely different decrees. Additionally, they do not include foods for infants and young children, foods for special medical purposes, or foods for weight control, substituting the entire daily diet, as well as foods intended for athletes, such as protein powders, if they fall into the category of "normal" foods according to the current regulation, and not into the category of dietary supplements.

Many people do not know, but when we joined the European Union, preliminary testing of dietary supplements has come to an end. The aforementioned ESZCSM decree 37/2004. (IV. 26.) provides for a notification obligation only **[1]**. Tasks related to the notification are carried out by the National Institute of Pharmacy and Nutrition (OGYEI - NIPN), to which the necessary documents have to be submitted no later than the day the product is placed on the market. The confirmation procedure pertaining to the notifications of dietary supplements, infant formulas and special-purpose formulas was modified by the NIPN, starting from November 20, 2017, which also resulted in the disappearance of the signs previously shown in the list published by the NIPN, such as the "green check mark" (everything OK), the „red exclamation mark" (not adequate) and the „black star" (not to be distributed). Nevertheless, in order to maintain proper information, the NIPN still publishes the list of notified products, and products affected by market supervision measures are indicated on a separate list. Risk assessment of notified dietary supplements that appear to be risky on the basis of the documents submitted is carried out by the NIPN in the period following the notification, if deemed necessary.

[1] National Food Chain Safety Office, Directorate of Food and Feed Safety

Since the entry into force of ESZCSM decree 37/2004 (IV. 26.) about the marketing regulations of dietary supplements, approximately 20,000 of these products have been notified with the NIPN by manufacturers and distributors. This also shows how much these products have become sought after nowadays, because a balanced, healthy diet is overshadowed, or at least is made difficult to achieve, by our eating habits and the high percentage of processed foods. The "natural" ingredients of some of the dietary supplements may also appeal to consumers who may be suspicious of the "artificial" ingredients of drugs or are afraid of their side effects.

Since dietary supplements are foods from a legal point of view, therefore, in addition to ESZCSM decree 37/2004. (IV. 26.), they must comply with all other food laws, starting with the general labeling obligation, through the notification obligation of the manufacturer or distributor of the product and the regulation of nutrition and health claims, to the compliance of the packaging material and any other specifications not listed here.

There are certain labeling elements that should be indicated in the case of dietary supplements both on the product and on the website, in addition to those contained in the labeling regulations of foods in general. These are listed in Paragraph 6 of ESZCSM decree 37/2004 (IV. 26.) about food supplements **[1]**:

- products satisfying the requirements of the decree may be placed on the market as "dietary supplements";
- in the course of their labeling, displaying and advertising, it is forbidden to attribute a preventive or curative effect to the product, or to imply such an effect;
- what is mandatory to indicate:
    - o the names of the characteristic nutrient groups or ingredients of the product, or a reference to the nature of the nutrients or ingredients;
    - o the recommended daily intake and a warning that the recommended daily intake should not be exceeded by the consumer;
    - o bringing to attention the fact that the dietary supplement is not a substitute for a mixed diet;
    - o a warning that the product should be kept out of the reach of small children.

As can be seen from the above, it is not required to indicate the NIPN number, received during the notification, on the product itself or on the website for distance selling.

Dietary supplements are controlled by a number of authorities from different perspectives. Based on Act XI of 1991 on the supervisory and administrative activities of the health authority **[2]**, the compliance of dietary supplements with specific nutritional goals is examined by the health administration body. Based on Act XLVI of 2008 on food chain and its control **[3]**, the food chain supervision body (i.e., NFCSO and the local food chain safety authorities) investigates the food safety and food quality compliance of dietary supplements. Bodies that perform consumer protection tasks act against "misleading labeling".

It is important to clarify that when we speak about food quality and food safety used in food law, the concepts defined by Act XLVI of 2008 on food chain and its control and by Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety are meant. Based on these, food quality is the sum of the characteristics of the food that it complies with the relevant specifications of food safety requirements other than those laid down in the regulation implementing the law or in a directly applicable European Union act, as well as the characteristics stated in the manufacturer's written documentation. According to Paragraph **[2]** of Article 14 of Regulation (EC) No 178/2002, food shall be deemed unsafe if it is injurious to heath or unfit for human consumption.

There are many organizations in Hungary that are committed to a clean market. These include the Hungarian Association of Pharmaceutical Wholesalers (GYNSZ - HAPW), the Hungarian Chamber of Pharmacists (MGYK - HCP), the Association of Hungarian Dietary Supplement Manufacturers and Distributors (MÉKISZ - AHDSM), the Hungarian Pharmaceutical Manufacturers' Association (MAGYOSZ - HPMA) and the National Board Against Counterfeiting (HENT - NBAC). These organizations try to support the control of the products within the framework of self-regulation.

It is a positive tendency that, since it is considered of the utmost importance by the Hungarian authorities and professional organizations to monitor dietary supplements as closely as possible and to clean the market, therefore, professional relationships and communication improve, helping each other's work to a great extent.

Internet commerce is present in a growing extent **[4]**, presenting many dangers, especially originating from inadequate, incomplete or misleading information (usually containing a lot of untrue or unauthorized information) or from products obtained from third countries.

The labeling regulation also provides for mandatory information in the case of pre-packaged foods offered for sale by means of a telecommunication device placed on the market within the European Union, and this information has to be made available before the end of the purchase and must be included in the distance selling promotion material.

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Inspections initiated on the basis of public interest notifications include on-site inspections and sampling, as well as purchases on websites, but it also happens that inspections are carried out based on information found on the website itself. Because of this kind of website inspection, in recent years, legal assistance has been requested through the international legal assistance system of AAC (the Administrative Assistance and Cooperation) for a number of products, and in the case of several products, proceedings were initiated by NFCSO, the result of which were usually food inspection fines and withdrawal from circulation. Violations included the indication of the wrong country of origin (e.g., EU instead of China), the lack of the name or the availability of the responsible company, unauthorized health claims, the complete absence of a Hungarian label, other labeling deficiencies and the presence of unauthorized new foods among the ingredients.

Dietary supplements often contain ingredients that are classified as novel foods. Novel food is defined as food that had not been consumed to a significant degree by humans in the European Union before 1997, and whose consumption can pose food safety risks due to the novelty of the food. The regulation currently in force, Regulation (EU) 2015/2283 **[4]**, contains a number of food categories which may pose a food safety risk to consumers due to their nature, structure, method of use or the production technology used, if a tradition of consumption before 1997 cannot be proven. For this reason, the placing of novel foods on the market is preceded by a rigorous safety assessment and authorization. You can read more about novel foods on the website of NFCSO.

Ingredients of dietary supplements also have to be examined to see if they are on the list of the Scientific Advisory Board of NIPN containing prohibited plant parts **[5]**. Members of the Board include the Faculty of Pharmacy of Semmelweis University, the Faculty of Pharmacy of the University of Szeged, the National Food Chain Safety Office (NFCSO), the Association of Hungarian Dietary Supplement Manufacturers and Distributors, an independent pharmaceutical expert invited by NIPN and the experts of the Directorate General of Food and Nutrition of NIPN. Their task is the professional, scientific evaluation and analysis of the applicability of herbs to be used in foods and dietary supplements, continuous reassessment of the current negative list and its extension, if necessary, and the evaluation of the applications submitted by food businesses. The negative list includes plants whose use in foods, such as dietary supplements, and consumption may be hazardous, as determined by the Board.

Of course, trial purchases and targeted inspections are carried out by NFCSO without public interest notifications as well. For example, in the spring of 2016, there was a large-scale, comprehensive targeted inspection, when a total of about 120 products were examined with the involvement of the government offices. Products available of store shelves were inspected by the government offices, following the guidance of NFCSO, while products available on the internet were examined by NFCSO. It should be emphasized that, during these targeted inspections, a number of laboratory tests were carried out by NFCSO (for almost all listed, measurable active ingredients and contaminants, as well as potentially present drug active ingredients in the case of certain products), and a complete check of labels was also a part of the task for both the government offices and NFCSO. During the online sampling, products that had been already suspicious were selected, 87% of which showed non-compliance. In most cases, the problem was some kind of labeling deficiency, including information found on websites, but proceedings were initiated also because of food quality and safety non-conformities and, for six products, even for food counterfeiting. Non-conformities were found in the case of 61% of products purchased from store shelves, 39% of which were food quality and composition problems, 9% were food safety objections and 71% were labeling problems (the percent values has to be understood with overlapping: in the case of several products more than one non-conformity were found).

Since the experience of 2016 showed that dietary supplements that promote potency growth, coming from third countries and found on the internet, pose a serious food safety risk, we continued to investigate them in subsequent years, especially for the presence of unauthorized drug active ingredient content (the most common of which are tadalafil and sildenafil), as well as for additives and labeling. Due to such food safety defects, more than 10 products have been withdrawn from the market in the last three years, with the problems including the presence of a drug active ingredient, as well as the use of a dye in amounts greatly exceeding the limit value.

Dietary supplements constitute a sensitive food group all around the world, therefore, several international campaigns have been organized to find and eliminate inappropriate products. One of these was the authority inspection of websites offering certain dietary supplements marketed over the internet and

containing novel foods (Agmatine ((4-aminobutyl) guanidine), *Acacia rigidula*, *Epimedium grandiflorum* and *Hoodia gordonii*), as well as dietary supplements promising to prevent, treat or cure bone and joint disorders, carried out between September 4, 2017, and September 29, 2017, and coordinated by the European Commission. During these inspections, the websites for 20 products were examined by NFCSO, as a result of which authority proceedings were initiated in each case, food chain supervision fines were imposed in 14 cases for failure to comply with new food authorization obligations and for inadequate consumer information, and in 5 cases the businesses involved had to be issued warnings due to inadequate consumer information and they were ordered to stop the infringements. According to the distributor's declaration, a product was classified as a medical device, and it was withdrawn from the market by the NIPN. Objectionable products most often came from the United States of America, China and India.

Last year's XI. Pangea Action has been specifically designed to combat drug and pharmaceutical active ingredient abuse. As a result of the international operation involving nearly 200 authorities of 116 countries, a total of 500 tons of counterfeit pills with a value of 14 million USD (about 3.96 billion HUF) were seized. Investigations were launched in more than 850 cases, and nearly 3,700 websites and online ads were suspended. As part of NFCSO's operation, a number of dietary supplements sold over the internet were sampled, primarily male potency enhancers and weight loss products. Analytical tests of the products were carried out by the laboratory of the NIPN. Potency enhancing products came from China, their distributors were Hungarian companies. All of the products included in the tests, which are found on most of the websites that sell potency enhancers, contained a potency enhancing pharmaceutical active ingredient (sildenafil or tadalafilt). Because of food safety non-compliance, the products had to be withdrawn from the market.

The consumer risk borne by dietary supplements is due, among other things, to the fact that certain active substances are not listed on the product labels. These ingredients may be either unauthorized active pharmaceutical ingredients, or authorized active pharmaceutical ingredients that are prohibited to use in dietary supplements, because they could only be marketed as drugs. It may also pose a risk if the consumer does not comply with the prescribed dosage or the daily intake has not been established correctly. In addition to these, infringements most often include the presence of unauthorized novel foods and unauthorized claims. Product with objectionable labels also suggest in certain cases that if the product is not consumed, the risk of developing certain diseases increases.

According to Act XLVI of 2008 on food chain and its control, also found in the collection of laws of NFCSO **[6]** updated monthly, a list should be kept of food safety infringements. In addition, in the case of foods distributed through distance selling with labels that contain misleading information regarding an essential characteristic of the product, foods of inadequate quality or unsafe foods, the list should include the name of the food, data suitable for the identification of the telecommunication device and the food, the irregularity found, as well as the name or company name of the food business that committed the infringement, its registered headquarters, site or branch, and the name of the senior official registered at the time of the infringement. The lists containing the infringements are available on the NFCSO website (https://portal.nebih.gov.hu/jogsertes-listak). Disclosure of the infringements is allowed after the decision has become final or after making an immediately enforceable decision, unless it is not possible to identify the entity responsible for the infringement, in which case it will be posted on the site without making a decision to inform consumers.

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