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FOOD SUPPLEMENT-RELATED RISKS IN THE LIGHT OF INTERNET AND RASFF DATA

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ABSTRACT

OBJECTIVE. Based on legal acts and RASFF information, this paper aimed at evaluating available facts on food supplements in comparison to the most popular data accessible via Internet for future and present consumers.

MATERIAL AND METHODS. Having analyzed legal acts and RASFF (*Rapid Alert System for Food and Feed*) database, the authors attempted to verify what kind of information on food supplements may be found by an Internet user, using the first webpage of Google.pl. This search engine was used in this study as it gained the highest popularity among Internet users. It was decided that exclusively search results displayed on the first webpage would be subject to analysis as 91.5% of Internet users limit their search to the first 9-10 results. Internet was searched using the following two terms: 'supplement' and 'supplements' as well as terms suggested by Google.pl. Subsequently, the results were subject to qualitative and quantitative analyses.

RESULTS. On the Internet, the most frequently searched terms were: 'supplements' (243 000 000), 'supplement' (9 290 000), 'supplements shop' (8 200 000). Having analyzed the content of particular websites, information on certain products, given by their manufacturers may be found. Then, data on supplement itself were provided, i.e. what is a supplement and when it should be used. Expert articles (written by physicians, dieticians, pharmacists) on a risk resulting from these products, including therapeutic indications or the presence of unauthorized substances were identified considerably less frequently. No warnings regarding the necessity of purchasing the products in legal and verified places were found.

CONCLUSIONS. There is a necessity of systemic education of consumers on reasonable use of food supplements. It is also advisable to consider the organization of alert system whose objective would be to monitor adverse reactions caused by an intake of food supplements or novel food launched into the country. To obtain reliable information on the composition and effects of food supplements, potential consumer should contact physician or dietician. Additionally, complementary information, using different sources with an example being health-related portals, presenting articles written by physicians or pharmacists, may be also searched.

Key words: *food supplements, food supplement use, food supplement effect*

INTRODUCTION

Food supplements are becoming more popular. Furthermore, they are also more accessible. It may be purchased not only in a grocery, which seems to correspond to its definition, but also in chemist's, gym, but above all on the Internet. Having analyzed the advertisements, it may be concluded that these products cure all of the possible conditions, ranging from hair loss, potency problems to the

quick loss of unwanted kilograms. Manufacturers eagerly inform of the lack of adverse reactions to supplement and its natural origin. Additionally, launching new products into a market is accompanied by aggressive marketing and advertising campaigns. Consequently, consumers may consider that if they are concerned about their health, they should increase the intake of supplements. Therefore, it is high time for reflection on dietetic and medical reasons of such high consumption of food supplements.

Except for certain physiological conditions, e.g. immunodeficiency or pregnancy, the intake of food supplements is not recommended if the principles of healthy diet are observed. An emphasis should be put on the fact that the composition of supplement may be different from what is on its label. Furthermore, it may contain hazardous substances. From the study conducted in the USA transpires that 20-90% of patients diagnosed with cancer use food supplements, however, their intake is not always approved by physicians. Not only the shortage of evidence suggesting the effectiveness of supplements, but also their questionable safety and possible interactions with medicinal products are raised. In this respect, a key element is good contact between patient and physician. It is also advisable to develop the guidelines for patients regarding the use of food supplements (1).

LEGAL ACTS PROTECTING THE CONSUMERS FROM THE RISK OF UNLIMITED ACCESS TO FOOD SUPPLEMENTS

Pursuant to the provisions of the Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements, 'food supplement' is defined as "any food the purpose of which is to supplement the normal diet and which is a concentrated source of vitamins or minerals or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form" (2). Definition of 'foodstuff', which is specified in the Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, is as follows: "food (or foodstuff) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans" (3).

Composition of food supplements, most frequently, includes vitamins, mineral substances, as well as plant- or animal-derived ingredients, which are present in food and consumed as its part. In this case, provisions, referring to medical devices, are not effective.

In Poland, the basic legal acts, regulating the launch of food supplements into the market, are the Act on Food and Nutrition Safety (4) and Regulation of the Minister of Health on the composition and labelling of food supplements (5). Chief Sanitary Inspectorate (CSI) is an institution which is liable for registering food supplements in Poland. CSI is also obliged to run the register of food supplements. If a food supplement is to be launched into the market, the entity introducing it should first submit a notification form to the CSI. Such form should contain the following information, i.e. the names of a supplement and notifying entity, label

in Polish language and addressee of the first notification. All required documents are accessible on the CSI website (6). Prior to the launch of food supplement, investigation procedure is initiated by the CSI to verify whether a supplement meets the criteria specified in the provisions of law as well as to determine if it does not have properties indicative of medicinal products. In the latter, such product is subject to other provisions of law and is not to be considered as a foodstuff.

It should be noted, however, that prior to the launch of a food supplement, its manufacturer is not required to present and accomplish detailed and expensive registration procedures and clinical trials which could confirm its effectiveness, quality and safety profile as it is in the case of medicinal products. Furthermore, manufacturer is not also obliged to inform on interactions with other substances, alcohol and medicinal products. Nevertheless, pursuant to the article 30 of the Act on Food and Nutrition Safety (4), for food supplements, containing vitamins, minerals or other substances with a nutritional or physiological effect, the CSI may initiate investigation procedures to verify the composition, properties of particular excipients and indications for use prior to the launch of product.

In case of food supplements, a special attention should be paid to the information provided for consumers. The majority of food supplements is labelled and advertised using nutrition and health claims. Pursuant to the provisions of the Regulation on nutrition and health claims made on foods (7) 'nutrition claim' is defined as "any claim which states, suggests or implies that a food has particular beneficial nutritional properties"; 'health claim' means "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health" while 'reduction of disease risk claim' denotes "any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease". Manufacturers cannot arbitrarily place such information on product's packaging or use them in advertisements.

It is allowed to use exclusively nutrition claims, which are specified in the register of nutrition claims, constituting an annex to aforesaid regulation. Having received a positive opinion of the European Food Safety Authority (EFSA), which is based on scientific evidence provided by manufacturer and confirms that the claims made are truthful, the European Commission should include a claim in the register.

Health claims may be used if the following information is provided: a statement suggesting the significance of balanced diet and healthy lifestyle; food quantity or its pattern of consumption ensuring beneficial effect specified in a claim; a statement for persons who should

refrain from consuming particular food, if deemed appropriate and adequate warning in case of products which can be hazardous to health if consumed excessively.

It is not permitted to use claims which suggest that health may be affected if certain products are not consumed. It is also prohibited to use claims referring to the pace or level of weight loss as well as those making reference to the recommendations of particular physicians, health professionals or associations, different from the ones listed in the aforesaid regulation.

In the light of increasing supply of food supplements on the local market (8), it is a liability of manufacturers to provide consumers with reliable and comprehensive information on the effect and purpose of products offered. In fact, consumers have to analyze the information on food supplements and investigate the market on their own as to purchase appropriate products of authorized composition and controlled origin. In Poland, the Cluster of Vegetable Medicinal Products and Food Supplements was constituted by the National Medicines Institute to grant Quality Certification. According to the regulation, accessible on the website - www.klasterzdrowia.pl (9): “The objective of Quality Certification granting is to promote products of documented, scientifically confirmed quality and safety profile, mainly to allow consumers to identify them on the market by using Quality Certification Mark”.

SAFETY PROFILE OF FOOD SUPPLEMENTS UNDER RASFF

To eliminate the sources of risk associated with the consumption of food potentially hazardous to human health, the European Union introduced the Rapid Alert System for Food and Feed (RASFF) (10) whose objective is to protect consumers from the risk of diseases. Since 1978, this system allows for the exchange of information in the EU. Having become an important element of public health protection policy, it consists in collecting and rapid communicating the information on foodstuffs, materials and devices designed for contact with food and feed which could be harmful for the health of consumers.

Within the Rapid Alert System for Food and Feed (RASFF), there are three types of notifications, i.e.:

- alert notification – notification on a risk which requires or may require rapid actions undertaken by other members of the RASFF;
- information notification - notification on a risk which does not require rapid actions.

Information notification may be sent with regard to a product for which a serious risk has been identified, however, it is available only on a local market, on a

limited territory, or it was not launched into a market or it is no longer present on a market.

- border rejection.

Furthermore, any information which has not been sent as alert, information or border rejection notifications, but is considered to be important for the safety of food and feed, is communicated as *News*.

Within the frames of RASFF, a risk to human health, resulting from the appearance of food, feed, materials and devices for contact with food, which could be harmful for both human health and environment, is assessed.

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 stipulates the criteria for the notification of risk to human health deriving from food or feed (3). According to the provisions of this Regulation, the Member States immediately notify the Commission, under the rapid alert system, of any actions undertaken to limit the launch into the market or to recall the food and feed to protect human health and requiring rapid action as well as any rejections related to a risk to human health, food and feed at a border of the European Union.

Notifications should include the events of a direct or indirect risk to human health. RASFF does not cover events in which there is no direct or indirect risk to human health. It should be interpreted that in case of inconsistencies with the law regarding food safety, it is not required to communicate other Member States. As it was stated earlier, the fact whether there is a risk for human or not should be considered as a decisive factor.

Having analyzed the provisions of law on food supplements and RASFF data, it should not be forgotten that irrespective of the fact that such information is accessible on the Internet for anyone, exclusively professionals are familiar with it. Furthermore, based on these data, only professionals can draw appropriate conclusions. Therefore, the authors decided to verify what kind of information on food supplements may be found by consumer, using the first webpage of Google.pl (11).

MATERIAL AND METHODS

Analysis of information, which can be found on the Internet, was performed on 18-19 September 2014. Due to its popularity, Google.pl was employed for analysis (11). It was decided to analyze exclusively search results displayed on the first webpage, i.e. about 9-10 results. It is dictated by the fact that 91.5% of persons limit their search to the first webpage. Only 4.8% Internet users look for the results on the next web pages (12).

Two search terms were entered into Google.pl, i.e. ‘supplement’ and ‘supplements’. The only difference is the usage of grammatical number - singular *versus*

plural. Subsequently, all the results (portals) were investigated with regard to the information on supplements. Results, similar to supplement/supplements, suggested by Google.pl were also analyzed. Additionally, the number of results for particular search terms was examined. No results, marked as advertisements, were subject to analysis.

RESULTS

Having analyzed the search terms 'supplement' and 'supplements', and then those suggested by Google.pl, no terms regarding sexual potency/erection occurred. From table I transpires that these terms are on the last position. Internet users were mostly interested in supplements for weight loss and shops with supplements.

Table. I Number of search results by search term.

No.	Search term entered into Google.pl	Approximate number of results
1.	Supplements	243 000 000
2.	Supplement	9 290 000
3.	Supplements shop	8 200 000
4.	Supplements for weight loss	3 670 000
5.	Food supplement	2 720 000
6.	Supplements for muscle building	816 000
7.	Supplements for sexual potency	436 000
8.	Food supplements	380 000
9.	Supplements for erection	164 000

Figure 1 presents the results of search. The first search term was 'supplement'. Search results that were displayed as first related to a supplement meaning a separate section added to a publication. The next term displayed was food supplement. As many as 3 out of 10 results applied for food supplements.

Supplement

■ section to publication ■ diet ■ definition ■ consultation

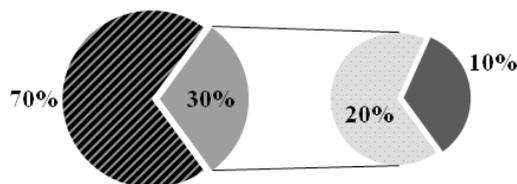


Fig.1 Percentage of search results concerning food supplements (search term - 'supplement').

Having analyzed information on supplements accessible on websites, it may be concluded that these are products used to complement everyday diet by lacking nutrients, including i.a. vitamins or minerals. These products, however, should not be considered as

medicinal products, but foodstuffs. Nevertheless, the fact that they may be purchased in chemist's gives an impression that these are medicinal products. From the survey conducted by the Centre for Public Opinion Research TNS OBOP „Self-healing through awareness in Poland” transpires that 41% of respondents consider supplements to have therapeutic properties (13). There are also products being on the borderline of definition of medicinal product and food (14). During the search, the website of the association – the Polish Council for Supplements and Nutritional Foods (KRSiO) was also displayed. This association was instituted to act for the adjustment of legal regulations, assist in the researches on food supplements and other activities protecting the interests of associated manufacturers as well as to provide reliable information for consumers. Manufacturers being the members of the KRSiO were also listed (15).

Information suggesting that supplements are to complement normal diet may be also found. However, if our diet is healthy, we do not need to use them. Furthermore, they are only applied in certain situations with an example being immunodeficiency. In a group of persons who administered food supplements within the last year, more than a half of them used these products to complement everyday diet (54%) and strengthen immune system (52%) while for only 13% persons its intake was recommended by physician (13). Other information indicates that excessive vitamin consumption may affect the health and supplements for weight loss do not result in the reduction of adipose tissue (16). Advertisements available on the Internet, however, do not suggest that supplements should be purchased from credible sources. It also applies to the products bought via Internet. In this respect, a possibility of control is rather limited. Thus, the products offered on the Internet may be falsified or contain substances which are not listed in their composition. They may also be composed of active substances or their analogues which are used in medicinal product manufacturing or even substances whose usage is forbidden by law provisions. Consequently, it may lead to health-and life-threatening conditions.

Out of 8 terms, Google suggested 5 terms concerning the content of this article, i.e. diet, weight loss or 'supplements for joints'. Having analyzed the search results for 'food supplements', Internet user may encounter a broad scope of information, ranging from legal regulations (6), online shopping, manufacturer's websites to the portals with articles warning against the risk of unreasonable use of supplements or hazardous substances identified in some weight loss products (17, 18). A list of search results for 'supplement for weight loss' includes mainly shops, forums/online social networking services, where the information on products available on the market can be exchanged. Exclusively

two search results referred to opinions based on scientific evidence, i.e. what are ‘supplements for weight loss’ and what is their mechanism of action. In case of ‘supplement for joints’, similar situation was observed (Fig.2).

Suggestions for ‘supplement’

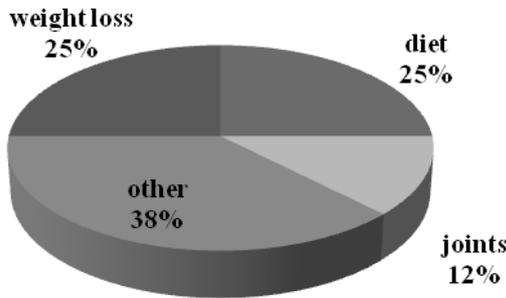


Fig.2 Google.pl suggestions for ‘supplement’.

Having modified the search term by ‘supplements’ (singular replaced by plural form), 100% of results referred to food supplements. Additionally, one search result concerned the definition while the remaining ones were with regard to shops. The latter concentrated on the sale of supplements for sportsmen and gym’s clients. These products are also referred to as sport nutrients (Fig.3).

Supplements



Fig.3 Percentage of links referring to food supplements (search term - ‘supplements’).

Suggestions for ‘supplements’ were mainly portals with information for persons interested in body composition, physical performance, muscle building or weight loss. Search results included shops, forums and website of manufacturer of nutrients for sportsmen and persons attending gyms (Fig.4).

Suggestions for ‘supplements’

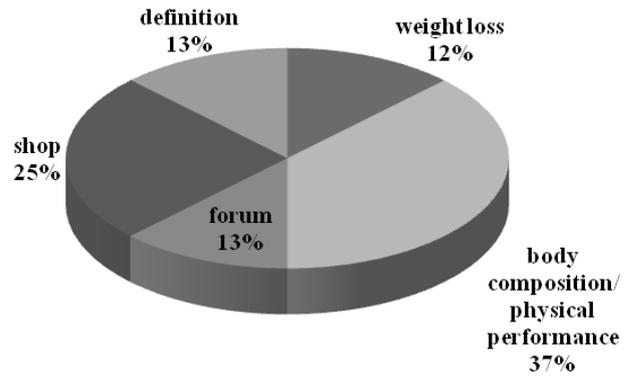


Fig.4 Google.pl suggestions for ‘supplements’- percentages.

Having entered the search term - ‘supplements’, the majority of results were with regard to diet. Most frequently, the searched supplements were designed for sportsmen (referred to as supplements for body composition, physical performance, muscle building). These websites, however, do not serve as the basis of information and education on food supplements. These are the websites concerning food supplement shops, then – those presenting general information on such products and finally those regarding the products for weight loss.

DISCUSSION

Pursuant to the provisions of law, food supplements are a kind of foodstuffs. Therefore, they are subject to legal acts different from those applying for medicinal products. Such a fact may be used by unfair manufacturers. Furthermore, 50% of respondents wrongly claimed that the quality of food supplements is equally controlled as it is in the case of over-the-counter medicinal products (13). Consequently, it may lead to negative consequences for health.

Due to the introduction of RASFF, aimed at protecting the consumers against hazardous products, the European Union allowed for the exchange of information on i.a. food supplements in the EU and EEA countries. In 2013, a total of 3,205 initial notifications were sent. For a group of the following products – ‘dietetic foods, food supplements, fortified foods’, 160 events were notified, including 33, 19 and 55 alert, information and border rejection notifications, respectively while the remaining ones concerned information on follow-up activities.

Having considered chemical contamination, a special attention should be paid to high concentrations of toxic metals (mercury - 9 notifications, lead - 9 notifications, arsenic - 4 notifications). It should be highlighted that several notifications concerned exceeding the maximum permissible concentrations for more than

one element. For one case, too high contamination with polycyclic aromatic hydrocarbons (PAH) was reported. Four notifications were with regard to poor microbiological quality of products.

A specific reason, in fact limited to the use of food supplements, consists in using physiologically active, unauthorized substances to trigger metabolic or medicinal actions (about 60% of initial notifications). The most frequently listed chemical compounds are: DMMA (3,4-dimethoxy-N-methylamphetamine) - 7 notifications, phenolphthalein (7 notifications), sildenafil and its derivatives (13 notifications), synephrine (16 notifications), yohimbine (4 notifications), sibutramine (5 notifications) and other (10 notifications). Such substances were identified in herbal products or those containing plant extracts, frequently referred to as 'natural' or 'traditional'. They were not, however, declared on their label. Such substances were identified in products for weight loss (DMMA, phenolphthalein, synephrine, sibutramine) and erection (sildenafil and derivatives, yohimbine).

Substances such as DMMA and other derivatives of amphetamine may trigger cardiac arrhythmia, which in extreme situations, may lead to circulatory failure and emaciation. Similarly, the analogues of ephedrine, e.g. synephrine may have such effects. Phenolphthalein is a compound of rapid laxative effect. Sildenafil use is contraindicated in persons diagnosed with ischaemic heart disease, hypertension, arrhythmia and with a history of recent myocardial infarction (19).

Official Medicines Control Laboratory report, regarding the study of food supplements for weight loss, provided similar results concerning illegal and unauthorized active substances use (20).

Supplements contain also materials which should be authorized as novel food. These are mainly products employed in the medicine of the Far East, which are not used as food in Europe. Scientific evidence, confirming the effect of these elements, is limited with an example being *Corilus versicolor*. Anti-cancer properties are attributed to this fungus, however, such action as well as its safety profile have not been scientifically confirmed.

In case of food supplements, a problematic issue is the use of unauthorized active substances. Thus, it constitutes a challenge for the authorities liable for food control. There is a necessity of implementing a new range of tests, which so far have not been routinely associated with food safety. Such tests would allow for identification and quantitation of active substances as well as identification of unauthorized compounds.

CONCLUSIONS

1. There is a necessity of systemic education of consumers on reasonable use of food supplements.
2. To obtain reliable information, confirming the composition and effect of food supplement, a potential consumer should first contact physician or dietician. Consumer may also search other sources for information with an example being health-related portals, where articles written by physicians or pharmacists are also accessible.
3. It is of importance to consider the initiation of alert system which would monitor adverse reactions resulting from the use of food supplements and novel food.
4. For official controls and food supplement monitoring, it is required to perform tests for identification and quantitation of active substances, identification of unauthorized compounds as well as drawing attention to a risk associated with microbiological and chemical contamination.

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Received: 29.09.2014

Accepted for publication: 27.10.2014

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