

PROCEDURE FOR THE INTRODUCTION OF DIETARY SUPPLEMENTS INTO THE MARKET – THE (IN)SECURITY OF LIBERAL REGULATIONS BASED ON THE EXAMPLE OF POLAND

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Purpose: The EU and national (especially Polish) rules of law on dietary supplements' marketing are relatively liberal. This creates potential opportunities and dangers in the market, especially for consumers. The aim of the paper was to analyse and assess the current regulations and to specify the required documentation for dietary supplements' marketing in the Republic of Poland.

Methodology: The study featured an analysis of literature concerning the current national and UE legislation as well as subject literature.

Findings: This resulted in the specification of the procedure for dietary supplements' marketing in Poland, the required documents and key aspects. The conducted studies and findings demonstrate that the marketing of supplements in Poland is not demanding.

Originality/value: The applicant must file the notification document to the Main Sanitary Inspectorate (MSI). Due to the above, this paper specifies the opportunities and dangers of adverse events deriving from the relevant regulations, especially for consumers. Hence, the paper encourages to continue the discussion on fundamental issues taken up in this elaboration at the international level.

Keywords: Supplement Dietary, Procedure for the Introduction, Regulations, Poland.

Category of the paper: Research paper.

1. Introduction

The market of supplements is characterised by unusual receptiveness, while globally demonstrating a continuous growing development trend – shown in Fig. 1 (Binns et al., 2018; Hys, 2018).

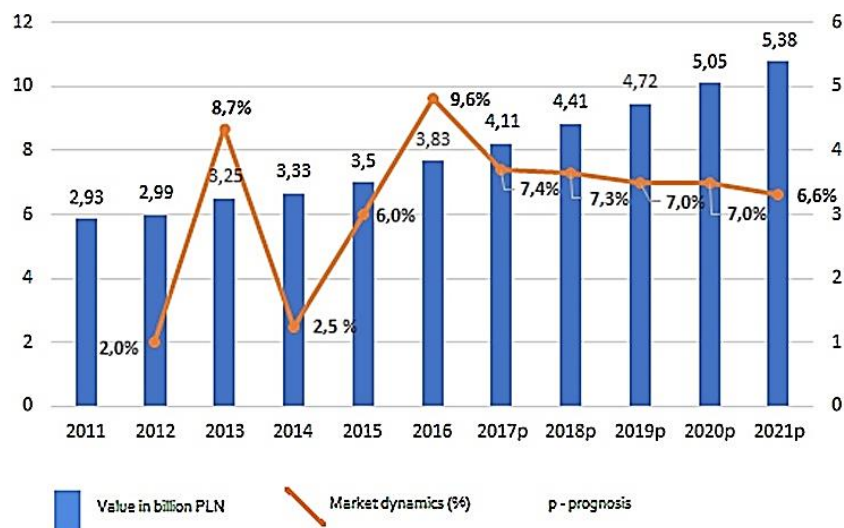


Figure 1. Dietary supplements market in Poland: values (in billions PLN) and dynamics (%), 2011-2020.

Source: Makowska, Jasiński, 2019.

Depending on interest groups articulated by the dietary supplement market's stakeholders (Hys, 2020; Hys, Koziarska, 2020, 2021), it seems important to take up the topic of identifying marketing procedures (Dickinson et al., 2015; Petroczi et al., 2011). This shall enable specifying certain relevant opportunities and restrictions for entrepreneurs (Brewster, Goldsmith, 2007). The term "dietary supplement" refers to a broad category of consumables whose primary function is to enhance the nutritional value of a person's regular diet by providing a more potent form of one or more nutrients (...) (Polish Journal of Laws; Dz.U. 2006, no. 171, item 1225, Article 3.3, paragraph 39). Dietary supplements were hence explicitly categorised as food. The institution that deals with providing scientific advice and notification on existing and emerging dangers related to the food chain in the European Union is the European Food Safety Authority – EFSA (European Food Safety Authority. Food Supplements).

In Poland, on the other hand, the institution that deals with supervising activities on public health, deriving from the citizens' use of dietary supplements, among others, is the Main Sanitary Inspectorate – MSI (Basic Information – Main Sanitary Inspectorate). In general, the EU's food law covers a series of complementary regulations, directives, executive acts and decisions issued by the European Commission (EC). It is necessary to mention, among others, the regulations on:

- specific product types (including dietary supplements, new food, GMO, additives, flavours, permissible contamination levels, trade standards),
- food information methods (e.g. labelling rules, food and health declarations),
- methods of conducting activity in the food sector (e.g. legal acts that regulate the requirements on hygiene, product identification, including the supply chain),
- risk management (e.g. official food controls or the RASFF system – Rapid Alert System for Food and Feed).

The review of the regulations on substances added to food, including dietary supplements, was developed by an international team of scientists (Magnuson et al., 2013; Tsokeva et al., 2016). The broad review presents a specification of the aforementioned regulations with reference to specific countries, such as: Argentina, Australia, Brazil, Canada, China, European Union, Japan, Mexico, New Zealand and the United States. The conducted analysis provides an image of the issue's multidimensionality and complexity. In addition, it features reference to institutions that are recognised counselling bodies and to the role they have in maintaining food safety (Chaloupkova et al., 2020; Vo Van Regnault et al., 2022). These include the following: Codex Alimentarius Commission (CAC) (WHO, International food standards, Codex Alimentarius, 2017) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

The issue of EU regulations on the safety of food, including dietary supplements, is continued in the international scientific discourse (Brewster, Goldsmith, 2007; Dwyer et al., 2018). By reviewing the EU regulations on dietary supplements, Pereira et al. (Pereira et al., 2017) specified the main food regulations (Fig. 2). The Directive 2002/46/EC (Directive 2002/46/EC) was the foundations of European law on food, including dietary supplements (Morrow, 2008). It can be assumed that the directive's adoption commenced the processes of deliberate food supplement management in all countries in the community (Skeie et al., 2009; Lim, Kirikoshi, 2008; Vissers, 1998).

According to the directive's entries, the legislation on dietary supplements' regulation is intended, among others, to facilitate the free movement of products in EU markets and provide consumers with access to products that pose no threat to their health or life (Justa Neves, Caldas, 2015; Directive 2002/46/EC). These products must be fitted with adequate labelling. In addition, the key regulations on dietary supplements include, among others, the following (Evans-Brown et al., 2019; Giunta et al., 2010; Pereira et al., 2017):

- Regulation (EC) No. 1924/2006 on nutrition and health claims on food.
- Directive 2000/13/EC, an EU statute that harmonises regulations among member states concerning food packaging and marketing.
- Labelling of goods in regards to their nutritional value (Directive 90/496/EEC).
- Directive 2006/37/EC of the European Parliament and of the Council of the European Union (Directive 2006/37/EC) - revising Annex II to Directive 2002/46/EC of the European Parliament and of the Council with respect to the inclusion of certain chemicals.

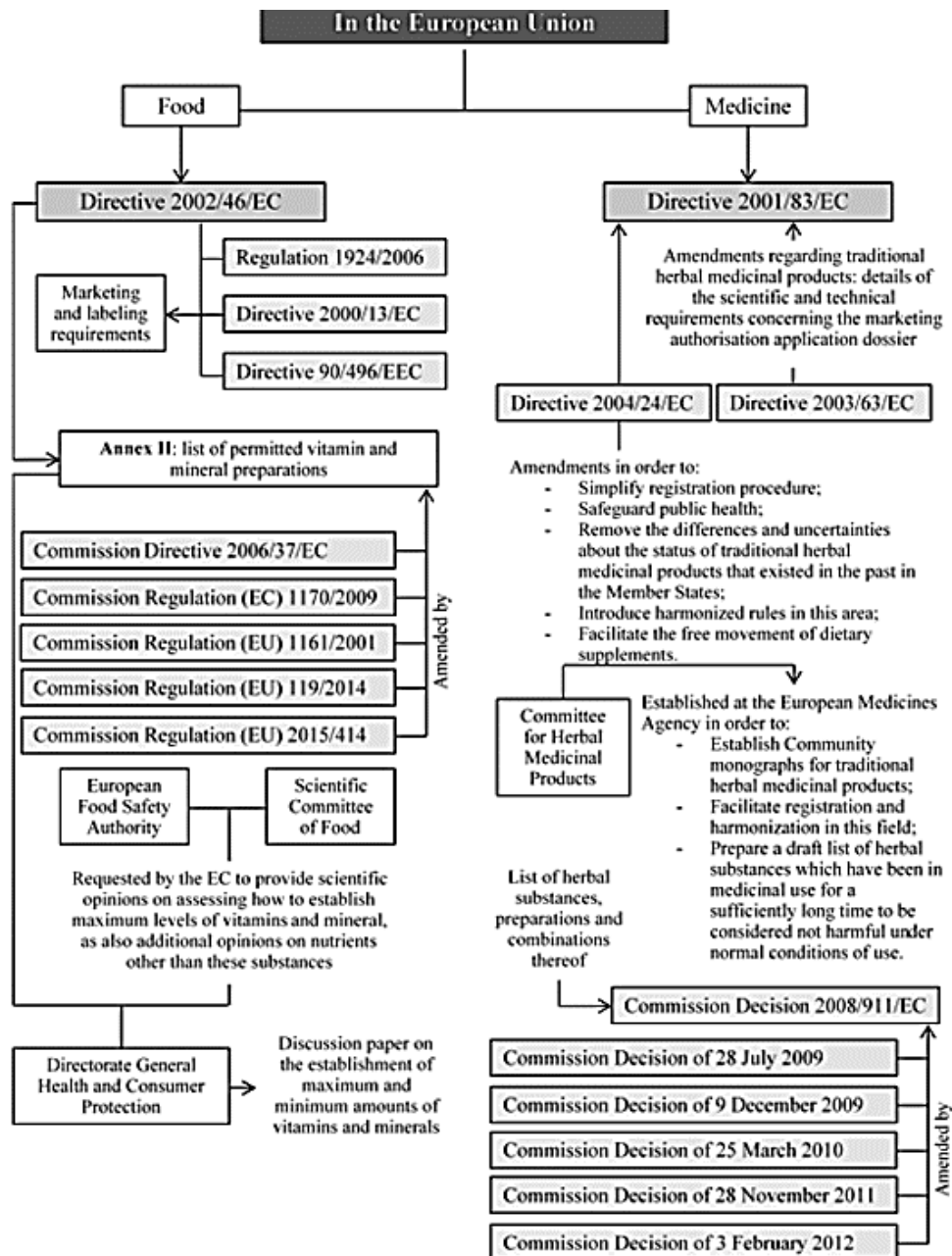


Figure 2. Overview of the legislation on dietary supplements in UE.

Source: Pereira et al., 2017.

- Regulation (EC) No 1170/2009 of the European Commission (Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and mineral additives and their forms in foods and food supplements.
- Regulation (EU) No 1161/2011 of the European Parliament and of the Council amending Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 of the European Parliament and of the Council with respect to the lists of mineral substances that may be added to foods.

- Regulation (EU) No 119/2014 of the European Parliament and of the Council amending Directive (EC) No 1925/2006 of the European Parliament and of the Council with respect to chromium-enriched yeast used in the production of dietary supplements and chromium (III) lactate tri-hydrate added to foods.
- Directive 2002/46/EC of the European Parliament and of the Council as regards (6S) was amended by Regulation (EU) 2015/414 of the European Commission. Glucosamine salt of 5-methyltetrahydrofolate, a nutrient additive.

The paper is focused on the requirements applying to the marketing of dietary supplements in Poland (for public trading). Thereby, it attempts to refer to the guidelines regulating the dietary supplements' marketing in Poland. It is based on the current regulations from the point of view of enterprises that deal in the marketing of the aforementioned products.

2. Materials and methods

The aim of the paper is to present the current rules of law and the required documentation on the marketing of dietary supplements in the Republic of Poland, with consideration of the relevant EU regulations. The review of literature analysis methodology is shown in Figure 3.

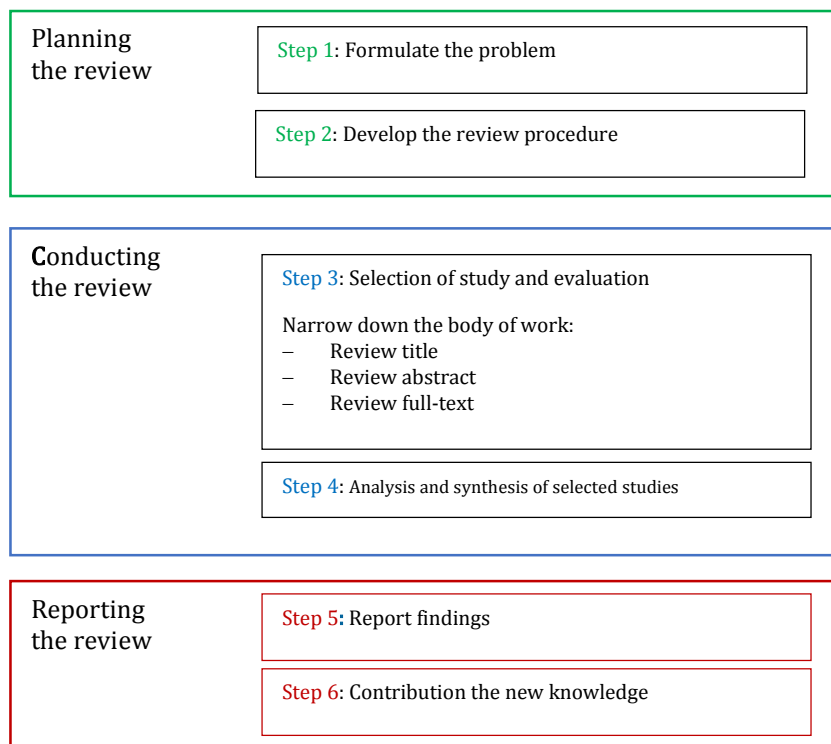


Figure 3. Review of literature analysis methodology.

The theses put forward by the authors is as follows: the current system for food safety, including dietary supplements, requires elaboration to adapt it to the current market conditions.

The paper features an analysis of literature concerning the current national and UE legislation as well as subject literature. The research was intended to present the current law on the dietary supplements' marketing based on the Polish example. It is especially intended to identify and specify the procedure and required documentation for the marketing of or the intent to market dietary supplements in the Republic of Poland. The performed research activities utilised the method of incomplete induction and document comparisons.

3. Results and discussions

3.1. Regulations on Dietary Supplements in Poland

Regardless of EU regulations, each member state is able to introduce their own detailed and complementary regulations, procedures and special requirements that are not regulated by EU law. This also applies to the system of notification on the dietary supplements' marketing in Poland. In the EU, the institution that supervises the safety of food products is the European Food Safety Authority (EFSA). In Poland, by contrast, this role was assigned to the Main Sanitary Inspectorate (MSI). The requirements on the safety of food and nutrition, including dietary supplements, are regulated in Poland with an act (Polish Journal of Laws; Dz.U. 2006, no. 171, item 1225) and the Regulation of the Minister of Health on the composition and labelling of dietary supplements (Polish Journal of Laws; Dz.U. of 2018, item 1951). These documents constitute the framework for the detailed national legislation, taking into account the requirements of the Directive of the European Parliament and of the Council, necessary to ensure food and nutritional safety (Directive 2002/46/EC) as well as the European Commission Regulation on additives that can be added to food (EC) no. 1170/2009 (Regulation (EC) No 1170/2009).

The Act on **food and nutritional** safety includes general conditions that must be met. These especially concern the additional substances and flavours, contaminants, pesticide residuals, food irradiation conditions, organoleptic features and activities that must be undertaken on all food production or trade stages to ensure the protection of human health and life (Act of 25 August 2006). Therefore, dietary supplements are admitted for trading in Poland by the Chief Sanitary Inspector (CSI). According to the act, in order to market or report the intent to market a dietary supplement, it is necessary to file a relevant notification to the CSI and present the packaging design (Act of 25 August 2006).

3.2. Marketing of Dietary Supplements in Poland

The path specifying the procedure for marketing a dietary supplement in Poland, including the legislation acts, institutions and required documents is presented in Figure 4.

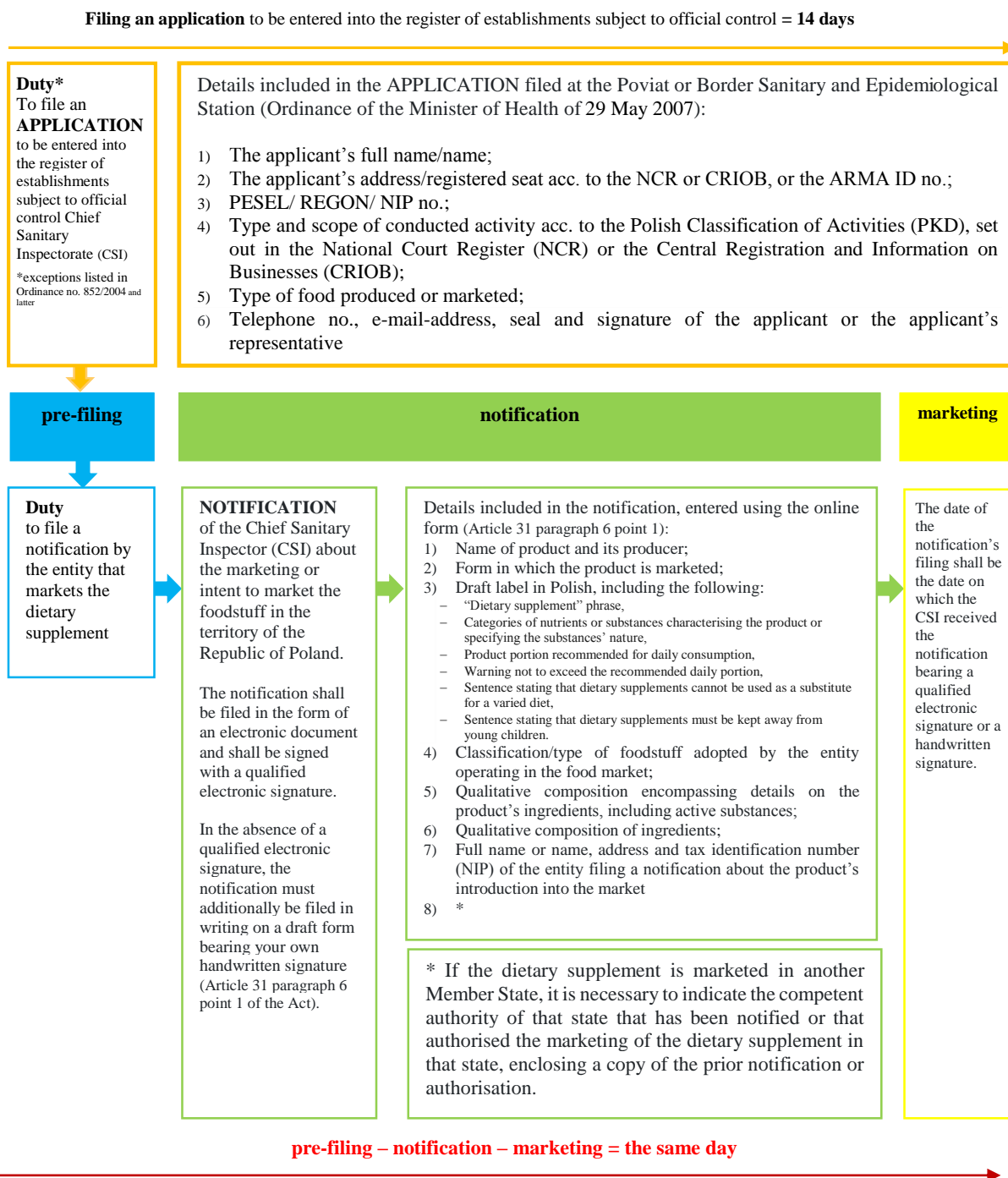


Figure 4. Procedure for the marketing of/intent to market a dietary supplement in Poland.

Due to the fact that the legal acts were presented in paragraph 3.1, this part of the paper will be focused on the notification form and its contents. The draft CSI notification form on products marketed in Poland was established in the Regulation of the Minister of Health (Polish Journal of Laws; Dz.U. 2019, item 2499).

The form is named “Notification about the marketing/intent to market in the Republic of Poland” (Appendix no. 1 to the Regulation of the Minister of Health of 21 December 2019). Firstly, the applicant is obliged to specify the identification details of the business entity that files the notification to the CSI. The identification details must especially include the full name of the person or the name and address of the entity filing the notification of the marketing of or intent to market a foodstuff, and its tax identification number (NIP). Then, the form includes an information clause specifying the legal entry that regulates the issue in Poland (Act of 25 August 2006).

Next, it is necessary to provide the CSI with information about the foodstuff’s trade name, classification (type) and form. In terms of the foodstuff’s *type*, the legislator proposes to use one of the foodstuff types mentioned in the adopted classification, i.e. dietary supplement, infant formula, follow-on formula, foodstuff replacing every-day diet, weight control foodstuff, enriched food, special medical purpose food. The definitions and distinction of particular categories was presented in relevant legal entries and discussed in scientific works (Polish Journal of Laws; Dz.U. 2019, item 2499; Appendix no. 1 to the Regulation of the Minister of Health of 21 December 2019; Food for Special Medical Purposes, 2017/C 401/01; Regulation (EU) No 609/2013; Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC).

In terms of the foodstuff’s *form*, the legislator requires the applicant to specify (Appendix no. 1 to the Regulation of the Minister of Health of 21 December 2019) the ingredient’s name, content (quantity per 100 g quantity per 100ml), quantity in a daily portion as well as additional information. Additional information is a category of information concerning ingredient features that ensure their explicit identification. It is important for plant products to specify the following data (Appendix no. 1 to the Regulation of the Minister of Health of 21 December 2019): Latin species name, plant part, plant ingredient form, concentration, ingredients with a physiological effect. On the other hand, in terms of mineral components and vitamins, it is necessary to specify the chemical form and origin of the components, while for other ingredients it is necessary to specify the information specific to the given ingredient type (chemical form, bacteria strain, origin) (Appendix no. 1 to the Regulation of the Minister of Health of 21 December 2019).

Furthermore, the applicant must specify the producer’s personal details or name and address. If the given foodstuff was already marketed in other EU member state(s) and if it is required to provide notification about this fact, the notification must include the name of the state body notified or that permitted the marketing of the foodstuff in their state.

The regulation also requires providing appendices to the notification, especially 1) draft labelling in Polish and 2) copy of notification filed or permit obtained in another EU member state. The draft labelling should include the necessary information that enable the evaluation of the adopted foodstuff classification (Regulation (EU) No 1169/2011).

The notification can be delivered to the CSI in two ways: in a traditional paper copy form via any certified mail institution or in an electronic form (the so-called e-notification) with a digital signature. The detailed recommendations and stages of procedure are specified in the so-called user station instructions for the Electronic Notifications System (ENS) available on the CSI's website (User instructions in the workplace Electronic Notification System (ESP)).

Aside from formal requirements, it must be noted that filing a dietary supplement notification at the CSI does not require paying any official fees. On one hand, this complies with the Directive's entries (Directive 2002/46/EC) as it makes it possible for any entity that meets the statutory conditions and ensures free access to these products to consumers to market dietary supplements. On the other hand, it is possible to state that there are no barriers to enter the market, thereby leading to market pathologies evidenced by official food control reports (e.g. the RASFF system, Supreme Audit Office's report). It can be noted that the marketing of dietary supplements in Poland features no quality control (RASFF – food and feed safety alert; Annual Reports of the Supreme Audit Office, 2017).

It is also not required to present the results of substance stability testing (Bojarowicz et al., 2012; Bojarowicz & Dźwigulska, 2012a, 2012b). Furthermore, dietary supplements are not tested in terms of possible interactions with medicine or other food substances, are not subject to pharmaceutical supervision control and are not monitored in terms of adverse effects. As result of the conducted inspections, the Supreme Audit Office also pointed to numerous violations in this scope (SAO's Report, 2017).

Moreover, in the case of dietary supplements, the legislator did not introduce the obligation to enclose a factsheet and only included entries on the information that must be placed on the packaging. The applicant is obliged to provide the following information on the packaging (Polish Journal of Laws; Dz. U. of 2018, item 1951): the "dietary supplement" phrase; category of nutrients or substances characterising the product or disclosing the substances' nature; product portion recommended for daily consumption; warning not to exceed the daily portion; sentence stating that dietary supplements cannot be used as a substitute for a varied diet; sentence stating that dietary supplements must be kept away from young children.

Therefore, the entries required on the packaging of dietary supplements are placed only for information, or even symbolic, purposes. From the consumer's viewpoint, the information placed on packaging does not provide useful information and the legislator's relevant liberal entries can enable incorrect or even criminal activities for dishonest applicants. On the other hand, in terms of factsheets that could be required for dietary supplements, two approaches are used in practice: there are none or are minimalistic. This means that factsheets contain limited information or information repeated from the packaging on indications, dosage, warning that

the preparations must not be used during pregnancy and breast feeding as well as preparations available for purchase. They are missing, as in the case of medicinal products, such information as: dosage, administration method and route, administration frequency, treatment duration, symptoms and procedure in case of over dosage, procedure if a dose is omitted, risk of withdrawal syndrome, specification of adverse effects, expiration date, specification of special storage conditions, specification of changes indicating deterioration of the product's quality, weight, volume or number of dosage units, the responsible entity's name and address, name and address of the producer or importer at which the series is released (...) (Polish Journal of Laws; Dz.U. no. 39, item 321; Polish Journal of Laws; Dz.U. no. 84, item 551). A comparison between a dietary supplement's leaflet and a medicinal product's leaflet is justified as in their publications, scientists raise the issue that consumers equate these two products and treat them as symbiotic (Angell, Kassirer, 1998; Dodge et al., 2011).

In addition, the published results of food safety inspections conducted by various institutes point to irregularities, including falsification of dietary supplements. In Poland, the CSI's website publishes warnings about hazardous products and decisions on the withdrawal of a particular dietary supplement from the market (if the supplement does not meet the requirements) (SAO's Report, 2017). Nevertheless, researchers specify the most common errors, including (Annual Report, The EU Agri-Food Fraud Network and the Administrative Assistance and Cooperation System): labelling, substitution of a declared ingredient (with a different one or with lower quality), lower "active" substance content than declared in the labelling as well as unauthorised substances content, irregularities related to documentation (including missing, falsified, forged documents), use of unlawful processing and intellectual property violations.

The specified irregularities provide further critical issues to the discussion and it is fundamental to implement an efficient system to monitor the correctness of marketed dietary supplements. Due to the above, the authors suggest to take regulatory action and solve the issue of preventing, according to the rules of law, the marketing of dietary supplements that are ineffective and may be hazardous to the consumers' health and life.

4. Conclusion

The observed rapid technical progress and development of production devices prevent regulations and legislations (both national and EU) from keeping up with regulating the dietary supplements market and the safety system requirements, especially for consumers and their interests. It must be noted that the adoption of the Directive 2002/46/EC (Directive 2002/46/EC) commenced the processes of deliberate food supplement management in all countries in the community. Nevertheless, these processes are insufficient and require further action (Sir Macara, 2002).

- This refers, among others, to liberal regulations on the provided consumer information, terminology inaccuracies, easy marketing of dietary supplements, no fees, etc. It is possible to notice that in this situation the barrier to enter the dietary supplements market is small, making it easy for pathologies (including food falsification) to occur. For consumers, it can cause bad decisions, financial losses and health disorders in extreme cases.
- In summary, it is possible to state that the specified procedure for marketing of dietary supplements in the Republic of Poland is reprehensibly liberal (undemanding). The notification form is not complicated. The applicant pays no fees related to the notification. There are also no regulations on factsheet contents.
- All of the above activities are only administrative in nature and in terms of numerous identified irregularities they should engage the legislator to define further non-liberal regulations that would prevent the occurrence of pathologies in the market. It is suggested to implement a systemic, community-wide support for food safety monitoring (control) institutions.
- It is important to resolve the following dilemmas: is the supervision system sensitive to irregularities in the current food safety system and whether it can eliminate any deviations and pathologies related to dietary supplements to in order to prevent endangering consumer health?

Acknowledgements

This work was financially supported by the Opole University of Technology as part of the DELTA project no. 066/21.

Author contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by [Hys Katarzyna], [Dominika Matuszek], [Krzysztof Olejnik] and [Karol Bierczyński]. The first draft of the manuscript was written by [Katarzyna Hys] and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Conceptualization: [Hys Katarzyna]; Methodology: [Hys Katarzyna], [Dominika Matuszek], [Krzysztof Olejnik] and [Karol Bierczyński]; Formal analysis and investigation: [Hys Katarzyna]; Writing - original draft preparation: [Hys Katarzyna]; Review and editing:

[Hys Katarzyna]; Funding acquisition: [Hys Katarzyna], [Dominika Matuszek]; Supervision: [Hys Katarzyna].

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