

## INVESTIGATION PROCEDURE REGARDING THE INTRODUCTION OF DIETARY SUPPLEMENTS INTO THE MARKET IN POLAND

Katarzyna HYS<sup>1\*</sup>, Dominika Barbara MATUSZEK<sup>2</sup>, Krzysztof OLEJNIK<sup>3</sup>,  
Karol BIERCZYŃSKI<sup>4</sup>

<sup>1</sup> Department of Biosystems Engineering and Chemical Processes, Faculty of Production Engineering and Logistics, Opole University of Technology; k.hys@po.edu.pl, ORCID: 0000-0003-0800-2804

<sup>2</sup> Department of Biosystems Engineering and Chemical Processes, Faculty of Production Engineering and Logistics, Opole University of Technology; d.matuszek@po.edu.pl, ORCID: 0000-0002-5200-1561

<sup>3</sup> Department of Logistics, Faculty of Production Engineering and Logistics, Opole University of Technology; k.olejnik@po.edu.pl, ORCID: 0000-0003-4391-0437

<sup>4</sup> Department of Biosystems Engineering and Chemical Processes, Faculty of Production Engineering and Logistics, Opole University of Technology; karol.bierczynski@doktorant.po.edu.pl, ORCID: 0000-0002-0184-5115

\* Correspondence author

**Purpose:** The purpose of the paper is to describe and graphically visualise the investigation procedure carried out by the Chief Sanitary Inspector (GIS) as part of an entity's introduction of foodstuffs, especially dietary supplements into the market in the Republic of Poland.

**Methodology:** The basis for the paper was a study of the legislation governing the investigation procedure carried out by the Chief Sanitary Inspector in Poland. In addition, it involved an analysis of the comments to the current legislation and of the subject literature available in international and domestic reference databases.

**Findings:** The conducted study resulted in the development of a visualisation of the investigation procedure for dietary supplements' notification in Poland. A criticism of the aforementioned procedure and issues that require regulation are included in the paper.

**Practical implications:** The developed procedure provides a useful visualisation of the legal requirements in the aforementioned area.

**Social implications:** The presented discussion is intended to draw attention to the legal provisions that are important in terms of the life and health of consumers of dietary supplements.

**Originality:** The procedure of introducing foodstuffs, especially dietary supplements into the market in the Republic of Poland is described in legislation. Similarly, legislation also describes the investigation procedure for non-compliances occurring during the notification of dietary supplements. Nevertheless, the authors proposed a description and visualisation of the procedure by analysing its legal conditions in detail. Furthermore, they drew attention to the provisions' ambiguity and the resulting formal doubts.

**Keywords:** dietary supplements, investigation, the Chief Sanitary Inspector, Poland.

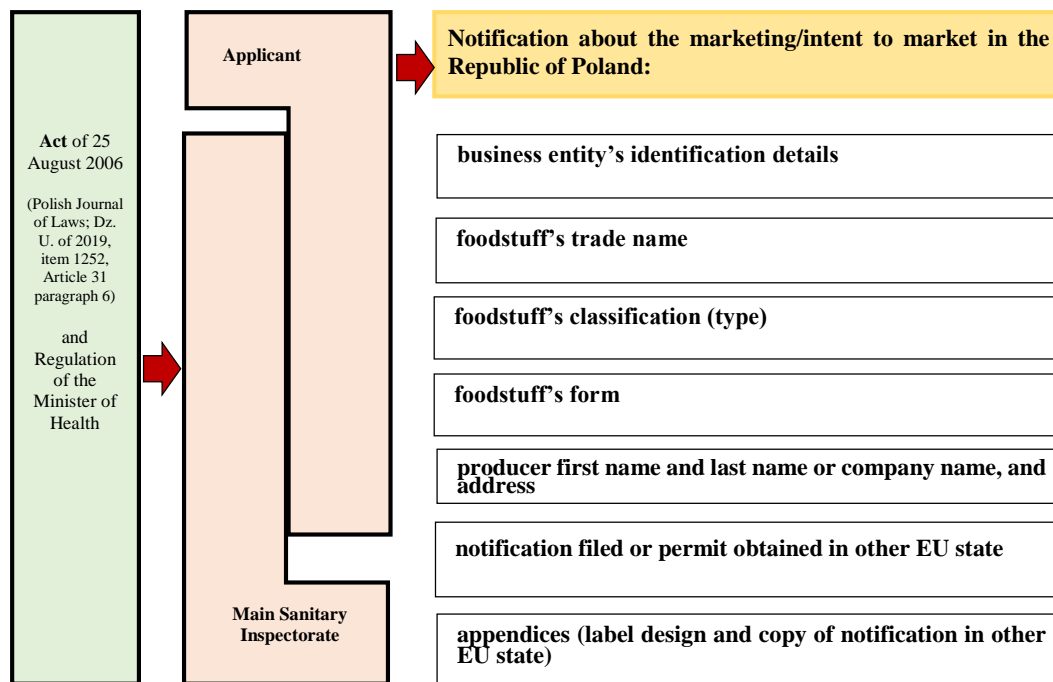
**Category of the paper:** research paper.

## 1. Introduction

The notification of dietary supplements for introduction into the Polish market is governed by relevant rules of law (Act of 25 August 2006; Ordinance of the Minister of Health of 23 March 2011). In Poland, the body with competence to accept a notification of an entity's intention to introduce a dietary supplement into the market is the Chief Sanitary Inspectorate (GIS).

From a formal perspective, the day on which the notification, signed with a qualified electronic signature or a handwritten signature, is sent by the notifying entity to GIS is the day on which it is possible to commence the sale of dietary supplements in the market (Hys, 2018, 2020; Hys, Koziarska 2020, 2021). Importantly, the notification service is free of charge. The exception is when the notification of the intention to introduce a supplement into the Polish market is filed by the entity's proxy. The notifying entity may then incur additional fees related to the proxy service (Resnik, 2018).

In general, the notification procedure involves sending by the notifying body of an official document stating its intention to market the dietary supplement in Poland (Report NIK, 2017; Wróbel et al., 2022). The notification process thereby consists of sending a formal notification which, according to the legislation, contains specific data (Figure 1).



**Figure 1.** Dietary supplement's notification procedure in Poland.

Source: own study.

The contents of the notification for the introduction of a dietary supplement into the market is governed by the provisions of the Ordinance of the Minister of health of 23 March 2011 *on the draft notification form on products introduced into the market of the Republic of Poland* (Regulation of the Minister of Health of 23 March 2011).

The information that the notifying entity must include in the notification pursuant to the provisions of the aforementioned Ordinance must especially include the following:

- the form in which the dietary supplement will be sold,
- the dietary supplement's content, i.e. precise quantitative and qualitative composition,
- the draft label (packaging) along with all marks and warnings for consumers.

Although the information contained in the notification is declaratory, it is noted that it should be marked in accordance with the facts. The issue is to adhere to both formal and substantive guidelines. Otherwise, the Chief Sanitary Inspectorate's employees have legal tools at their disposal, with which they can temporarily suspend the trade of a given dietary supplement or completely remove it from the market.

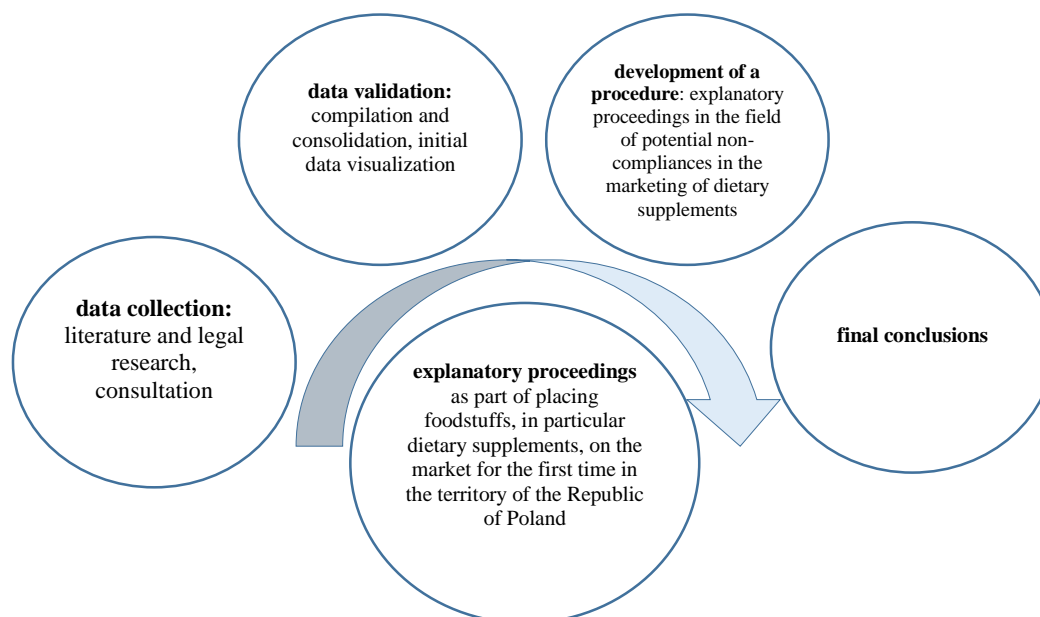
Due to the possible need for the GIS to verify the notification filed by the notifying entity, the paper addresses the issue of the investigation procedure governed by legislation and applied to foodstuffs, especially dietary supplements (hereinafter referred to as dietary supplements) that are being introduced into the market of the Republic of Poland (Regulation of the Minister of Health of 29 May 2007; Regulation of the Minister of Health of 21 December 2019).

## 2. Methodology

An analysis of the subject literature was the basis for the study carried out in this paper. The analysis particularly included a review of the current legislation on the investigation procedure carried out by the GIS and of the available literature in the subject matter (Figure 2).

The literature review became the basis for an analysis of the current knowledge on the subject, ultimately enabling the development of a graphical visualisation of the procedure used in the aforementioned procedure.

The review of subject literature was carried out through the following activities: data collection (relevant subject literature identification), data validation, the investigation procedure establishment, visualisation of the aforementioned procedure and presentation of final conclusions, with particular emphasis of the criticisms of the aforementioned procedure.



**Figure 2.** Subject literature review methodology.

The subject literature analysis allowed for developing a graphic visualisation of the investigation procedure carried out by GIS against an entity that filed a notification about its intent to introduce dietary supplements into the market in the Republic of Poland.

### 3. Result and discussion

The Chief Sanitary Inspector may carry out an investigation procedure upon receiving a notification about the introduction of or the intent to introduce dietary supplements into the market in the Republic of Poland, aimed at clarifying whether the notified product meets the requirements set out in the Act (Polish Journal of Laws; Dz.U. 2006, no. 171 item 1225; Polish Journal of Laws; Dz.U. 1960, no. 30 item 168; Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004; Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017). Importantly, the GIS may carry out an investigation, but does not have to and does not carry out such an investigation for every notification submitted, unless it considers it appropriate to do so. The investigation procedure is governed in Poland by relevant legal provisions, with the individual stages of its implementation recorded in the form of a flowchart (Figure 3).

If the GIS decides that it is necessary to initiate an investigation procedure against an entity that filed a notification of its intent to introduce a given dietary supplement into the market, the aforementioned investigation is carried out to a specific extent.

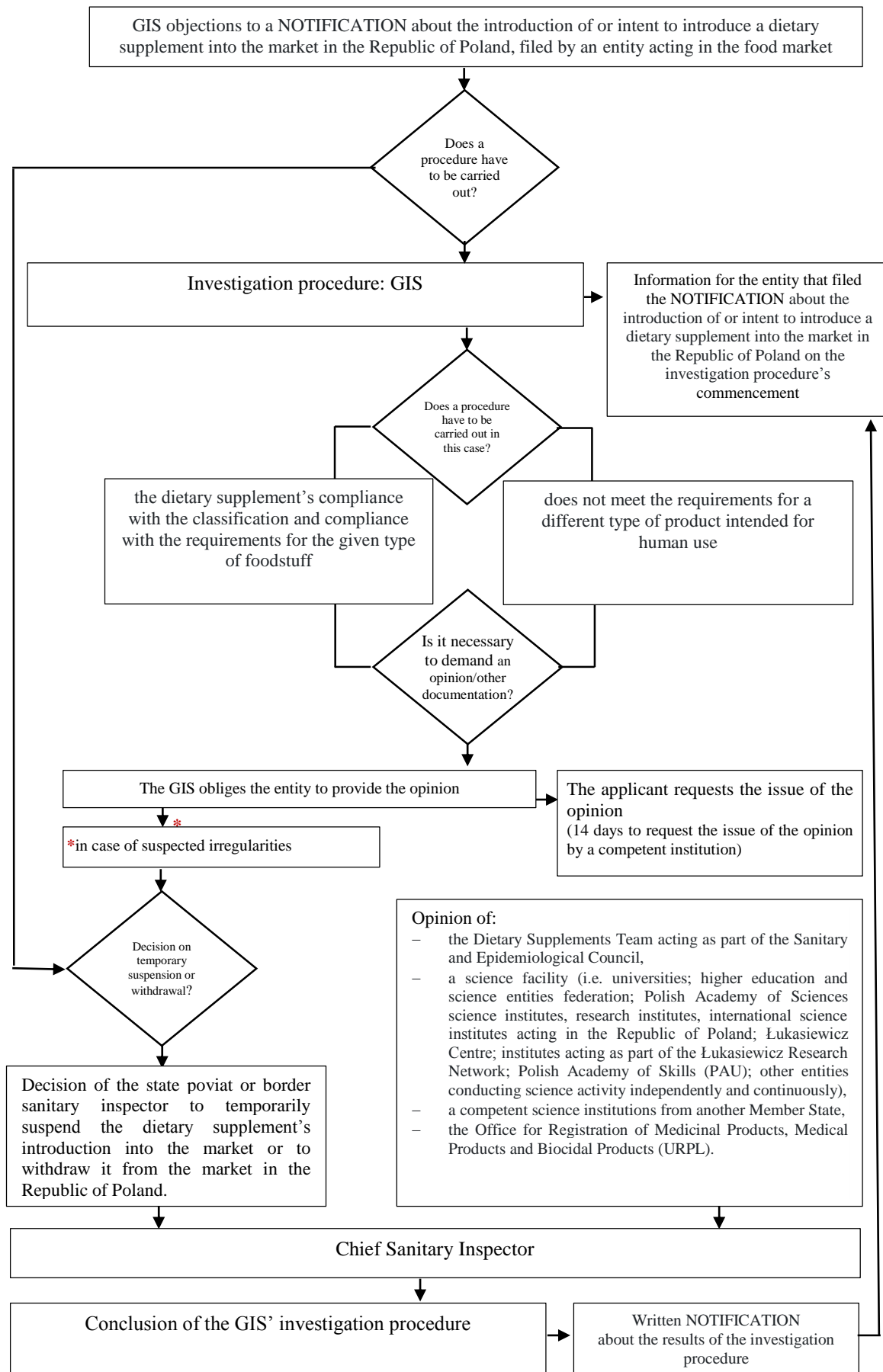


Figure 3. The investigation procedure carried out by the GIS.

It is the primary responsibility of the GIS to inform the entity without delay that an investigation procedure has been undertaken against the notification concerning the dietary supplement in question.

The investigation procedure is to provide an answer on the following issues, i.e. whether the given product (Article 30 paragraph 1 points 1-2):

- is a foodstuff according to the classification proposed by the entity acting in the food market and whether it meets the requirements for the type of foodstuff in question (especially in terms of its composition, properties of individual ingredients and the intended use of the dietary supplement in question, or
- does not meet the requirements of another type of product intended for human use (especially a medicinal product - within the meaning of the pharmaceutical law; a cosmetic product - within the meaning of the cosmetic products law; a medical device - within the meaning of the medical devices law).

The statutory deadline for the GIS to carry out an investigation is 60 days. However, additional time (if necessary) should be added to the period of the procedure to document that the entity filing the notification has met the requirements.

The costs of documenting compliance with the requirements (so-called opinions) shall be borne by the entity filing the notification to the GIS. The opinion may be issued by the Dietary Supplements team acting as part of the Sanitary and Epidemiological Council, science facilities, the Office for Registration of Medicinal Products, Medical Products and Biocidal Products (URPL) or by competent science institutions of another Member State.

If irregularities are suspected in the notification filed by the entity, it is possible to temporarily suspend the dietary supplement's introduction into the market or to completely withdraw the product from the Polish market. The decision is made by the state poviast or border sanitary inspector.

Once the investigation procedure has been completed, the GIS informs the notifying entity in writing about the results of the investigation.

#### **4. Conclusion**

The investigation procedure concerning the dietary supplement notified for trade was presented graphically based on the analysis of the subject literature. Nevertheless, despite the seemingly unambiguous procedure, literature features many critical references about the procedure's ambiguity.

The authors raise criticisms of the investigation procedure carried out by the GIS, with regard to, among others, the following (e.g. Zboralska, 2011; Szymecka-Wesołowska, 2014; Van Regnault et al., 2021):

- the timing, scope and mode of the inspection carried out by the GIS with regard to, among others, the following issues (Supreme Audit Office's Report):
  - a) dietary supplements are subject to testing as part of official food inspections only after they have been introduced into the market and only to a selected extent,
  - b) the notification is not verified before the dietary supplements are introduced into the market,
  - c) the commencement of an investigation procedure does not halt the distribution of dietary supplements in the market,
- the prerequisites for commencing an investigation procedure are not clarified,
- the timing and legal form of commencing an investigation procedure are not clarified,
- the opinions of science facilities, the URPL and other indicated entities on the following:
  - a) the notifying entity's inability to challenge a provision requiring it to submit an opinion,
  - b) the notifying entity's inability to challenge an opinion issued by the indicated opinion-making facilities, because the GIS is bound by this opinion (Balicki),
- the legal form of the investigation procedure's conclusion; there is no administrative decision (only an obligation to notify the entity in writing of the investigation's results, but no legal form of this notification, which results in doubts as to the legal effects of such an act, or the possibilities of appeal),
- there are no regulations concerning the notification procedure's conclusion,
- there are no regulations concerning the corrective notification.

Hence, the authors point out that, in the context of so many doubts articulated in the subject literature concerning the mode of the investigation procedure, it is necessary to start a discussion and take steps to clarify the legal provisions allowing for the regulation of the aforementioned issues.

The authors of this paper have developed a visualisation of the investigation procedure that can be commenced by the GIS regarding dietary supplements to be sold in the market of the Republic of Poland. The procedure and its description are useful and represent a new form of presentation of the relevant legal provisions. At the same time, references to the subject literature allow for a direct reference to the relevant legal regulations.

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