Food supplements' non-conformity in Europe – Poland: a case study

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Abstract

Background: Mislabelling and substitution of ingredients in food supplements is a growing concern for regulators, businesses and consumers. Whilst there is a body of literature that has considered food and drink substitution and mislabelling, there is limited published research on the compliance of food supplements with regulatory requirements.

Scope and Approach: Using secondary data, the aim of this research was to identify the main factors influencing food supplements non-compliance in the European Union (EU) but with specific emphasis on Poland. The sources of data in this review were: (1) the register of pro-health foods maintained by the Chief Sanitary Inspector (GIS) in Poland; (2) unpublished data from the European Commission DG Health and Food Safety (EC DG SANTE); (3) the EU Food Fraud Network and the Administrative Assistance and Cooperation System (EU FFN & AAC) Reports; (4) the Polish Trade Inspection (IH) Report; and (5) the Rapid Alert System for Food and Feed (RASFF) Portal.

Key findings and conclusions: The level of food supplements non-compliance with stated legal requirements especially mislabelling is identified in this research. Policy needs to be strengthened both at the EU level, where overarching regulatory governance can be introduced, and also in individual member states, such as Poland, where situational socio-economic factors

such as health-care provision, the associated absorptive capacity of the food supplements' market and the level of ability of national institutions to institute effective regulatory and market governance influence the incidence of food supplements.

Highlights

- The incidence of food supplement non-conformity is a concern in Europe.
- Problems involve composition, nutrition, and health claims.
- Effective food supplement governance is essential for consumer protection.

Keywords: dietetic foods, food supplements and fortified foods; RASFF; EU FFN&AAC;

1. Introduction

In the last few years, food adulteration has been a growing issue for the European Commission (EC), governments, official food control bodies, food standards' setters, food business operators and academic researchers (Kowalska, 2018; Marvin et al. 2016; Spink & Moyer, 2011). Recent media coverage of instances of food adulteration demonstrates the economic, environmental and socio-political consequences of such activity (Fox, Mitchell, Dean, Elliot, & Campbell, 2018; Manning, 2018). Globalisation and the liberalisation of trade, combined with the increased vulnerability of frequently long and complex supply chains makes product adulteration a tangible risk for a broad group of supply chain actors (Kowalska, 2018; Marvin et al. 2016; Spink & Moyer, 2011). Consumer rights in relation to food are enshrined in Article 9 of Regulation (EC) No 178/2002. Mislabelling, if intentional is one form of adulteration, and denies a consumer their right to make an informed choice. Whilst many food supplement products are produced by reputable organizations, in 2017 and 2018, 'dietetic foods, food supplements and fortified foods' was the most frequently reported non-compliant product category in the EU Food Fraud Network & Administrative Assistance and Cooperation System (EU FFN & AAC). Thus making non-conformance connected with this category worthy of further investigation. An important initial milestone on the journey of regulating the EU food

supplements market was the issuance of Directive 2002/46/EC on the approximation of the laws relating to food supplements. In 2006, further legislation relating to nutrition and health claims made on foods (including food supplements) was introduced. Under Article 10(1) of Regulation (EC) No 1925/2006, health claims made on foods are prohibited unless they are authorised by the EC and the European Regulation (EU) No 432/2012 introduced a list of permitted claims. Adopted in 2013, the EU's Food for Specific Groups (FSG) Regulation (EC) No 609/2013 abolished the concept of 'dietetic food' by repealing Directive 2009/39, which then set out general rules for 'food for particular nutritional uses' or PARNUTS. The scope of the FSG regulation is limited to infant and follow-on formula, processed cereal-based and other baby food, food for special medical purposes and also total diet replacement for weight control. Food supplements are described in the aforementioned Directive 2002/46/EC as:

> "foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities."

Thus, as part of their registration process, food supplements are considered as foods and are not required to be tested, registered and checked as exhaustively as medicines or synthetic drugs (Rocha, Amaral & Oliveira, 2016). Food supplements and synthetic drugs have certain characteristics in common. Firstly, they are both marketed in dose form and designed to be taken in measured small unit quantities. Secondly they are offered for sale in pharmacies and on-line; thirdly if guidelines for use are not followed, overdosing can exceptionally occur.

Use of food supplements is growing globally and current sales are close to 7 billion Euros annually (Czepielewska, Makarewicz-Wujec, Różewski, Wojtasik & Kozłowska-

Wojciechowska, 2018). Consumers view food supplements as 'natural' and therefore safe (Berginc & Kreft, 2015), but the presence of an undisclosed adulterant in a food supplement can cause adverse health effects to those that unwittingly consume it (Wheatley & Spink, 2013). Economically motivated adulteration is simply deception through activities such as substitution of ingredients with substandard or inferior products, unapproved additions or enhancements, misbranding or misrepresentation, tampering, counterfeiting, or using stolen goods for economic gain (Kowalska, 2016; Spink & Moyer, 2011; Morozzi et al. 2019). Zhang and Xue (2016) state that fraudulent activities mostly occur in locations where regulatory loopholes exist. *Is this true for Poland?* According to Polish food law, foods are considered adulterated when they are mislabelled in terms of product composition irrespective of whether there was a motivation to do so i.e. if the product fails to comply with its compositional labelling it is deemed as being adulterated (Kowalska, Soon & Manning, 2018). There are about 60,000 food supplements and fortified foods on the Polish market (GIS, 2018). Moreover, it is significant in Poland that "discount pharmacies" are getting more and more popular and emerging price asymmetries between legitimate and illicit sources could act as a motivating factors influencing the incidence of economically motivated adulteration. These issues have wider implications as there is no fee for notifying for food supplements firstly placed on the Polish market compared to other EU countries (Kotynia, Szewczyk, & Tuzikiewicz-Gnitecka, 2017). The ease of entry to the Polish and then the EU harmonised market, and the absorptive capacity of the national and regional food supplements' markets, thus makes Poland an interesting case study and is the research lens through which food supplement adulteration is now considered in more details.

A survey conducted by PMR Research in 2011 on a representative sample of adult residents in Poland (n=1000) highlights that two-thirds of Poles buy over the counter (OTC) drugs and food supplements, and they favour traditional pharmacies. The place of purchase influences consumer trust in product authenticity and consumers appreciate the advice given by

pharmacists (Kasperczyk, 2012). A further survey conducted by TNS Poland in 2014, (n=1000), shows that 41% of respondents attribute medicinal properties to food supplements. Half of these respondents believe that food supplements are subject to the same regulatory controls as synthetic drugs with only 27% of respondents correctly describing food supplements as foodstuffs intended to supplement the normal diet, and alarmingly one quarter of those surveyed believed that there was no unsafe dose of a food supplement (Kozłowska-Wojciechowska, 2014; SCO, 2017). There is a popular belief in Poland that food supplements are healthier and safer than synthetic drugs (Czepielewska, Makarewicz-Wujec, Różewski, Wojtasik & Kozłowska-Wojciechowska, 2018).

In 2016, on average, Poles devoted 10.1% of their household income to synthetic drugs prescribed by doctors (the Polish Public Opinion Centre (CBOS), 2016) and overall, they spent about 14.7% of their household income on synthetic drugs (DNB and Deloitte, 2015). The situation in Poland is different to some other EU Member States. In Poland, high prices of drugs, very long queues or extremely long waiting times (up to several months) for a specialist doctor's appointment influence Polish citizens' growing interest in food supplements (Stepurko, Pavlova, & Groot, 2016; Kister, 2018). This contributes to the growth of the food supplements' market in Poland which would not increase risk to consumers if goof governance is in place. Indeed in certain European countries, such as Poland, Bulgaria, Croatia, Romania, Latvia and Sweden, those without access to health care comprise over 10% of the population. In Spain, a lack of health insurance, the availability of generic cheaper alternatives and the degree of self-medication for minor ailments all influence the amount of OTC drugs used per household (Costa-Font, Kanavos & Rovira, 2007).

Another further factor of interest in Poland is the level of advertising of food supplements, drugs and pharmaceuticals, across all communications channels. In 2015, a quarter of TV commercials and half of radio commercials concerned health products and drugs and this

124 ranked first amongst types of products promoted (Hys, 2017; Zboralska, 2018). Indeed in 2015,
125 Polish citizens purchased an average of 4.94 unit packs of food supplements per person
126 (Kasperczyk, 2012; Kotynia, Szewczyk, & Tuzikiewicz-Gnitecka, 2017). As Poland leads
127 European countries in terms of annual drug and food supplements consumption, the global
128 pharmaceutical companies are very interested in the Polish market (Kasperczyk, 2012).

129 Using secondary data, the aim of this research was to identify the main factors influencing
130 food supplements non-compliance in the European Union (EU) but with specific emphasis on
131 Poland. The paper is structured as follows. Section 1 provides a brief overview of the concept
132 of food supplement adulteration and mislabeling and provides the underlying rationale for the
133 research in Poland. Section 2 outlines the approach employed to analyse the secondary data
134 used in the study. Section 3 highlights the findings and synthesizes secondary data to review
135 the development of the food supplements' market in Poland and issues surrounding the issue of
136 food supplement adulteration in the EU and Poland. Section 4 discusses the results and Section
137 5 provides conclusions from the study and recommendations for future research.

138 **2. Study approach**

139 The approach used in this research was firstly to review existing literature to define and
140 outline the challenge of food supplement adulteration and then to analyse the outcome of the
141 RASFF data local (national) and European data on the prevalence of food supplement
142 adulteration and mislabelling more generally, and specifically in Poland. The source data
143 consulted for this research comprised:

144 (1) the register of pro-health foods maintained by the Chief Sanitary Inspector (GIS) in
145 Poland;
146 (2) unpublished data from the European Commission DG Health and Food Safety (EC DG
147 SANTE);

(3) the EU Food Fraud Network and the Administrative Assistance and Cooperation System (EU FFN & AAC) Reports;

(4) Polish Trade Inspection (IH) Report; and

(5) the Rapid Alert System for Food and Feed (RASFF) Portal.

The analysis of data from the aforementioned sources used the Excel 2016 Forecast Sheet. Before November 2015, the RASFF database was the most important tool for exchanging information on food safety and food adulteration issues in the EU. However, some forms of product non-compliance do not sit well with the existing classifications in the RASFF system and needs to be addressed by additional means at EU level. The 2013 horsemeat crisis, whilst being an infringement of consumer rights, and causing supply chain disruption leading to a loss of sales and widespread product recalls did not show any profiles of public health risks (Premanandh, 2013; Czinkota, Kaufmann & Basile, 2014). In response to the horsemeat crisis, the EU Food Fraud Network (EU FFN) was set up in 2013 and the Administrative Assistance and Cooperation System (AAC) was made available for Member States in 2015 (Prandi et al. 2019). Since then, the EU FFN & AAC System and the RASFF System have been working together in synergy to maintain the EU safety and compositional standards for food and feed (EC, 2016). The difference between the systems is that the RASFF members are obliged to notify and to exchange information on food and feed safety issues and measures while the EU FFN & AAC System works on voluntary basis and only for cross-border non-compliances (EC, 2016; RASFF, 2018).

The EC recognised four operational criteria for appropriate qualification of a case exchanged in EU FFN & AAC as being food fraud (Food Fraud cases, AAC FF) (EC, 2016). These were (a) a violation of EU law; (b) an intention to commit an offence; (c) identification of activities that seek to defraud others; or (d) more generally cause the wider deception of customers (EC, 2016). Cases that do not meet all four key criteria are considered as other non-

compliances with EU food law (Administrative Assistance cases, AAC AA). Between the food fraud databases that have developed in recent years, there is a lack of consistency in food fraud categorisations (including adulteration), especially around the criteria of demonstrable intent, (Bouzembrak et al. 2018), but each database, despite their limitations (see Manning & Soon, 2019) is a valuable source of intelligence that can contribute towards the effective governance of product adulteration. Unpublished data received by the authors in May 2018 and January 2019 from European Commission DG Health and Food Safety, Directorate G. Crisis Management in Food, Animals and Plants, Unit G5. Alerts, Traceability and Committees in Brussels, Belgium responsible for EU FFN & AAC System showed, when compared to non-compliance for other categories, the great number of EU food law violations were for dietetic foods, food supplements and fortified foods and this was a starting point for further analysis. In this research, the data for dietetic foods, food supplements, fortified foods provided in the RASFF Portal and the EU FFN & AAC System were grouped together, and it was a limitation in this research that in using the secondary data no distinction could be made between dietetic foods, food supplements and fortified foods. The results from testing by the IH concerned with labelling and presentation of food supplements has been synthesized with the data from the other two sources.

3 Findings from analysing the datasets

3.1. Food supplement market trends in Poland: review of GIS register for pro-health foods

To enter the Polish market, suppliers must notify the Chief Sanitary Inspector (hereinafter: GIS) via an electronic system about placing dietetic food, food supplement or fortified food on the market and also provide a sample of the product packaging. Article 29.2 of the Polish Act of the Safety of Food and Nutrition (2006) (Food and Nutrition Safety Act, hereinafter: FNSA) states that:

198 "the on-line notification to GIS covers the following information: the name of a
199 product and its producer, the form of a product, draft label in Polish, suggested classification
200 of a foodstuff, the qualitative and quantitative composition including active substances, the
201 first and last name of a person or the name of a company that notifies a product, the address
202 and the tax identification number of the notifier."

203 The number of new notifications to GIS of products from the category of foods for
204 specific groups, food supplements and fortified foods entering the Polish market, has been
205 growing rapidly since 2011 (Figure 1). As the selected base period should be recent, the year
206 2011 has been taken as the base year for the analysis here. As time goes on, the relevance of
207 any base period in the past decreases in terms of comparison with values in the present (Aczel
208 & Sounderpandian, 2009). With respect to the base period, there has been a noticeable increase
209 in a number of new notifications of 29% in 2012, 62% in 2013, 101% in 2014, 127% in 2015,
210 195% in 2016, 308% in 2017 and 332% in 2018. The computed indexes prove that the number
211 of new products in Poland of dietetic foods, food supplements and fortified foods has therefore
212 increased rapidly since 2011.

213 **Take in Figure 1**

214 Compound annual growth rate (CAGR) of new notifications within the studied period 2007-
215 2018 is approximately 18.7%, and average annual growth rate (AAGR) is equal to 25.1%. The
216 data confirms a steady growth of the number of new notifications to GIS. Furthermore, the
217 linear trend fits to the observations very well (r^2=0.8518). This provides the opportunity to
218 make a forecast, despite the short time series of the data employed (Hyndman & Kostenko,
219 2007; Aczeland & Sounderpandian, 2009). Estimation of the linear trend gives: $Z_t =$
220 $987{,}04\,\mathrm{t} - 430{,}11, \mathrm{t} = 1,2, \ldots$. Therefore, the number of new notifications is predicted from
221 the linear trend to be 12,401 in 2019 and 13,388 in 2020. Using exponential smoothing, where

the most recent observations have a higher weighting, the forecasted number of new supplements for the year 2019 is 15,551 notifications with the confidence interval (12,734-18,367) and 17,296 notifications with the confidence interval (12,221-22,371) for the year 2020 (Figure 1). These forecasts are larger than the future predictions obtained by using the linear trend, highlighting that the growth in the number of new notifications of products from this category is faster in more recent years than earlier years. The number of notifications of new food supplements to GIS in Poland, together with limited control capacity of PIS, calls into question the effective regulatory governance of food supplements and the ability to implement an effective regulatory surveillance programme and this vulnerability is worthy of further investigation.

3.2. Patterns of non-compliance for dietetic foods, food supplements and fortified foods

3.2.1. Consideration of AAC AA and AAC FF data

The total number of AAC AA and AAC FF cases in Europe in 2016 was 243, in 2017 was 775, and in 2018 was 1,392. These cases have been analysed by product type and show in 2016 there were 26 authenticity cases associated with dietetic foods, food supplements and fortified foods. In 2017, the number of incidents increased dramatically to 214 cases well above any other product category (Figure 2). In 2018, the number of AAC AA and AAC FF cases associated with dietetic foods, food supplements and fortified foods stayed at a similar level (221 cases).

Take in Figure 2

Figure 2 clearly shows that there is a higher incidence of confirmed cases of non-compliance associated with dietetic foods, food supplements and fortified foods than any other category. In 2018, most of the irregularities reported and associated with dietetic foods, food supplements and fortified foods (77%) were related to **mislabelling** (Figure 3). One in ten of

all the cases was due to **replacement, dilution, addition and/ or removal of compositional elements** of the product which could be instances of intentional adulteration, the next 8% of the cases exchanged were due to **absent, falsified and/ or manipulated documentation,** and **unapproved treatment and/ or processes** accounted for 4.5% of recorded incidents. Only one controlled and notified production batch was suspected of **infringement of certain intellectual property rights** (IPR).

Take in Figure 3

Analysing more detailed EC DG SANTE (2017) data for dietetic foods, food supplements and fortified foods shows that both final **composition** of the product (31%) and **nutrition/ health claims** (29%) were the two major areas of non-compliance (Figure 4). Another quite frequently reported alleged violation for this product category was related to **nutrition declaration** (14%). Such commercial practices are definitely misleading because they promote false claims or false information on the composition and nutrients and health benefits of the product. False claims about the innate and attributed characteristics of the product are likely to lead to the consumer taking a transactional decision that he/she would not have otherwise taken (Directive 2005/29/EC on 'Unfair Commercial Practices Directive'). False claims thus infringe the consumer's expectation that products are genuine, of undisputed origin and consistent with the product claims.

In order to differentiate in this paper between wider non-compliance and product adulteration more specifically, *innate characteristics* are described here as those characteristics of a product that can be tested or confirmed by analysis as being true or false in terms of label descriptions e.g. compositional and nutritional content. *Attributed characteristics* are inferred characteristics of a product. These attributes could be a health claim or stated benefit for which either no test or analysis can be formally confirm an association with specific ingredients or

there are no independent medical studies that have been undertaken that have demonstrated efficacy or the stated health benefit.

Take in Figure 4

3.2.2. Consideration of IH inspections on food supplements

As non-compliance occurring in dietetic foods, food supplements and fortified foods may represent a number of threats to public health and harm consumers' economic interests, the official food control system in Poland does not seem to be appropriately designed. First of all, the Agricultural and Food Products Quality Inspection (IJHARS) in Poland appeared not to have had the production, transportation and storage of those products under control before 2018 (Kowalska, Soon & Manning, 2018). This year two IJHARS administrative decisions regarding adulterated food supplements were publicised on the IJAHRS webpage. The Trade Inspection (hereinafter: IH) in Poland controls the authenticity and labelling of foods for specific groups, food supplements and fortified foods in retail and wholesale trade. Although the National Sanitary Inspection (PIS) in Poland carries out independent supervision and checks in processing plants regarding the safety and quality of these foods, the size of the market exceeds the control capacities of PIS (SCO, 2017). PIS is responsible for the supervision of the hygienic conditions of production and the trade of these products on Polish territory. Article 30 of FNSA states that GIS **may** conduct an investigation to confirm the intrinsic characteristics of the product declared as either food for a specific group, food supplement or fortified food with special attention given to compliance with EU and national food law. GIS is overloaded, with the notification process still pending for over 75% of the notified foods for specific groups, food supplements and fortified foods that have already entered the Polish market (39% of the products notified in 2007 and 29% of the products notified in 2008 have not been checked by GIS so far) (GIS, 2018). Therefore some products have been on the market for over a decade with very little regulatory assessment. The Supreme Chamber of Control (hereinafter: SCO)

stated in 2017 that half of the notified food supplements over the period between 2014 and 2016 were not even sampled for verification. Verification for half of the products was taking an average of 8 months (SCO, 2017). Thus these challenges with effective enforcement of food supplement regulations in Poland provides the context for this research.

In 2017, IH in Poland assessed the commercial quality of food supplements in retail trade, focusing on communicating food information to consumers. The checks undertaken covered 443 production batches in 80 retail stores (including 3 online retailers) in Poland. IH queried 20% of the controlled food supplement batches (n=89). Most of them (71 out of 89) were a concern for mislabelling, but only 14 production batches were challenged due to specific labelling provisions for food supplements. 3.2% of food supplements batches were non-compliant with specific labelling provisions for this group of products and 2.5% of the checked batches did not conform with EU regulatory requirements and national food law. A further 2% of the production batches were past their expiration date but were still traded (IH, 2017). Laboratory tests for 79 food supplements identified nine samples as non-compliant with composition standards; mostly vitamin, mineral, or other nutrient levels were incompatible with producer's declaration (IH, 2017). Wider publicising of the findings of IH on irregularities found in food supplements would probably undermine consumers' trust in food.

3.2.3 Food safety issues: reflection on RASFF data with emphasis on Poland

Three hazard categories within the RASFF database: adulteration/fraud, composition and labelling absent/incomplete/incorrect have been assessed. The product category dietetic foods, food supplements and fortified foods on the RASFF database was searched for notifications **associated with Poland**. There were 328 notifications for **dietetic foods, food supplements and fortified foods** between May 1, 2004 and December 10, 2018, either because the products were notified to RASFF by Poland itself (n=123) or there was the potential for distribution within Poland. The majority of the notifications during the period considered were

information notifications (information (n=24), information for follow-up (n=140), information for attention (n=19) with alerts (n=129) and border rejections (n=16)). Almost 40% of notified products were withdrawn from the market (n=130). One in ten products was subject to a product recall from consumers (n=34). The most common problem associated with the products withdrawn from the market was unauthorised substance 1,3 dimethylamylamine (DMAA) in food supplements (n=8). Over 27% of all the incidents associated with Poland were categorised as *serious risk* when a rapid action is required.

Over this time there were no RASFF notifications related to dietetic foods, food supplements and fortified foods in the hazard category **adulteration/ fraud** associated with Poland. There were 3 notifications for the hazard category **labelling absent/ incomplete/ incorrect**, with two alerts and one border rejection. One out of the three incidents was categorised as serious risk (details: unauthorised ingredients, high content of caffeine in and insufficient labelling of a food supplement from unknown origin, via the UK; notifying country: Germany).

Most 2004-2018 notifications for dietetic foods, food supplements and fortified foods associated with Poland related to the hazard category **composition** (n=188), with information notifications (n=97) (including information for follow-up (n=72)), alerts (n=82) and border rejections (n=9). About 36% of the incidents were notified by Poland (n=67), followed by Lithuania (n=27) and Germany (n=22). The composition "non-compliance" included the following issues: unauthorised substance or novel food ingredient (n=160; 85.1% of all the composition notifications); unauthorised placing on the market of food product/ unauthorised substance/ novel food ingredient (n=17; 9%); (too) high content of vitamins/ minerals/ caffeine/ other substances (n=15; 8%); risk of over dosage with nicotinic acid (n=7; 3.7%), and too low content of a substance (n=1). Over 60% of the reported dietetic food, food supplement and fortified food products (n=113) originated from the US, then from Poland (n=21), Canada (n

345 =10), and several products originated from a range of countries including China, Hungary, the
346 UK, the Netherlands, Germany, the Czech Republic (Czechia), India, Spain, Hong Kong, and
347 Luxemburg. The risk decision was serious for over 28.7% of composition incidents (n=54),
348 most commonly due to the presence of an unauthorised substance or novel food ingredient
349 (n=42; with 77.8% of the incidents categorised as serious risk).

350 Analysis of the RASFF data associated with Poland demonstrates that the number of
351 non-compliance incidents regarding dietetic foods, food supplements and fortified foods
352 generally has been growing since 2005 (Figure 5). The observations of the time series are not
353 sequentially correlated, but the time series is short and the variance is not so small. Finally, the
354 trend line does not fit to the data well ($r^2 = 0.56$). Consequently, it may be difficult or even
355 impossible to predict food supplement non-conformity, probably due to the multiplicity of
356 variables outlined in this paper. However, Figure 5 shows an increasing trend in the number of
357 notifications for this product category associated with Poland. The forecast from exponential
358 smoothing is not very accurate, however, it indicates that the problem is growing (Aczel &
359 Sounderpandian, 2009; Hyndman & Kostenko, 2007).

360 **Take in Figure 5**

361 ## 4. Discussion

362 Over the period 1997-2005, sales of food supplements in Poland increased in real terms by
363 219%, the highest level amongst EU member states (Kotynia, Szewczyk, & Tuzikiewicz-
364 Gnitecka, 2017). Dynamic growth of the sale of food supplements in Poland and increasing
365 demand for these products for the past decade or so have led to high level of competition
366 (pressure) in the industry which increases the motivation of potential perpetrators to take
367 advantage of deceptive behaviour for economic gain. High prices of numerous drugs and price
368 asymmetries among different points of sale (especially pharmacies) also motivate perpetrators

to commit this crime. The classic "fraud diamond" model proposes that four factors influence the potential for food supplement deviance: motivation, pressure, capability, and opportunity (Wolfe and Hermanson, 2004). Capability rests on the individual perpetrators and their ability to undertake deceptive activities and opportunity provides the commercial window to commit the activity and especially if there is a low degree of deterrence. Manning, Soon, de Aguiar, Eastham & Higashi (2017) propose that in the food context the motivation to undertake deceptive practice is driven by additional socio-economic dimensions which are of influence. In the context of food supplement use in Poland many of these socio-economic factors, such as access to health care and cost of health care related to household income play a role in driving consumer vulnerability to deception. Food supplement supply chains can be considered as socio-economic networks with inter-related strategies, activities, dynamic components i.e. the products, processes and technical knowledge employed and structural elements being the actors that interlink to bring the product to the consumer (Soon, Manning & Smith, 2019). Thus, the nature of these socio-economic networks can create generic threats driven by the external environment and also specific situational threats implicit in the supply and demand dynamics that are at play with a given organisation or supply chain.

The complexity of dietetic foods, food supplements and fortified foods and innate variability of products' composition adds to analytical testing challenges so the products might be more vulnerable to deceptive practices as a result (Diuzheva et al. 2018). The three food subsets taken into consideration as a whole category in the RASFF database and the EU FFN & AAC System, are quite different in terms of the governance associated with their production e.g. PARNUTS are normally produced by companies with high quality standards and controlled manufacturing practices. Growing supply and demand for food supplements, dietetic foods and fortified foods in Poland may result from key health care system issues in Poland, i.e. reduced access to adequate health care and high prices of drugs for the average citizen. In addition, as

previously described Polish people perceive the taking of food supplements as a non-drug form of treatment. This is specific to Central and Eastern European countries where some people remember how the markets functioned before the more recent social and political transformations. They remember domestic shortages of most consumer goods and the use of grey, uninformative packaging. In comparison, the current use of colourful packaging of food supplements and other products is especially attractive to older people (Kowalska, 2017).

The Europeanisation process, i.e. the domestic institutional and policy change supposedly triggered by 'Europe' (Bauer et al. 2007), was faster or indeed slower in different areas of social and economic life in Poland. It is true in Poland that Europeanisation effects and their impact on national systems depends very much on domestic factors such as cultural trajectories and traditions in public administration (Abels & Kobusch, 2010), and also per capita gross domestic product and unemployment level. The regulatory system has not kept pace with the convergence and growth of consumer sectors such as the food supplements market. This means that the structure and organisation of official food control system in Poland needs to be fundamentally changed so that there is greater governance of this sector. Indeed, the absorptive capacity of the food supplements' market in Poland and the extremely easy way to enter the food supplements market in Poland, impacts on the wider EU harmonised market i.e. the Polish market may be a "point of entry" to the wider EU market for deceptive food supplement products.

The results of EU data analysis show that the frequency of reported incidents of food supplement non-compliance when compared to other food products is high. Data from the EU FFN & AAC System and the IH Report show similar trends: most of the irregularities reported associated with food supplements are related to mislabelling, especially composition and nutrition/ health claims. Moreover, the incidence of RASFF notifications for food supplements associated with Poland is increasing over time. Food supplement fraud represents a public health threat (Wheatley & Spink, 2013). Polish physicians who recommended food

supplements, the issues that attend their use and efficacy should be regulated by the Polish Pharmaceutical Law of 2001 instead of FNSA.

The current status of the institutional framework surrounding and affecting dietetic foods, food supplements and fortified foods industries in Poland has contributed to an increase in market and consumer vulnerability. In response to the publishing of SCO 2017 report on *Market authorisation of food supplements*, the Chief Sanitary Inspectorate drafted amendments to FNSA for food supplements. Among other recommendations, it was suggested there was an obligation to provide additional information on food supplement packaging i.e. "food supplement is a food product which is to supplement normal diet". There is also a proposal to introduce levies for both notifications and their modifications to protect the Chief Sanitary Inspectorate against a further flood of notifications. There are such levies in some European countries, e.g. Spain, Greece, Latvia, and Belgium, which can be as high as several hundred euros (Kotynia, Szewczyk, & Tuzikiewicz-Gnitecka, 2017). GIS should also be empowered to impose an appropriate amount of financial penalty for violation of Polish food supplement law, at present, such power is vested in the President of the Office for Competition and Consumer Protection (Zboralska, 2018). These options are still pending at the time of writing this paper.

The most effective approach to combat the deceptive practices described herein is to focus on prevention (Spink, Ortega, Chen, & Wu, 2017; Kowalska, 2018; Kowalska, Soon & Manning, 2018), and addressing non-compliance through the refinement of existing food safety and food integrity management systems and vulnerability assessment approaches (van Ruth, Huisman & Luning, 2017; GFSI, 2018; Fox, Mitchell, Dean, Elliot, & Campbell, 2018; van Ruth et al. 2018). However, a detailed knowledge base is currently lacking i.e. there is limited knowledge about new adulterants or illegal claims or how a weakening of governance controls in a given context can create situational vulnerability.

5. Conclusion

For the fast developing food supplements' market in Poland, the current capacity of official food control authorities to effectively regulate is insufficient. As a result, Polish consumers' health and economic interests are not being protected. Further, the EC DG SANTE data a higher incidence of non-compliance with EU food law associated with the dietetic foods, food supplements and fortified foods category compared with other food categories. Poland is simply acting as a "back door" and the access of these products to a harmonised market within the EU means that consumers from other European countries are vulnerable too.

Both Polish national data on food supplement fraud and European data show similar trends that most irregularities reported are related to mislabelling, and especially innate characteristics in terms of final product's composition and attributed characteristics related to nutrition/ health claims. The data analysed has shown there are clear concerns with the integrity of food supplement labelling and supply. Governance needs to be strengthened both at the EU level where overarching regulation can be introduced and also in individual member states, such as Poland and other countries where situational socio-economic factors such as health-care provision and the associated absorptive capacity of the food supplements' market and the ability of national institutions to institute effective governance all play a role in creating vulnerability and an economic space for deceptive behaviour to occur.

Conflict of Interest

The authors declare that they have no conflict of interest.

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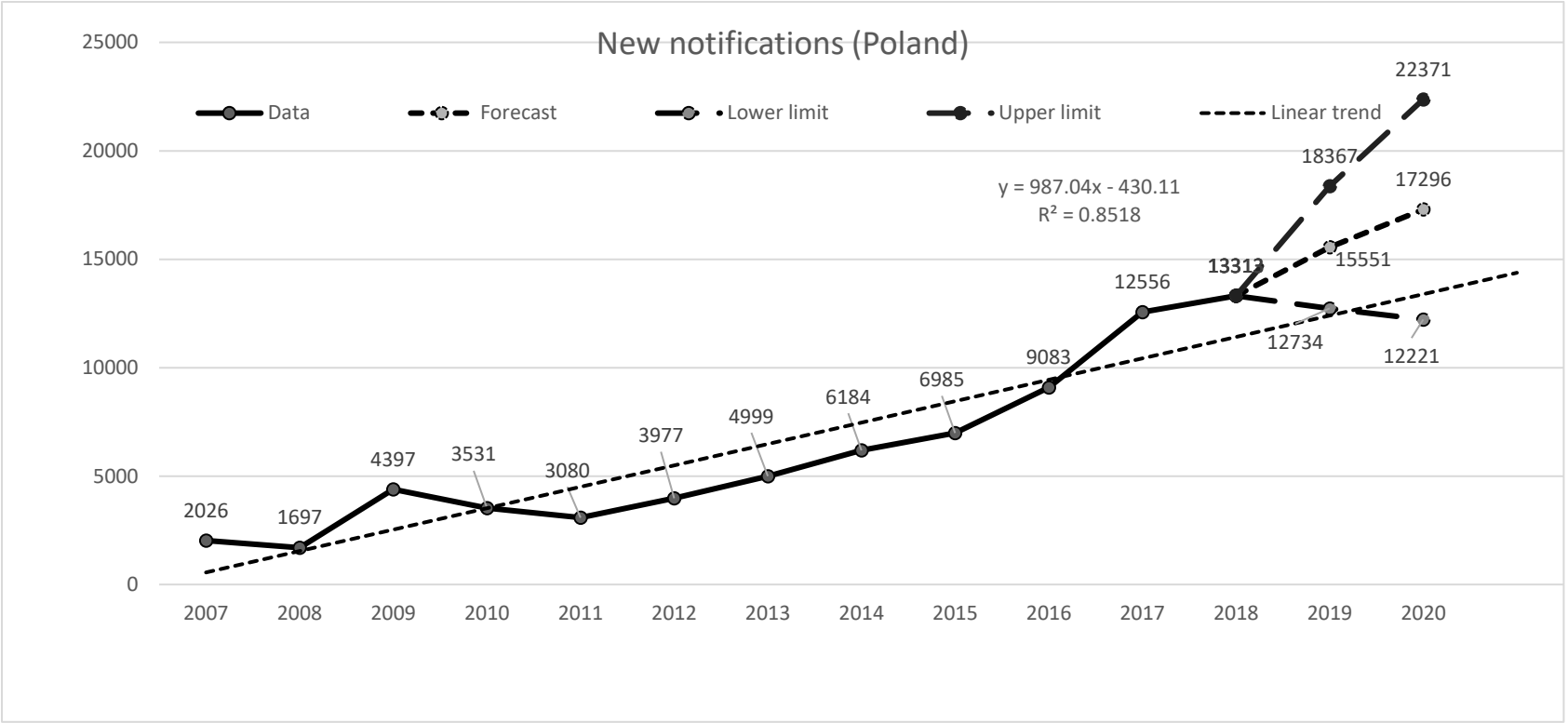

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653 **Figure 1. Number of new notifications of dietetic foods, food supplements and fortified foods, to the Chief Sanitary Inspector (GIS) in**
654 **Poland (Source: GIS, 2018)**

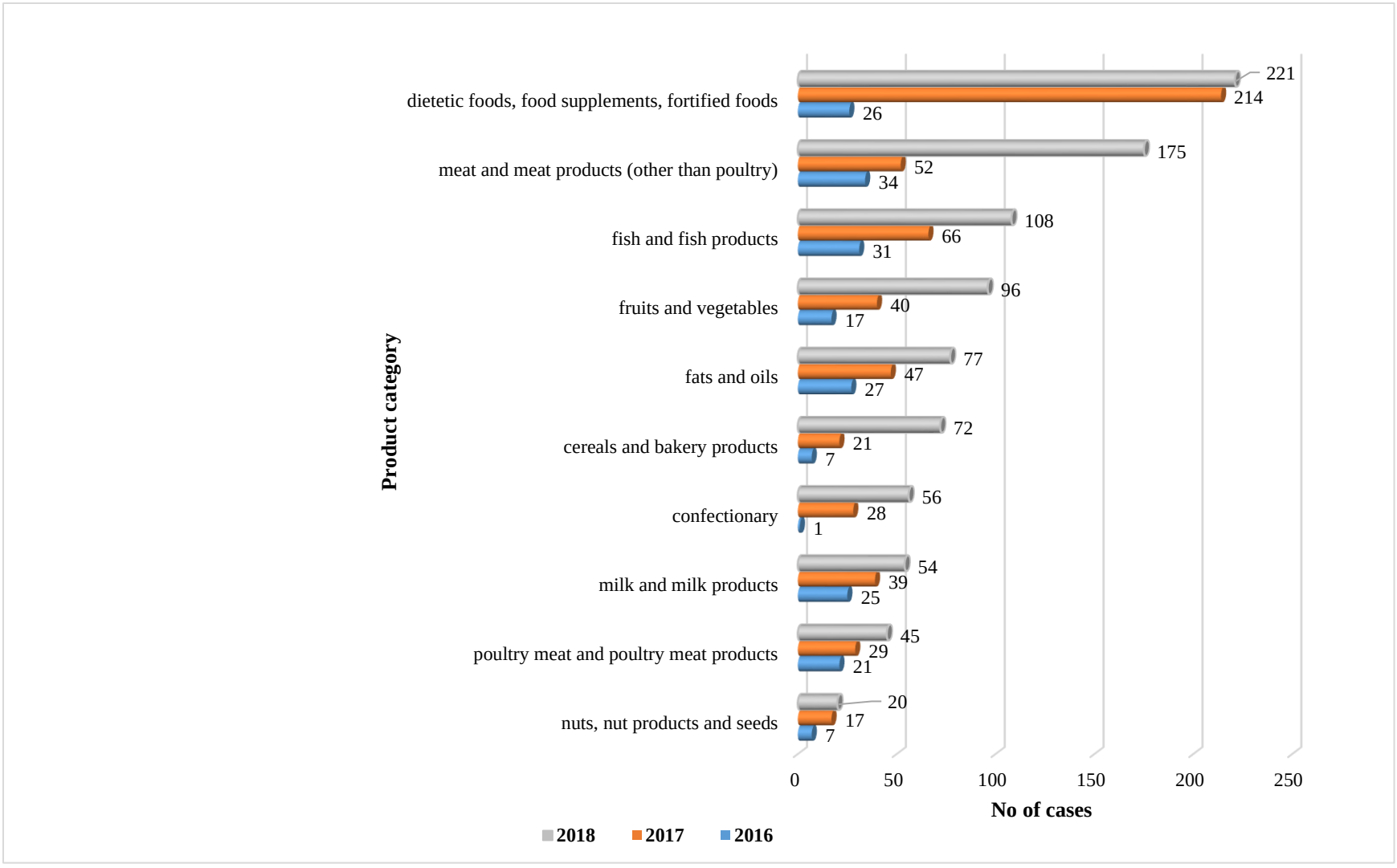


Figure 2. Food Fraud and Administrative Assistance (FF AA) cases per product category over the period 2016-2018 (top 10) (Source: Own elaboration based on EC, 2016; Unpublished DG SANTE data, 2018).

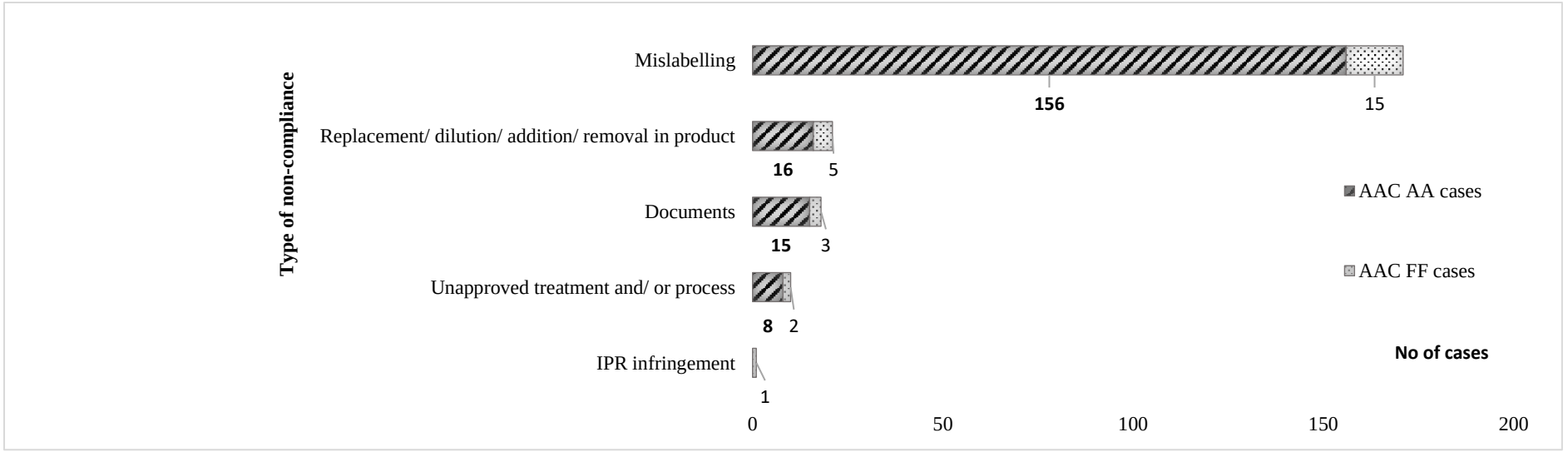
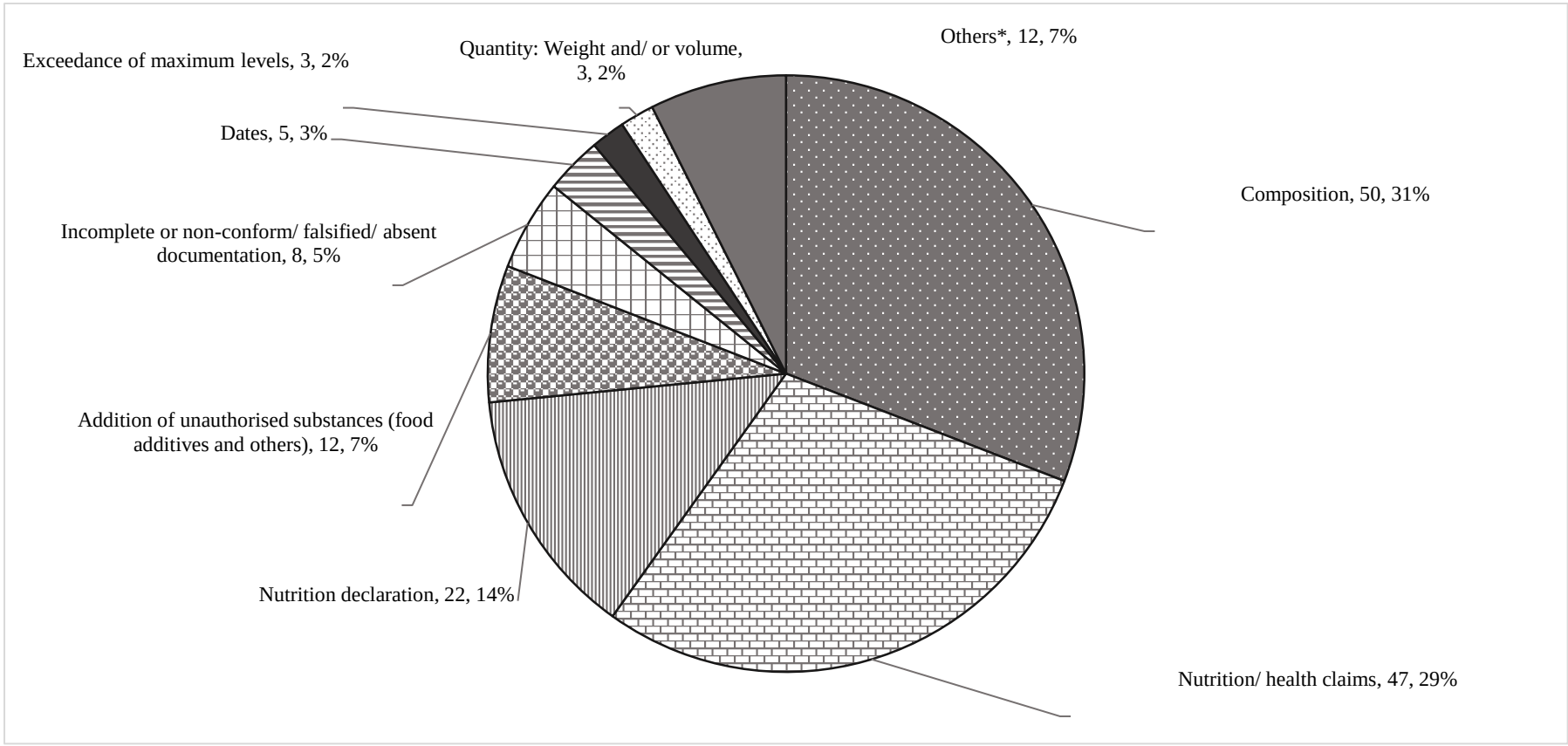
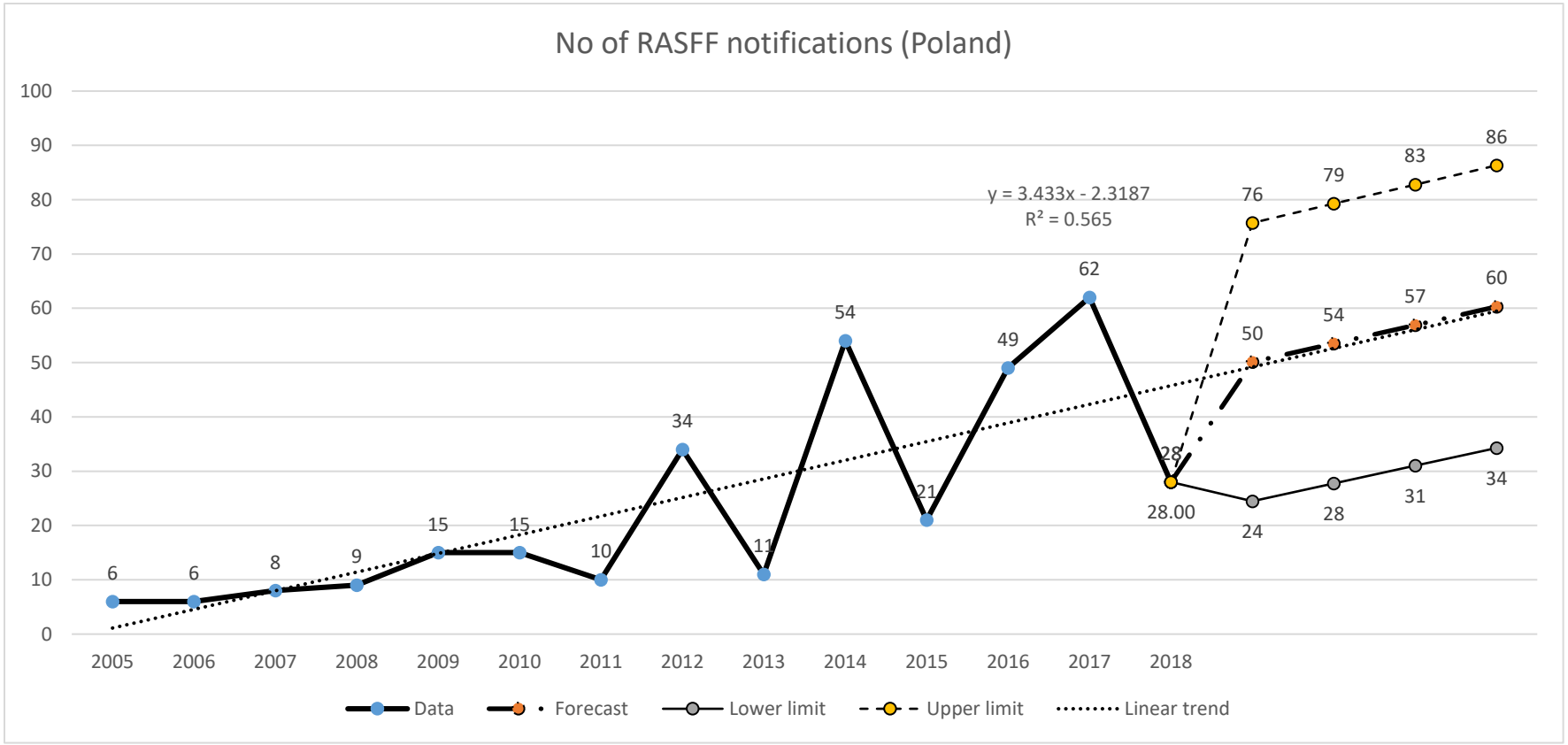


Figure 3. Cases associated with dietetic foods, food supplements and fortified foods per type of violation exchanged within the EU FFN & AAC System in 2018 (n=221) (Source: Own elaboration based on unpublished DG SANTE data, 2018).



*Other issues (collectively 12 notifications) had a lower frequency of occurrence. These are: addition of undeclared substance, denomination, quality terms, treatment and/ or process, protected origin, counterfeit goods, method of manufacture, veterinary medicines.

Figure 4. Dietetic foods, food supplements and fortified foods non-compliances reported to EU FFN & AAC System in 2018 (Source: Own elaboration based on unpublished DG SANTE data, 2018).



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669 **Figure 5. Number of reported products from the RASFF category: dietetic foods, food supplements and fortified foods, associated with**

670 **Poland from 01/05/2004 to 10/12/2018 (n=388) (Source: RASFF, 2018)**