

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

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7 **Abstract**

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

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15 health foods maintained by the Chief Sanitary Inspector (GIS) in Poland; (2) unpublished data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

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

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

27 **Highlights**

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

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

32 **1. Introduction**

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

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

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

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

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

74 Wojciechowska, 2018). Consumers view food supplements as ‘natural’ and therefore safe
75 (Berginc & Kreft, 2015), but the presence of an undisclosed adulterant in a food supplement
76 can cause adverse health effects to those that unwittingly consume it (Wheatley & Spink, 2013).
77 Economically motivated adulteration is simply deception through activities such as substitution
78 of ingredients with substandard or inferior products, unapproved additions or enhancements,
79 misbranding or misrepresentation, tampering, counterfeiting, or using stolen goods for
80 economic gain (Kowalska, 2016; Spink & Moyer, 2011; Morozzi et al. 2019). Zhang and Xue
81 (2016) state that fraudulent activities mostly occur in locations where regulatory loopholes
82 exist. *Is this true for Poland?* According to Polish food law, foods are considered adulterated
83 when they are mislabelled in terms of product composition irrespective of whether there was a
84 motivation to do so i.e. if the product fails to comply with its compositional labelling it is
85 deemed as being adulterated (Kowalska, Soon & Manning, 2018). There are about 60,000 food
86 supplements and fortified foods on the Polish market (GIS, 2018). Moreover, it is significant
87 in Poland that “discount pharmacies” are getting more and more popular and emerging price
88 asymmetries between legitimate and illicit sources could act as a motivating factors influencing
89 the incidence of economically motivated adulteration. These issues have wider implications as
90 there is no fee for notifying for food supplements firstly placed on the Polish market compared
91 to other EU countries (Kotynia, Szewczyk, & Tuzikiewicz-Gnitecka, 2017). The ease of entry
92 to the Polish and then the EU harmonised market, and the absorptive capacity of the national
93 and regional food supplements’ markets, thus makes Poland an interesting case study and is the
94 research lens through which food supplement adulteration is now considered in more details.

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

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

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

121 Another further factor of interest in Poland is the level of advertising of food supplements,
122 drugs and pharmaceuticals, across all communications channels. In 2015, a quarter of TV
123 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);

- 148 (3) the EU Food Fraud Network and the Administrative Assistance and Cooperation
149 System (EU FFN & AAC) Reports;
150 (4) Polish Trade Inspection (IH) Report; and
151 (5) the Rapid Alert System for Food and Feed (RASFF) Portal.

152 The analysis of data from the aforementioned sources used the Excel 2016 Forecast Sheet.
153 Before November 2015, the RASFF database was the most important tool for exchanging
154 information on food safety and food adulteration issues in the EU. However, some forms of
155 product non-compliance do not sit well with the existing classifications in the RASFF system
156 and needs to be addressed by additional means at EU level. The 2013 horsemeat crisis, whilst
157 being an infringement of consumer rights, and causing supply chain disruption leading to a loss
158 of sales and widespread product recalls did not show any profiles of public health risks
159 (Premanandh, 2013; Czinkota, Kaufmann & Basile, 2014). In response to the horsemeat crisis,
160 the EU Food Fraud Network (EU FFN) was set up in 2013 and the Administrative Assistance
161 and Cooperation System (AAC) was made available for Member States in 2015 (Prandi et al.
162 2019). Since then, the EU FFN & AAC System and the RASFF System have been working
163 together in synergy to maintain the EU safety and compositional standards for food and feed
164 (EC, 2016). The difference between the systems is that the RASFF members are obliged to
165 notify and to exchange information on food and feed safety issues and measures while the EU
166 FFN & AAC System works on voluntary basis and only for cross-border non-compliances (EC,
167 2016; RASFF, 2018).

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

173 compliances with EU food law (Administrative Assistance cases, AAC AA). Between the food
174 fraud databases that have developed in recent years, there is a lack of consistency in food fraud
175 categorisations (including adulteration), especially around the criteria of demonstrable intent,
176 (Bouzembrak et al. 2018), but each database, despite their limitations (see Manning & Soon,
177 2019) is a valuable source of intelligence that can contribute towards the effective governance
178 of product adulteration. Unpublished data received by the authors in May 2018 and January
179 2019 from European Commission DG Health and Food Safety, Directorate G. Crisis
180 Management in Food, Animals and Plants, Unit G5. Alerts, Traceability and Committees in
181 Brussels, Belgium responsible for EU FFN & AAC System showed, when compared to non-
182 compliance for other categories, the great number of EU food law violations were for dietetic
183 foods, food supplements and fortified foods and this was a starting point for further analysis. In
184 this research, the data for dietetic foods, food supplements, fortified foods provided in the
185 RASFF Portal and the EU FFN & AAC System were grouped together, and it was a limitation
186 in this research that in using the secondary data no distinction could be made between dietetic
187 foods, food supplements and fortified foods. The results from testing by the IH concerned with
188 labelling and presentation of food supplements has been synthesized with the data from the
189 other two sources.

190 **3 Findings from analysing the datasets**

191 **3.1. Food supplement market trends in Poland: review of GIS register for pro-health** 192 **foods**

193 To enter the Polish market, suppliers must notify the Chief Sanitary Inspector (hereinafter:
194 GIS) via an electronic system about placing dietetic food, food supplement or fortified food on
195 the market and also provide a sample of the product packaging. Article 29.2 of the Polish Act
196 of the Safety of Food and Nutrition (2006) (Food and Nutrition Safety Act, hereinafter: FNSA)
197 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 $987,04 t - 430,11$, $t = 1, 2, \dots$. 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

222 the most recent observations have a higher weighting, the forecasted number of new
223 supplements for the year 2019 is 15,551 notifications with the confidence interval (12,734-
224 18,367) and 17,296 notifications with the confidence interval (12,221-22,371) for the year 2020
225 (Figure 1). These forecasts are larger than the future predictions obtained by using the linear
226 trend, highlighting that the growth in the number of new notifications of products from this
227 category is faster in more recent years than earlier years. The number of notifications of new
228 food supplements to GIS in Poland, together with limited control capacity of PIS, calls into
229 question the effective regulatory governance of food supplements and the ability to implement
230 an effective regulatory surveillance programme and this vulnerability is worthy of further
231 investigation.

232 **3.2. Patterns of non-compliance for dietetic foods, food supplements and fortified foods**

233 **3.2.1. Consideration of AAC AA and AAC FF data**

234 The total number of AAC AA and AAC FF cases in Europe in 2016 was 243, in 2017
235 was 775, and in 2018 was 1,392. These cases have been analysed by product type and show in
236 2016 there were 26 authenticity cases associated with dietetic foods, food supplements and
237 fortified foods. In 2017, the number of incidents increased dramatically to 214 cases well above
238 any other product category (Figure 2). In 2018, the number of AAC AA and AAC FF cases
239 associated with dietetic foods, food supplements and fortified foods stayed at a similar level
240 (221 cases).

241 **Take in Figure 2**

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

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

252 **Take in Figure 3**

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

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

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

272 **Take in Figure 4**

273 **3.2.2. Consideration of IH inspections on food supplements**

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

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

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

312 **3.2.3 Food safety issues: reflection on RASFF data with emphasis on Poland**

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

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

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

334 Most 2004-2018 notifications for dietetic foods, food supplements and fortified foods
335 associated with Poland related to the hazard category **composition** (n=188), with information
336 notifications (n=97) (including information for follow-up (n=72)), alerts (n=82) and border
337 rejections (n=9). About 36% of the incidents were notified by Poland (n=67), followed by
338 Lithuania (n=27) and Germany (n=22). The composition “non-compliance” included the
339 following issues: unauthorised substance or novel food ingredient (n=160; 85.1% of all the
340 composition notifications); unauthorised placing on the market of food product/ unauthorised
341 substance/ novel food ingredient (n=17; 9%); (too) high content of vitamins/ minerals/ caffeine/
342 other substances (n=15; 8%); risk of over dosage with nicotinic acid (n=7; 3.7%), and too low
343 content of a substance (n=1). Over 60% of the reported dietetic food, food supplement and
344 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

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

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

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

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

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

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

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

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

444 **5. Conclusion**

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

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

462 **Conflict of Interest**

463 The authors declare that they have no conflict of interest.

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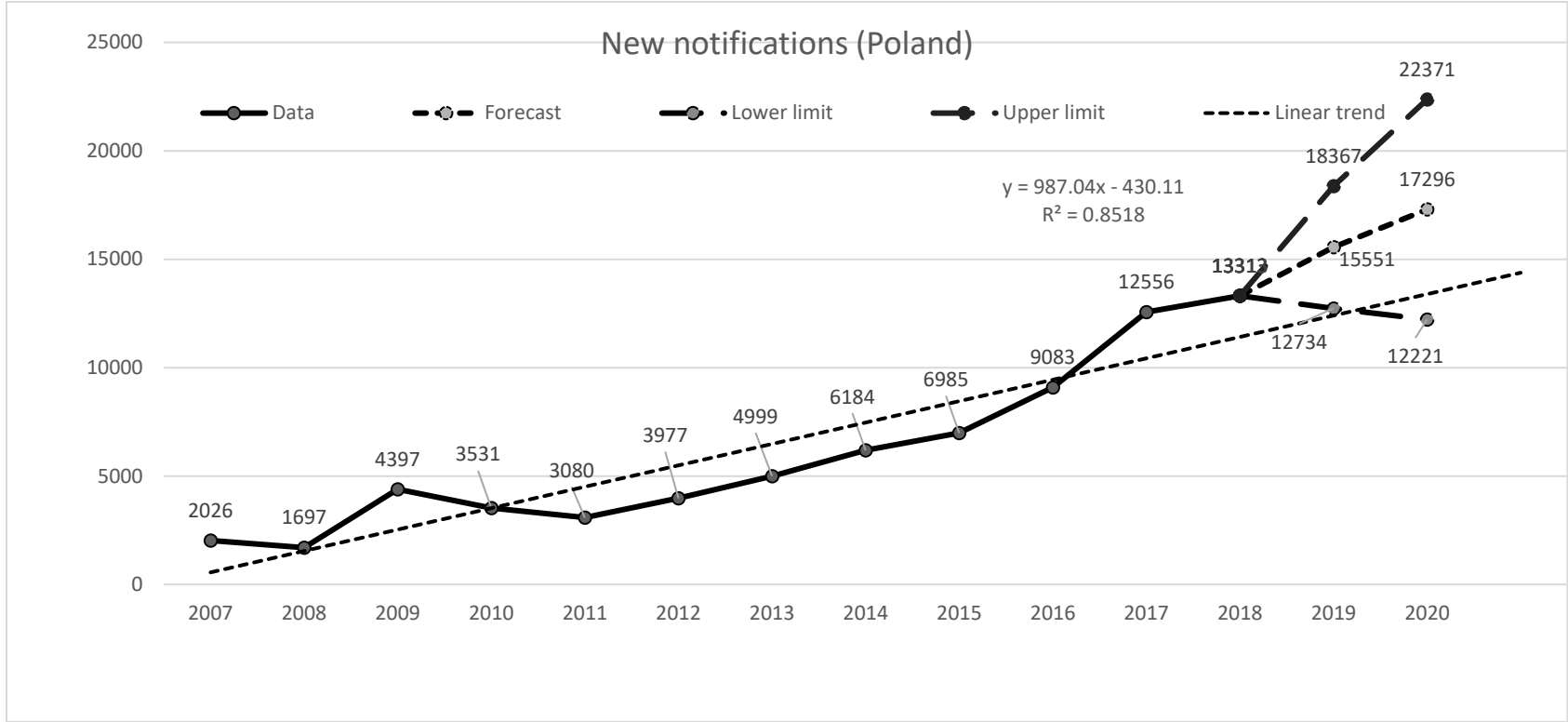
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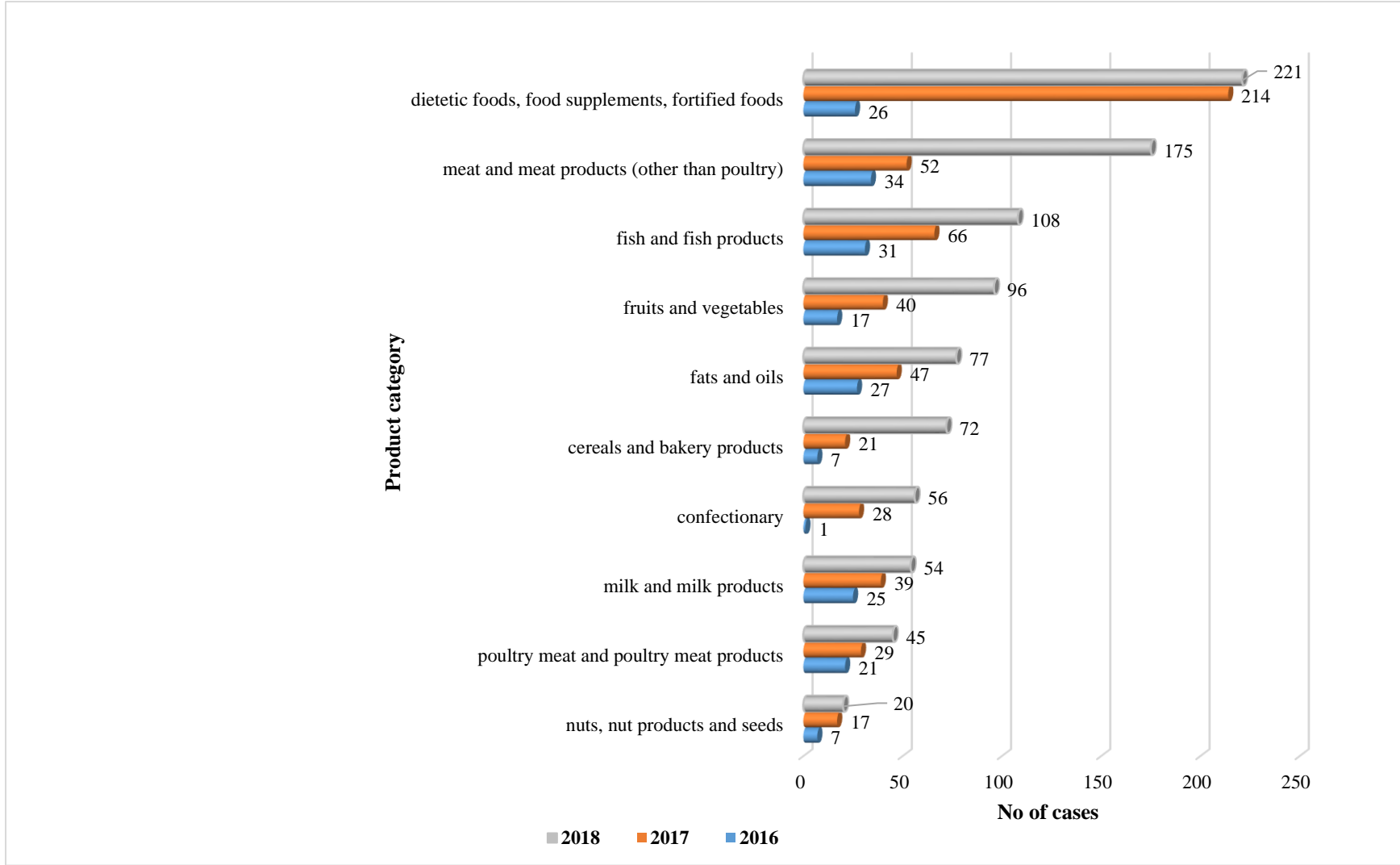
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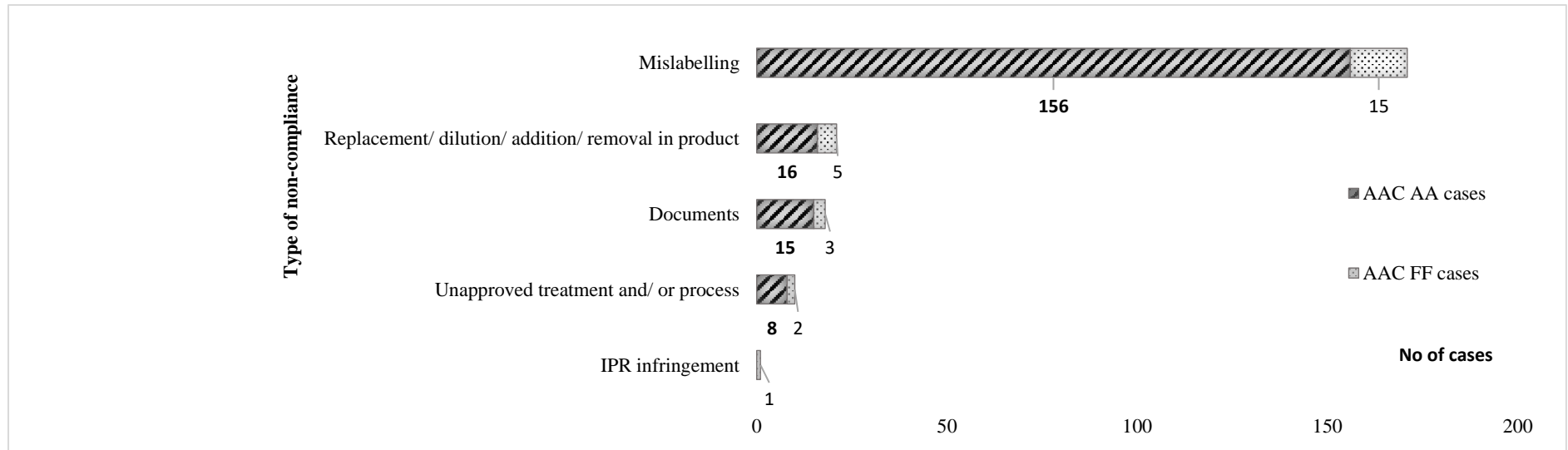
Figure 1. Number of new notifications of dietetic foods, food supplements and fortified foods, to the Chief Sanitary Inspector (GIS) in Poland (Source: GIS, 2018)



655

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

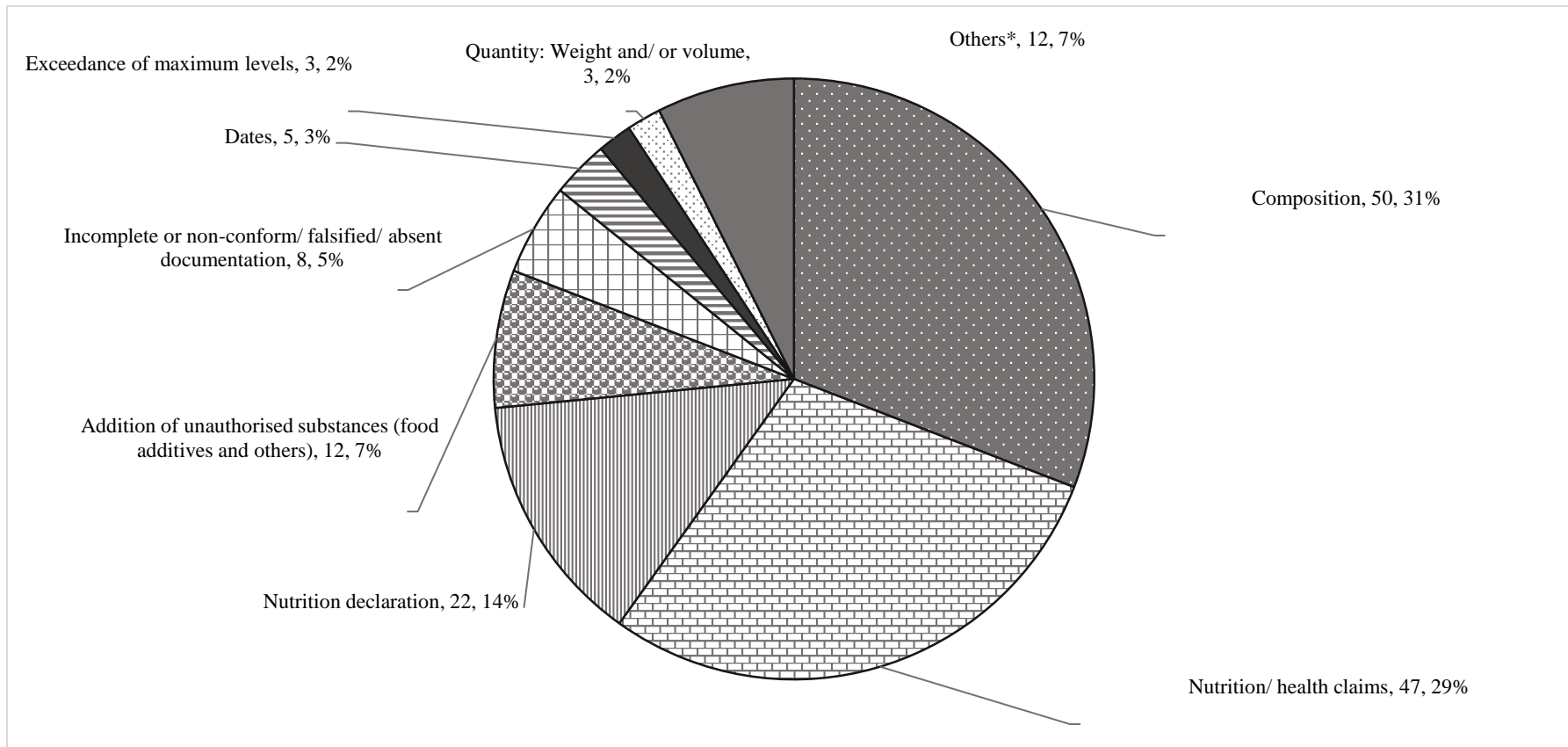
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659

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

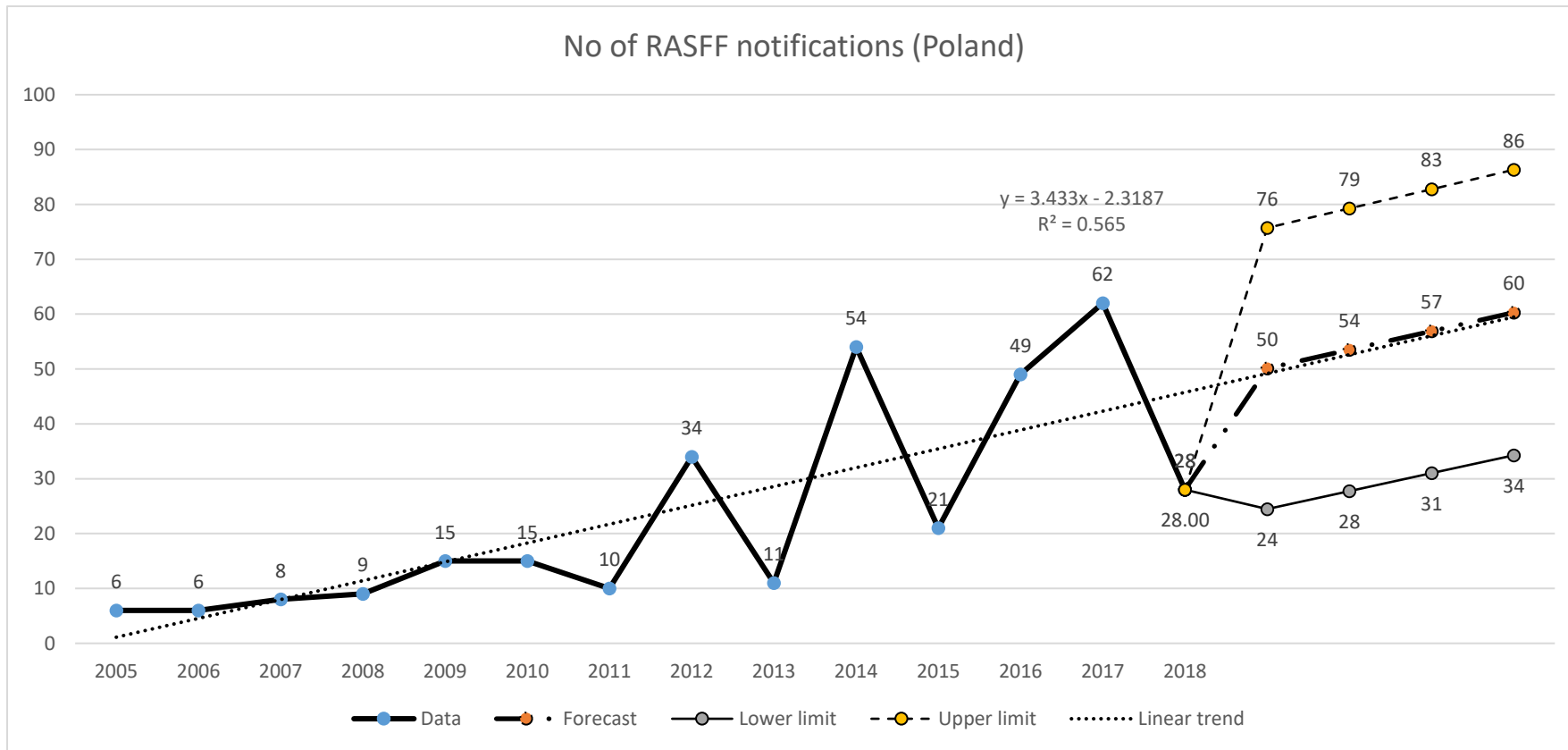
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663

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

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



668

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)**