

1 **Proposal of 0.5mg of protein /100g of processed food as threshold for**
2 **voluntary declaration of food allergen traces in processed food – a first step in**
3 **an initiative to better inform patients and avoid fatal allergic reactions - A**
4 **GA²LEN position paper**

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15 **Conflict of interest**

16 The authors declare no conflict of interest.

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18
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29 that legally binding thresholds would be preferred. The authors certainly share this
30 view.

31 **ABSTRACT**

32
33 **Background:**

1 Food anaphylaxis is commonly elicited by unintentional ingestion of foods containing
2 the allergen above the tolerance threshold level of the individual. While labelling the
3 14 main allergens used as ingredients in food products is mandatory in the EU, there
4 is no legal definition of declaring potential contaminants. Precautionary allergen
5 labelling such as “may contain traces of” is often used. However, this is
6 unsatisfactory for consumers as they get no information if the contamination is below
7 their personal threshold. In discussions with the food industry and technologists, it
8 was suggested to use a voluntary declaration indicating that all declared
9 contaminants are below a threshold of 0.5 mg protein per 100 g of food. This
10 concentration is known to be below the threshold of most patients, and it can be
11 technically guaranteed in most food production. However, it was also important to
12 assess that in case of accidental ingestion of contaminants below this threshold by
13 highly allergic patients, no fatal anaphylactic reaction could occur.

14

15 Therefore, we performed a systematic review to assess whether a fatal reaction to
16 5mg of protein or less has been reported, assuming that a maximum portion size of
17 1kg of a processed food exceeds any meal and thus gives a sufficient safety margin.

18

19 **Methods:**

20 MEDLINE and EMBASE were searched until 24th January 2021 for provocation
21 studies and case reports in which one of the 14 major food allergens was reported to
22 elicit fatal or life-threatening anaphylactic reactions and assessed if these occurred
23 below the ingestion of 5mg of protein. A Delphi process was performed to obtain an
24 expert consensus on the results.

25

26 **Results:**

27 In the 210 studies included, in our search no reports of fatal anaphylactic reactions
28 reported below 5 mg protein ingested were identified. However, in provocation
29 studies and case reports, severe reactions below 5mg were reported for the following
30 allergens: eggs, fish, lupin, milk, nuts, peanuts, soy, and sesame seeds.

31

32 **Conclusion:**

33 Based on the literature studied for this review it can be stated that cross-
34 contamination of the 14 major food allergens below 0.5 mg/100 g is likely not to

1 endanger most food allergic patients when a standard portion of food is consumed.
2 We propose to use the statement “this product contains the named allergens in the
3 list of ingredients, it may contain traces of other contaminations (to be named, e.g.
4 nut) at concentrations less than 0.5 mg per 100 g of this product” for a voluntary
5 declaration on processed food packages. This level of avoidance of cross-
6 contaminations can be achieved technically for most processed foods, and the
7 statement would be a clear and helpful message to the consumers.
8 However it is clearly acknowledged that a voluntary declaration is only a first step to
9 a legally binding solution. For this, further research on threshold levels is
10 encouraged.

15 INTRODUCTION

17 Allergic reactions to foods are a major health problem that has increased in
18 prevalence in recent years and affects 5 to 10% of the population in industrialized
19 countries [1]. In children and adolescents, food allergy is common and considerably
20 impacts the quality of life in these patients, as well as their families and caretakers
21 [2]. In this age group, food allergens are also most commonly the cause of
22 anaphylaxis, the most severe form of an allergic reaction. Although fatalities are rare,
23 these reactions to food allergens are potentially life-threatening. Anaphylaxis elicited
24 by food allergens is most commonly reported after unintentional ingestion of foods
25 containing the relevant allergen.

27 While labelling food products with the 14 main allergens is mandatory in the EU,
28 precautionary allergen labelling such as “may contain”, “may contain traces of” or
29 “manufactured in a setting where ‘allergen’ is processed” is voluntarily placed by food
30 manufacturers. The inconsistent food labelling approaches are met with the
31 uncertainty of consumers, among whose knowledge about the regulations and
32 meaning of this labelling is largely missing [3]. It also has implications for the
33 manufacturers since consumers with a history of severe allergic reactions are less
34 likely to buy food products with the current precautionary allergen label even though

1 other products without precautionary labelling may contain the allergen in the same
2 quantities and the same likelihood as the labelled product [3].

3
4 The implementation of concentrations over which food allergen traces should be
5 declared on the package would therefore be helpful for consumers as well as for
6 manufacturers. The major problem is that the threshold for elicitation of allergic
7 reactions against foods is different in different individuals. The vast majority of food
8 allergic patients have no problems with contaminants and traces of the relevant
9 allergen. For example, most pollen allergic patients with oral food allergy syndrome
10 often only react to the pure cross-reacting food allergens if they are present in
11 amounts above 1000 mg. On the other hand, there are some severely affected food
12 allergy sufferers, especially to peanuts with thresholds below 1mg. In addition, a true
13 no-observed-adverse-events-level (NOAEL), as in cosmetic allergy, is not known for
14 food allergens. In summary, this situation is unsatisfactory: overcautious reporting of
15 potential contamination of allergens creates unnecessary fears in most food allergy
16 sufferers and is not helpful. On the other hand, underreporting of potential
17 contamination is endangering those severely affected by food allergies reacting to
18 minimal amounts.

19
20 As this problem is internationally recognized, some national authorities have
21 implemented threshold values over which food allergens have to be labelled on the
22 package. Japanese authorities have decided on a threshold value based on the
23 precision of ELISA test kits [4]. As precision parameters of medical measurement
24 equipment are subject to change, jeopardizing the scientific value of this rule, this
25 approach is met with serious concerns. Switzerland obligates all food producers to
26 list involuntary cross contaminations above 1 g allergen per 1 kg food product as
27 “may contain traces of ...” [5]. The German authorities indicate that the threshold
28 depends on the respective allergen [6]. A similar approach is pursued in Australia
29 and New Zealand, where there are no regulations regarding the mandatory
30 declaration of unintentionally present allergens [7]. The VITAL® (Voluntary Incidental
31 Trace Allergen Labelling) program is a joint venture of Australia's leading food
32 manufacturers and the Australian Food and Grocery Council (AFGC). It provides a
33 standardized approach for assessment and declaration of food allergen
34 contamination, recommending thresholds based on scientific data that has been

1 processed in a stacked model averaging program using a range of statistical
2 calculation models [8]. However, this leads to modifying the thresholds for each
3 allergen with every revision of the program. The aim is to protect the 'vast majority of
4 people with food allergy' and they state that below the thresholds, only 1% of allergic
5 patients may develop an allergic reaction, this reaction however may be severe [9,
6 10]. The data processed must adhere to high-quality standards and to include only
7 double-blind, placebo-controlled, food challenge studies [10-12]. While this is a very
8 rigorous approach, some issues may cause bias. One is that especially severe
9 allergic reactions are comparatively rare and are often published as case reports or
10 case series only. As this form of study is considered low-quality evidence in medical
11 science, such are not included in the data evaluated by VITAL. Therefore, it is likely
12 that the most severe allergic reactions described in the literature are not included.
13 Also, fatal reactions are not likely to happen while under clinical observation while
14 unintentional ingestion of food allergen out of hospital may be more likely to lead to
15 death and may be reported only in case reports. In this systematic review, an
16 alternative solution for this dilemma is assessed.

17 Of course, it is acknowledged that some food allergy sufferers who have not
18 undergone placebo-controlled tests may not know their thresholds but still may have
19 a feeling for it based on previous experiences. Therefore, it would be beneficial to
20 know that the allergens included in the food product do not exceed a certain level.
21 However, this food contamination level, or concentration, needs to be low enough to
22 ensure that no life-threatening or fatal reactions have been observed at this level, but
23 also one which can be easily measured with existing technologies in the food
24 industry without increasing the cost of food production. Therefore, in this systematic
25 review, we assess whether a level of 0.5 mg protein /100 g of food of allergenic
26 protein would be less than the lowest published observed adverse effect level
27 (LOAEL) for a fatal reaction. As portion sizes vary, a maximum portion size of 1 kg of
28 processed food was assumed to exceed any meal and thus giving a sufficient safety
29 margin. Therefore, we used 5 mg protein as a threshold in this investigation.

30

31

32 **METHODS**

33

1 This systematic review was conducted according to the PRISMA guidelines for
2 systematic reviews and meta-analyses [13]. The review was registered on
3 PROSPERO as CRD42018110170.

4
5 To find an acceptable threshold levels of allergen contamination in processed food
6 that would benefit food allergy sufferers and would be feasible for the food
7 manufacturers, the first talk was conducted on this topic at the BLL meeting of the
8 allergens specialists committee that took place on July 8th 2019 in Berlin, Germany.
9 The conference included representatives of the German food industry, including food
10 technicians and food manufacturers. The main question was which level of food
11 allergen contamination in processed food could be detected analytically and
12 reproducibly in quality management of food production without increasing the price of
13 the food? The level of 5 mg protein was discussed as it is a typical challenge dose in
14 provocation studies. It was also discussed if voluntary labelling would be an option
15 for food production companies. The discussion resulted in the proposal to use the
16 concentration of 0.5 mg of protein per 100 g food as a threshold for voluntary
17 declaration of allergen traces in processed food. In this systematic review it was
18 deemed mandatory that even if allergy sufferers would not know their personal
19 threshold, that at this level, fatal reactions would have never been observed.

20 21 Study Eligibility

22 This systematic review includes provocation studies and case reports describing life-
23 threatening anaphylactic reactions to one of the 14 main allergens in food products
24 were reported. Main food allergens were defined in accordance with the European
25 Union's Food Information Regulation No. 1169/2011: crustaceans, cereals containing
26 gluten, eggs, fish, peanuts, soybean, milk, nuts (namely: almond, hazelnuts, walnuts,
27 cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts),
28 celery, mustard, sesame seeds, sulphur dioxide and sulphites (sensu stricto,
29 sulphites are not an allergen but known to induce intolerance reactions), lupin, and
30 molluscs (Table 1). Anaphylactic reactions were considered life-threatening in case
31 of a fatal outcome, potentially fatal outcome without intervention (i.e. administration of
32 epinephrine, severe dyspnoea/asthma, loss of consciousness), positive shock index,
33 and/or hypotension, and/or heart failure. Included studies and case reports had to

- 1 give information on the approximate amount of ingested food, e.g. “one bite”.
- 2 Publications had to be written in English.. Animal studies were excluded.
- 3 There is also an abundance of scientific literature that is written in Spanish,
- 4 French, German and Japanese language for which quoted reviews in English exist.

5

6 **Table 1:** Main food allergens according to the European Union’s Food Information
7 Regulation No. 1169/2011

Allergen name	Including	Amount of protein per 100g of food.
Celery		Celery root 2g/100g
Cereals containing gluten	Wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof	Wheat 12g/100g Rye 9g/100g Barley 10g/ 100g Oats 12g/100g
Crustaceans		Shrimp 19g/100g
Eggs		13g/100g
Fish		Between 17-20g/100g
Lupin		40g/100g
Milk		Cow’s milk 3g/100g
Molluscs		Mussel 11g/100g Cuttlefish 16g/100g
Mustard		6g/100g
Nuts	Almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts, and products thereof	Almond 19g/100g Brazil nut 14g/100g Cashew 18g/100g Hazelnut 12g/100g Macadamia 9g/100g Pecan nut 11g/100g Pistachio 18g/100g Walnut 14g/100g
Peanut		25g/100g
Sesame seeds		21g/100g
Soybeans		Soybeans 38g/100g Soydrink 4g/100mL

Allergen name	Including	Amount of protein per 100g of food.
Sulphur dioxide and sulphites	At concentrations of more than 10mg/kg or 10mg/litre in terms of the total SO ₂ . Sulphites are not an allergen but known to induce intolerance reactions	Not applicable

1

2 Search Strategy and Literature Screening

3

4 MEDLINE and EMBASE electronic databases were searched via Ovid from their
5 inception until January 2021. The exact search terms are presented in Appendix 1.
6 Titles and abstracts of the retrieved references were screened by a team of three
7 reviewers, duplicates were eliminated, and potentially relevant references were
8 identified. A full-text review of the remaining references was performed. Studies in
9 which relevance was unclear were discussed by the team of reviewers. In addition,
10 the bibliographies of included studies and case reports revealed by the search
11 strategy were searched for eligible articles missed by the search strategy.

12

13 Data Extraction and Analysis

14

15 Data regarding the type of ingested food, the approximately ingested amount of food,
16 and the type of life-threatening anaphylactic reaction were extracted onto a
17 predefined datasheet by the three reviewers. In addition, we searched and noted the
18 usual concentration of allergenic protein for every food product used in the included
19 provocation studies or described in the included case studies and calculated the
20 amount of ingested allergenic protein. This process was verified by a registered
21 dietitian. The studies were analysed regarding the occurrence of life-threatening
22 reactions and the reported amount of food protein provoking the reaction. Finally, the
23 data was presented in a table and summarized narratively.

24

25 Inclusion of authors and discussion with stakeholders

26 An open call for participation was made within the GA²LEN network, which includes
27 EAACI and EFA as members. In addition further patient organizations and other
28 experts in the field of allergology and immunology were actively approached. Some

1 non-GA²LEN members accepted the invitation. Participation was denied either due to
2 a lack of time or stating a conflict of interest. A Delphi process was performed which
3 included all participants. A consensus was obtained after two rounds of expert panel
4 evaluations that took place on October 10th 2020 and June 10th 2021. The expert
5 panel consisted of German patient organizations, the members of the CODEX
6 alimentarius working group, food industry legal advisors and food technologists.
7 Additional data provided by the panel members were evaluated and included if
8 eligibility of the study was given.

9

10 Risk of bias

11

12 The approach that was used in this systematic review has a high level of evidence to
13 suggest that at the concentration of 0.5 mg/ 100 g limited to no food fatal reactions
14 will occur, however there is a lower level of evidence regarding the no observed level
15 threshold in severely affected allergy sufferers. This is based on the search string
16 which will not find these provocation tests in which no life-threatening symptoms
17 have occurred.

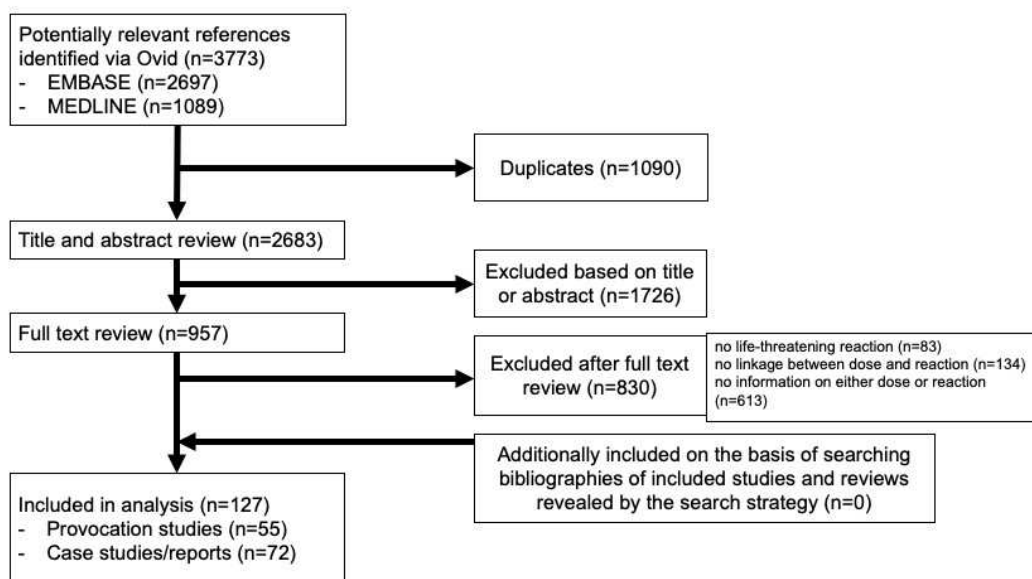
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20 **RESULTS**

21

22 The search in MEDLINE and EMBASE via Ovid yielded 3289 references, of which
23 we included 90 provocation studies and 88 case studies. Figure 1 gives the PRISMA
24 flowchart that presents an overview of the search results and study selection.



1
2
3
4

Figure 1. Search results and selection of studies.

5 We analysed double-blind, placebo-controlled provocation tests and case report
6 different minimal threshold levels for different allergens. Some of the other 14
7 allergens, which must be declared in the European Union, such as mustard and
8 molluscs, have not been reported as being the trigger of a severe allergic reactions at
9 very low levels. Table 2 summarizes the findings from all studies included in this
10 analysis that reported severe allergic reactions after ingestion of less than 5 mg
11 allergen protein or where the ingested amount was unclear. In addition, a summary
12 with all provocation studies and case reports included in this analysis is found in the
13 supplementary tables 1 and 2.

Table 2: Summary of data from provocation studies and case reports in which ingestion of less than 5 mg of allergen protein elicited a severe allergic reaction. Fatal reactions were not reported at all at this level.

Allergen	Food product	Nature of life-threatening allergic reaction	No. of participants (no. experiencing a severe reaction) **	Amount of food that provoked a severe reaction	Amount of allergen protein (mg) that provoked a severe reaction	Study
Cereals	No report found for reactions at or below 5 mg					
Celery	No report found for reactions at or below 5 mg					
Crustacean	No report found for reactions at or below 5 mg					
Egg	Mortadella	abdominal pain, throat itching, vomit, dyspnea	1(1)	Mortadella 25 mg	0.0503	Tripodi et al. 2009 [14]
Fish	Fish	Asthma or mild anaphylaxis	1(1)	Fish 8 mg	1.36	Lefevre et al. 2016 [15]
Lupin	Short crust pastry containing lupin flour as	asthma	2(1)	Small amount	Not determinable	Bansal et al. 2014 [16]

Allergen	Food product	Nature of life-threatening allergic reaction	No. of participants (no. experiencing a severe reaction reaction) **	Amount of food that provoked a severe reaction	Amount of allergen protein (mg) that provoked a severe reaction	Study
	minor ingredient					
Milk	Cow's Milk	Asthma or mild anaphylaxis	5	CM <0,05 mg	0.0015	Lefevre et al. 2016 [15]
Milk	Cow's milk	Systemic symptoms		Even traces	Not determinable	Poza-Guedes et al. 2014[17]
Milk	Cow's milk		10(?)	Trace amounts	Not determinable	Paiva et al. 2009[18]
Milk	Cow's milk	Syncope, hypoxia, and drop in blood pressure treated with epinephrine	1(1)	Accidental ingestion of trace amounts	Not determinable	Lisann et al. 2014[19]
Milk	Cow's milk	Syncope, hypoxia, and drop in blood pressure treated with epinephrine	1(1)	Accidental ingestion of trace amounts	Not determinable	Lisann et al. 2014[19]

Allergen	Food product	Nature of life-threatening allergic reaction	No. of participants (no. experiencing a severe reaction) **	Amount of food that provoked a severe reaction	Amount of allergen protein (mg) that provoked a severe reaction	Study
Molluscs	No report found for reactions at or below 5 mg					
Mustard	No report found for reactions at or below 5 mg					
Nut	Cashews (Placed in same jar as walnuts)	loss of consciousness		Some nuts + febrile infection	Not determinable	Laliotou et al. 2018[20]
Nut	Pinon nut (SPT extract)	dyspnea		One drop cutaneously	Not determinable	Sindher et al. 2015[21]
Nut	Walnut	Acute anaphylactic reactions including angioedema, dyspnoea, and cyanosis	1(1)	Trace amount	Not determinable	Noh et al. 2009[22]
Peanut	Peanut	Asthma	33(1)	15 mg	3.75	Moneret-Vautrin 2001[23]
Peanut	Peanut oil	Asthma	33(1)	5 mL	Not	Moneret-Vautrin

Allergen	Food product	Nature of life-threatening allergic reaction	No. of participants (no. experiencing a severe reaction) **	Amount of food that provoked a severe reaction	Amount of allergen protein (mg) that provoked a severe reaction	Study
					determinable	2001[23]
Peanut	Peanut oil	Asthma and/or FEV ₁ ↓, vomiting and/or abdominal pain	103(6)	5 mL	Not determinable	Morisset et al. 2003[24]
Peanut	Peanut oil	Asthma	62(14)	5 mL Peanut oil	Not determinable	Moneret-Vautrin et al. 1998[25]
Peanut	Peanut dust	Severe anaphylaxis treated with epinephrine	1(1)	Peanut dust sprinkled on meal	Not determinable	Robertson et al. 2017[26]
Sesame	Sesame seed oil	"Anaphylactic shock"	12(1)	1 mL	Not determinable	Morisset et al. 2003[24]
Sesame	Sesame seed	Throat closure, generalized urticaria and	1(1)	5 seeds	3.15	Dua et al. 2011[27]

Allergen	Food product	Nature of life-threatening allergic reaction	No. of participants (no. experiencing a severe reaction reaction) **	Amount of food that provoked a severe reaction	Amount of allergen protein (mg) that provoked a severe reaction	Study
		vomiting				
Soy	Soy milk	“Systemic reaction”	2(1)	0.01 mL	Not determinable	Hudes et al. 2019[28]
Sulphites	No report found for reactions at or below 5 mg					

** Total number of participants in the study mentioned, while number in brackets give the number of participants experiencing the reaction described. If no number is given, only the total number of participants is listed.

1 In a cohort of food allergic children used by Moneret-Vautrin et al. [23] for the
2 evaluation of personalized care projects, 2 asthmatic reactions resulting from peanut
3 protein amount lower than 5 mg have been described. However, the authors state in
4 their paper that no fatal reactions were observed. One anaphylactic shock was
5 observed in this study which occurred after ingestion of 965 mg peanut, which
6 amounts to more than 240 mg protein.

7
8 Ebrahimi et al. [29] report respiratory distress after 3 drops of milk-based formula in
9 one study subject who needed to be treated with epinephrine. They used BioMeal,
10 Fassbel, Belgium, a formula which is no longer available. According to the EU
11 regulations, infant formula may contain 1.08 to 3.6 g protein/100 mL [30] provided
12 correct preparation. The volume of a “drop” depends on the viscosity of the liquid,
13 however, in pharmacy and medicine, a drop is generally defined as being 0.05 mL.
14 The amount ingested may therefore range between 1.6 mg to 5.4 mg, although,
15 given that the formula is no longer on the market, the protein content cannot reliably
16 be verified. We therefore do not know the amount of milk protein which resulted in
17 the described reaction. The same holds true for the reaction described by Hudes et al
18 [28] which reported a “systemic reaction” to 0.01 mL of soy milk. However, the
19 amount of soy protein differs widely between the different brands of soy milk, so the
20 exact amount ingested by the patient is not determinable. Furthermore, the authors
21 do not describe the systemic reaction in detail and any life-threatening potential
22 cannot be determined.

23
24 Tripodi et al [14] report a case of a 11-year-old with egg allergy developing dyspnoea
25 after ingestion of a mortadella sandwich. They analysed the mortadella and found the
26 reactive amount being 0.45 mg hen’s egg, which would mean a protein content of
27 0.05 mg. They did, however, not analyse the other components of the sandwich so
28 there is no way to know if this is the real threshold dose.

29
30 Dua et al. describe one patient who experienced „throat closure“ after ingestion of 5
31 sesame seeds. We weighed different sesame seeds on a high precision scale and
32 found an average of 15 mg per 5 seeds, and could determine that 5 seeds contain
33 approximately 3.15 mg sesame protein. However, the patient was not treated with
34 epinephrine but with oral antihistamines and intravenous hydrocortisone only[27],

1 excluding the likelihood that treating physicians regarded it as a truly life-threatening
2 situation.

3
4 Both, Morisset et al. [24] and Moneret-Vautrin et al.[25] described potentially life-
5 threatening reactions after the ingestion of sesame or peanut oil. As the protein
6 content of oil varies considerably and protein amounts have not been measured for
7 the oils used, it is not possible to determine an amount.

8
9 Hourihane et al. [31], Leung et al. [32] and Lefevre et al. [15] list reactions to
10 allergenic amounts <5 mg, but do not describe them further. Therefore, those
11 reactions cannot be evaluated further to determine their life-threatening potential,
12 which is acknowledged to be a problem. The same holds true for the following
13 reports where no amounts are stated, with one of them being however a clear outlier.
14 Robertson et al. [26] report on a criminal case where a wife spread peanut dust on
15 her husband's meals. It can be expected that the amount was more than 5 mg
16 protein. Poza-Guedes[17], Paiva [18] and Lisann [19] report potentially life-
17 threatening reactions to accidental ingestion of trace amounts of cow's milk. As the
18 amounts are not specified it is not possible to determine the allergenic threshold.
19 Laliotou[20] and Noh [22] also state "trace amounts" as triggering an anaphylactic
20 reaction to nut. Again, the missing quantification does create a problem and it is
21 possible that a whole nut has been ingested.

22 The same holds true for the report of Bansal et al. [16] where a "small amount" of
23 lupin flour in short crust pastry triggered a reaction.

24
25 Levin et al [33] described the case of a 9-month-old child reacting with episodes of
26 asthma, vomiting and urticaria after ingestion of a soy formula which was
27 contaminated with 32.4 mg milk protein per litre. Here it is unclear how much of the
28 formula was administered but if it were the typical amount of one bottle containing
29 150 – 200 mL, this would be most likely more than 5mg and furthermore it is unclear
30 if the reactions were life threatening.

31
32 Yunginger et al [34] reported 7 fatal cases, 6 of whom had eaten at least "one bite"
33 but mostly one cookie or one piece of cake, without further specification of the
34 amount of the relevant allergen. In one case of a fish allergic patient, French fries

1 had been consumed, which other guests reported tasted of fish. Unfortunately, there
2 is no way to estimate in this case, as it is unclear if the reaction was due to the sauce
3 offered with the fries.

4
5 Azmi et al [35] describe two cases of allergic reactions to vegan ice cream containing
6 lupin flour, one of them potentially life-threatening. The amount of lupin flour is
7 however not stated and is likely more than 5 mg protein since vegan ice cream
8 usually has lupin flour as the main ingredient.

9 10 **DISCUSSION**

11 *Interpretation of results*

12
13 Remarkably, none of the case reports or provocation tests in a clinical setting
14 reported a LOAEL, the lowest ingested dose at which there was an observed
15 adverse effect, less than the evaluated threshold of 0.5 mg protein /100 g of food, to
16 cause a life-threatening or even fatal reaction. The case reports have revealed 8
17 cases of fatal food allergy reactions, however, all at higher levels than 0.5mg/100 g of
18 food. Looking at the list of the 14 different allergens which need to be declared
19 (celery, cereals containing gluten (such as barley and oats), crustaceans (such as
20 prawns, crabs and lobsters), eggs, fish, lupin, milk, molluscs (such as mussels and
21 oysters), mustard, peanuts, sesame, soybeans, sulphur dioxide and sulphites), the
22 following statements can be made:

- 23 1. No severe reactions to trace amounts of molluscs or mustard have been
24 reported
- 25 2. Sulphite is added as an allergen in the list; however, sulphite is in reality a
26 cause for pseudoallergic reactions. Life-threatening or fatal reactions against
27 sulphites were never reported at all. Still, it is important to also look at sulphite
28 as severe asthmatic reactions have been described in a single report with a
29 threshold of 50mg
- 30 3. No severe reactions have ever been reported to low amounts of any other
31 allergen that is not listed in the 14 which have to be declared according to the
32 EU regulations.
- 33 4. No fatal reactions have ever been reported with levels clearly documented
34 below 5mg of protein for any allergen.

1 5. In a small subset of patients allergic but not life-threatening reactions can
2 occur at levels below 5mg of protein

3
4 The most important finding of our search is that no fatal allergic reactions to food
5 were reported below an estimated amount of 5 mg protein.

6
7 Any interpretation of the results regarding the reporting bias should differentiate case
8 reports of accidental reactions and provocation tests. They differ regarding the
9 accuracy of determining the amount of allergen ingested and in classifying the
10 reaction as “life-threatening”. While case reports are very valuable, as they usually
11 represent more accurately everyday life situations in which allergic reactions to food
12 occur, the determination of the exact amount ingested allergen is difficult and
13 additional cofactors like exercise, alcohol, or sleep deprivation may have influenced
14 the manifestation or outcome of the reaction [36]. Furthermore, case reports depend
15 partly on chance because the author has to decide if it was worth publishing. An
16 underreporting is therefore possible but less likely for fatal cases.

17 For the second uncertainty, the amount of food ingested, there is a potential bias of
18 patients tending to mention smaller amounts than truly eaten. In daily practice, a
19 phenomenon often observed is that patients feel “guilty” and try to explain with
20 statements such as “I hardly took a bite”. Still, as stated in the methods section, the
21 over-estimation of allergen amounts was chosen generously in case reports to avoid
22 false low assumptions leading to inappropriate reassurances. Similarly, it should be
23 mentioned that for any ingested nut or seed that was reported in the literature, in this
24 review we considered the amount of the nut or seed ingested which is definitely
25 greater or equal to the amount digested, therefore once again having potentially a
26 slight overestimation of the total allergen protein amount, this provides a greater
27 safety margin.

28
29 Regarding classification accuracy, the courses of actions triggering the label “life-
30 threatening” may be more reliable in the out-of-clinic setting. Particularly when
31 looking at the injection of epinephrine, which in our methodology categorized the
32 case as potentially fatal, there may be great differences between case reports and
33 provocation studies. Many studies have shown that the psychological barrier of

1 injecting adrenaline is very high in food allergic patients and their caretakers [37-39],
2 resulting in a delay or an omission of intramuscular epinephrine administration.
3 On the other hand, handling epinephrine is routine in the clinical setting. Since those
4 undergoing a provocation test are monitored closely, the first signs of an anaphylactic
5 reaction will generally be noticed earlier and trigger counteractive measures, which
6 will influence the natural course and disguise the severity of the allergic response.
7 For example, epinephrine may be administered in cases where no life-threatening
8 reaction would develop.

9
10 Despite the potential over-estimation in the severity of reactions in our study,
11 categorizing all events in which epinephrine was administered as “life-threatening”
12 increases safety, albeit at the expense of accuracy.

13
14 In accordance with the findings in this review, a cross sectional study of food allergy
15 prevalence in the population of Berlin by Zuberbier et al. revealed that in all open
16 challenge tests, no adverse reaction occurred at the level of 5mg of protein [40].

17
18 However, a study by Ballmer-Weber et al., not included in the review as it did not
19 meet all eligibility criteria, found estimated doses eliciting reactions in 10% of the
20 study population (ED10), as low as 1.6 to 10.1 mg of protein for hazelnut, peanut,
21 and celery [41]. It should be noted that one limitation of this review is the defined
22 search criteria that may have excluded a few other publications that may contain
23 further data regarding allergen tolerance thresholds.

24
25 This systematic review revealed that 0.5 mg /100 g as a threshold value for traces of
26 allergens in processed food is generally a safe level for avoiding any allergic reaction
27 to at least 6 of the 14 major allergens, even in the unlikely maximum portion size of 1
28 kg. Even for those allergens, a 0.5 mg/100 g threshold is highly likely to be a safe
29 level below which fatal allergic reactions will not occur. Depending on the portion
30 size, this level is also beneficial for the rare severely affected patients. For example,
31 if a patient knows their personal threshold level is 2 mg they can still safely eat a
32 portion of 100 g. However, the vast majority of all food allergic patients have a much
33 higher threshold level for the elicitation of reactions. Very few individuals will
34 experience symptoms below this level. Our finding of the level of 0.5 mg/100 g of

1 food, 100 g of food being a common portion size, is in accordance with the FAO-
2 WHO expert group recommendations on allergen thresholds, published on August
3 20th 2021 [120].

4 Based on these results, 5 mg/100 g of food is a concentration that can be used in the
5 food industry as the safety level for most food allergy sufferers. The advantage of 5
6 mg/100 g of food is that it can be readily detectable for all 14 food allergens with the
7 currently existing technology. In addition, avoiding contamination at this level should
8 be technically feasible for the food industry as the feasibility has been discussed at
9 three different meetings with food technologists and analytical laboratories. Rare
10 exceptions may occur if machinery is difficult to clean. For example, pieces of nut in
11 chocolate may be a problem, as the allergen is not evenly distributed in the food
12 matrix.

13

14 There has also been a lot of discussion with different patient organisations which
15 would prefer to have legally binding legislation regarding the declaration of food
16 allergen contaminants as it remains an unmet need. However, we view the voluntary
17 declaration as a positive direction that would benefit food allergy sufferers and their
18 families.

19

20 Such a declaration would not only help all food allergic patients who have a known
21 threshold above 5 mg, but it would be also helpful to the family of those patients who
22 have anaphylaxis against allergens at levels of < 1 mg, to purchase processed foods
23 for the household, as they would be informed that the food allergic family member
24 would not be endangered if products with possibly such low concentrations of
25 contaminants would be used within the household. The current situation is that often
26 the whole family of severely food allergic patients is afraid to buy any processed food
27 at all.

28

29 In addition, physicians, dietitians, and nutritionists could better advise patients about
30 their risk level in daily practice. This of course is mandatory for the exceedingly rare
31 patients described in the literature who react below 5 mg protein. They should be
32 counselled about which processed food, in general, they should avoid.

33

1 We propose as a voluntary labelling for the European Union that no traces of the 14
2 main food allergens in a given processed food are above 0.5 mg/100 g, together with
3 a warning that traces below this level can occur but are likely not harmful. This
4 message can improve the situation where manufacturers often state on the packages
5 that traces can be contained without stating the amount of the trace, that the product
6 has been processed in a facility which also processed e.g. peanut products. Both
7 kinds of information are more for the sake of the producer to keep away from liability
8 issues than for the true benefit of the consuming patient who wants to know the exact
9 levels. The 0.5 mg/100 g level, as a clear statement on packages, would cover the
10 vast majority of food allergic patients.

11

12 Finally, this proposal has been discussed with the food industry authorities and a
13 statement that it is regarded as positive has been received, found in the Appendix 2.

14

15 **LIMITATIONS**

16 There are limitations that should be noted in the interpretation of the present work.
17 First, due to the defined literature search query, there may be some available
18 literature that was not identified in this review and therefore the data was not taken
19 into consideration. An example would be publications on immunotherapy trials where
20 low doses of allergen caused reactions, but they were not reported as life threatening
21 or fatal. Due to the large volume of hits obtained from the first round of literature
22 screening, the publications were screened based on their title and abstract, therefore
23 it is possible that some data included only in the text were overseen. Also, large
24 number of studies which were found by our search strategy did not report direct
25 relation of the amount of allergen ingested to the observed reaction, therefore, a lot
26 of data addressing food anaphylaxis could not be included in our analysis. It should
27 also be taken into account that we relate to the amount of allergenic protein ingested.
28 If the information was not reported by the investigators, it was calculated based on
29 the usual protein content of the food product used in the provocation test or reported
30 in the case report. Despite the careful evaluation and supervision of a professional
31 dietitian, it cannot be ruled out that the amounts given differ from actual amount of
32 protein ingested. It should also be mentioned that the screening of the data was done
33 by the reviewers separately, data of uncertain relevance however was discussed by
34 all three reviewers. Lastly, the summary of case reports may give the impression that

1 in most cases the dose amount is unknown, suggesting that the information is
2 incomplete and insufficient. As case reports are a valuable data source of real-life
3 situations, it is an unmet need to standardize the investigation and tracking of fatality
4 in food allergy.

5

6 **CONCLUSIONS**

7 No fatal reactions have been reported below 5 mg of protein exposure in food allergic
8 patients. The individual eliciting threshold differs considerably between patients, but
9 the vast majority of patients do not react at levels below 5mg of protein. For these
10 patients it would be helpful to know that contamination with allergens in processed
11 food do not exceed this level. Looking at a further safety margin it is therefore
12 proposed that 5mg/kg of contaminating allergen in processed food is not exceeded
13 acknowledging that the usual portion size is far lower than 1 kg.

14 The labelling could read as follows: “this product contains the named allergens in the
15 list of ingredients, it may contain traces of other contaminants (to be named, e.g. nut)
16 at concentrations less than 0.5 mg per 100g of this product” for a voluntary
17 declaration on processed food packages.

18 We further see this only as a first step as legally binding thresholds would be
19 preferred. The authors however feel that realistically it would take a long time before
20 this will be implemented on a global scale and in the meantime the more precise the
21 labelling is the better.

22 Furthermore we conclude that also this review is only a first step in research
23 concentrating on a threshold to avoid fatal reactions, more research is needed to
24 identify thresholds for milder symptoms of food allergy.

25

26

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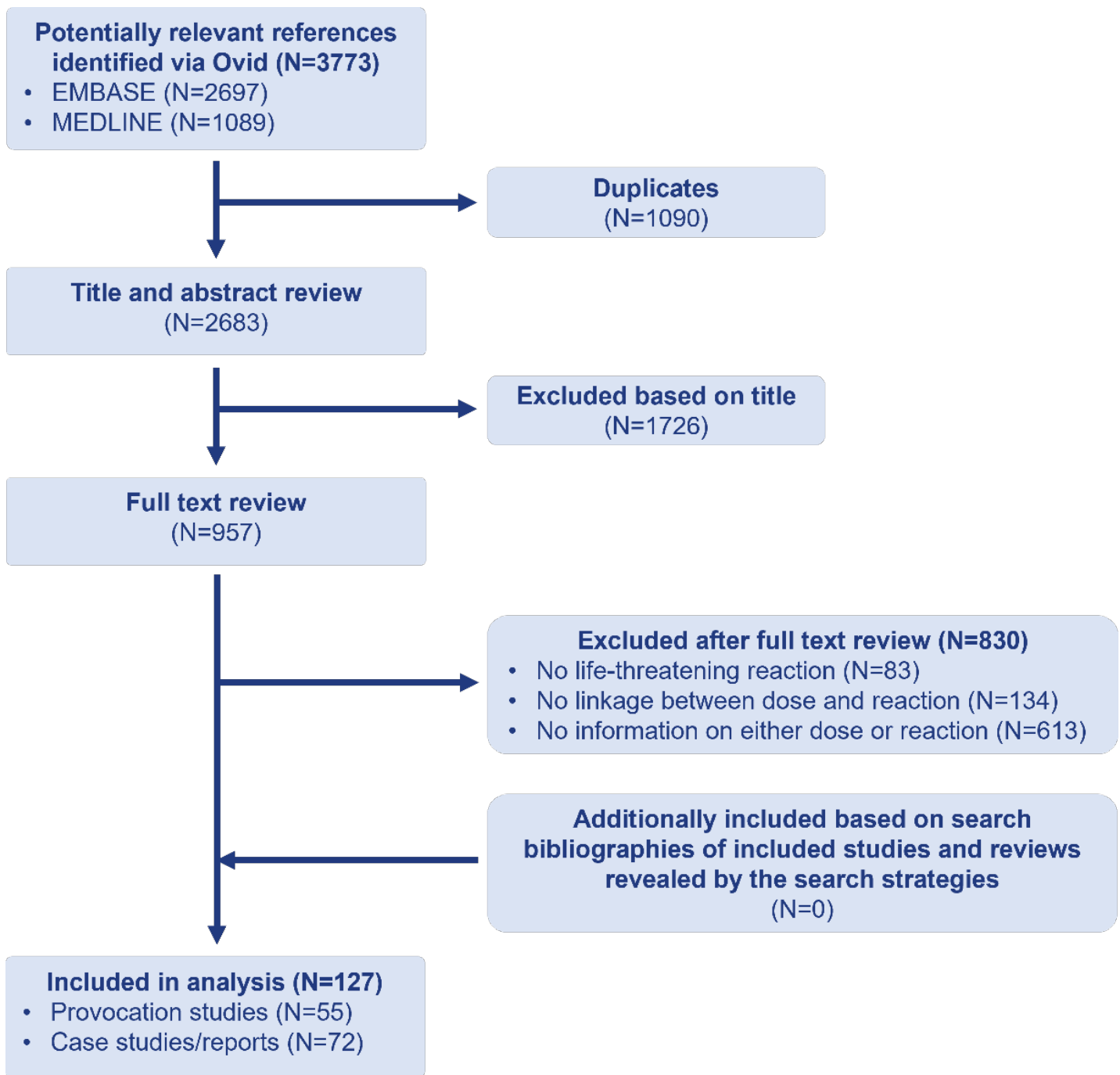
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