

Codex Recommendations on Food Allergens - will they work for Allergic Consumers?

Dr Paul Turner

National Heart & Lung Institute, Imperial College London

Type	Company
Employment full time / part time	Imperial College London / Imperial College Healthcare NHS Trust UK Health Security Agency
Spouse / Family member employment / engagement	None
Research Grant (P.I., collaborator or consultant; pending and received grants)	Medical Research Council National Institute for Health Research European Commission Horizon 2020 JM Charitable Trust Action Medical Research
Other research support	NIHR/Imperial BRC
Speakers Bureau / Honoraria	None in last 3 years
Ownership interest (stock, stock-options, patent or IP)	None
Consultant / advisory board	Allergenis UK Food Standards Agency WHO/FAO Codex Expert Committee on Allergens Ex Chair, BSACI Paediatric Committee Chair, WAO Anaphylaxis Committee Joint lead, UK Resuscitation Council Anaphylaxis Guideline

- Why the status quo isn't good enough
- Recommended “priority” allergens
- PAL RA
- PAL risk communication





FILLED BELGIAN CHOCOLATES (PRALINÉ 65%)
INGREDIENTS: Sugar, hazelnuts, whole milk powder, cocoa butter, cocoa mass, soya lecithin (emulsifier), vanillin. Cocoa based ingredients: milk chocolate min. 34%, white chocolate min. 25%. Milk solids: milk chocolate min. 22%, white chocolate min. 30%. May contain traces of nuts and/or gluten.

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MAGNUM[®]

CLASSIC

INGREDIENTS: VANILLEESCREME MIT 9% FETT UND MILKSCHOKOLADE. ZUTATEN: EINGEKÜLTETE ENTRAHMTE MILCH, MILKSCHOKOLADE (28%), ZUCKER, BUTTERFÄHIGKEIT, GLUKOSESYRUP, MICH-KHAKH-KHAKH, EMULGATOR (E471), STABILISATOREN (E410, E407), VERMÄHLTE VANILLE, FRUCHTIGES AROMA, FARBSTOFFE (E102). **VEGETARIAN:** VANILLA ICE CREAM AND MILK CHOCOLATE. **INGREDIENTS:** CONCENTRATED SKIMMED MILK, MILK CHOCOLATE (28%), SUGAR, BUTTEROIL, GLUCOSE SYRUP, WHEY SOLIDS, EMULSIFIER (E471), STABILISERS (E410, E407), VANILLA PODS, FLAVOURING, COLOURING (E102). **VEGETARIAN:** VANILLA ICE CREAM AND MILK CHOCOLATE. **INGREDIENTS:** LAIT ÉCRÉMÉ REHYDRATÉ, CHOCOLAT AU LAIT (28%), SUCRE, BEURRE CONCENTRÉ, SIROP DE GLUCOSE, LACTOSE ET PROTÉINES DE LAIT, EMULSIFIANT (E471), STABILISANTS (E410, E407), GOÛTS DE VANILLE BRÛLÉE, AROME, COLORANT (E102). **VEGETARIAN:** DELATO ALLA VANIGLIA RICOPERTO DI CIOCCOLATO AL LATTE. **INGREDIENTS:** LATTE SCONFIATO REIDRATATO, ZUCCHERO, BURRO CONCENTRATO, SCIROPO DI GLUCOSIO, LATTOSIO E PROTEINE DEL LATTE, EMULSIONANTE (E471), ADDENSANTI (E410, E407), BACCOLI DI VANIGLIA, AROMA, COLORANTI (E102). **VEGETARIAN:** HELADO CRAMA VANILLA Y CHOCOLATE CON LECHE. **INGREDIENTES:** LECHE DESNATADA CONCENTRADA, CHOCOLATE CON LECHE (28%), AZÚCAR, MANTECILLA, UNEDOR, AROMA, COLORANTE (E102). **VEGETARIAN:** VANILLE ROOMJS EN MELKSCHOKOLADE. **INGREDIENTEN:** DIERFVETTERMILK, MAGERE MILK, MILKSCHOKOLADE (28%), ZUCKER, MICHKEFETT, GLUKOSESYRUP, MICH-KHAKH-KHAKH, EMULGATOR (E471), STABILISATOREN (E410, E407), VANILJEN, FRUCHTIGES AROMA, FARBSTOFFE (E102). **VEGETARIAN:** VANILJÄRÄDGÄSS OCH MÖRK MJÖLKSCHOKLAD. **INGREDIENTER:** KONCENTRERAD SKUMMÖLK, MJÖLKSCHOKLAD (28%), SÖCKER, SMÖRFETT, STÄRKELSESÄR, VÄSSHUVEN, FÄRVSÄRINGSMEDEL (E410), STÄRKELSERINGSMIDEL (E410, E407), VANILJÄRÄRNINGAR, AROMA, FÄRVSÄRINGSMEDEL (E102). **VEGETARIAN:** DELADO DE BAUNILHA E CHOCOLATE DE LEITE. **INGREDIENTES:** LEITE NATURAL CONCENTRADO, CIOCCOLATO DO LEITE (28%), AÇÚCAR, MANTEIGA CONCENTRADA, AROMA DE GLUCOSE, PROTEÍNAS DE LACTOSE, EMULSIONANTE (E471), ESPESANTES (E410, E407), AROMA DE BAUNILHA, AROMATIZANTES (E102). **VEGETARIAN:** VANILLEFLODES OG MALKESCHOKOLADE. **INGREDIENTER:** KONCENTRERTE MILCH, MAGERE MILCH, MILKSCHOKOLADE (28%), ZUCKER, MICHKEFETT, GLUKOSESYRUP, MICH-KHAKH-KHAKH, EMULGATOR (E471), STABILISATOR (E410, E407), VANILJES, FRUCHTIGES AROMA, FARBSTOFFE (E102). **VEGETARIAN:** VANILJAKERMAJÄÄTELÄÄ JA TURVAA MANTOSUKLAATA. **INGREDIENTIT:** KASVAVAINEMILK, MUKAVAINEMILK, MUKAVAINEMILK, AROMA, FÄRVSÄRINGSMEDEL (E102), STÄRKELSESÄR (E410, E407), VANILJÄRÄRNINGAR, AROMA, FÄRVSÄRINGSMEDEL (E102).

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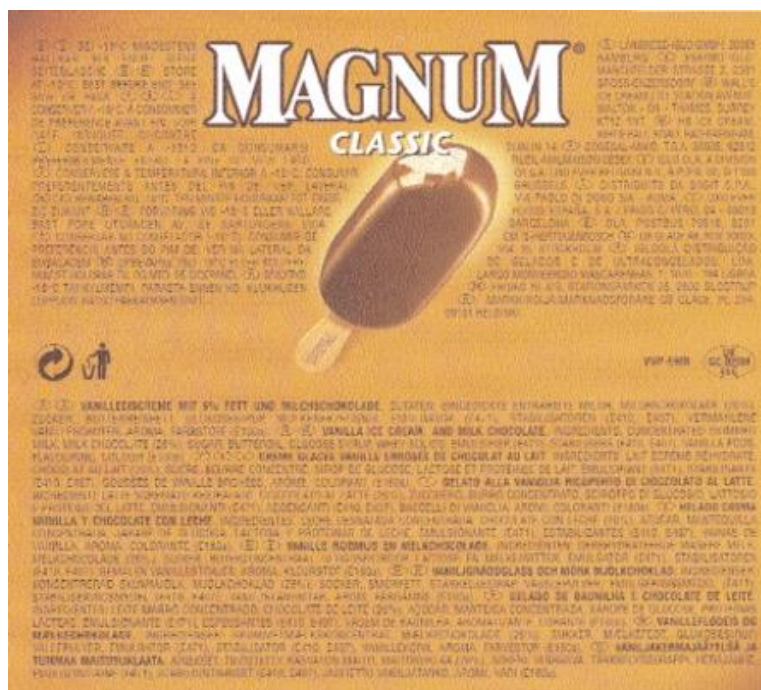
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Allergy advice

- Contains **milk, wheat, gluten, egg.**
- **Recipe:** No nuts.
- **Ingredients:** Cannot guarantee nut free.
- **Factory:** No nuts.



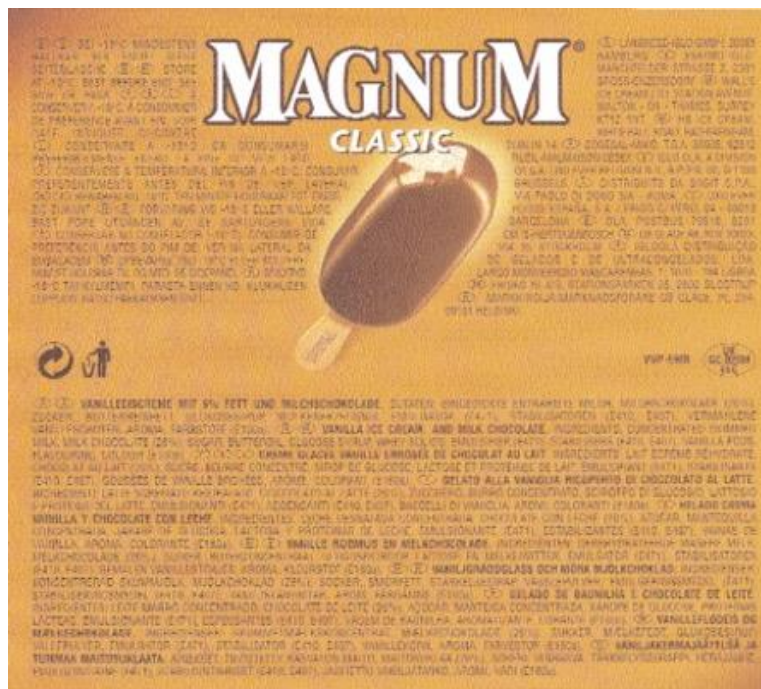


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Recent trends

MEDIA BRIEFING

Kellogg's Intentionally Adding Allergens to Food Products



UPDATE: Please note that on May 17, 2016, Kellogg's finally admitted to KPIX TV San Francisco that the reason they added peanut flour to eight varieties of Keebler and Austin crackers was because they were manufactured on shared lines with peanuts. This allowed them to add peanuts to the ingredient list as stated in this article. To see the newscast with Kellogg's admission, see our update entitled [Kellogg's, Unintended Consequences, and the Death of 'May Contain'](#).

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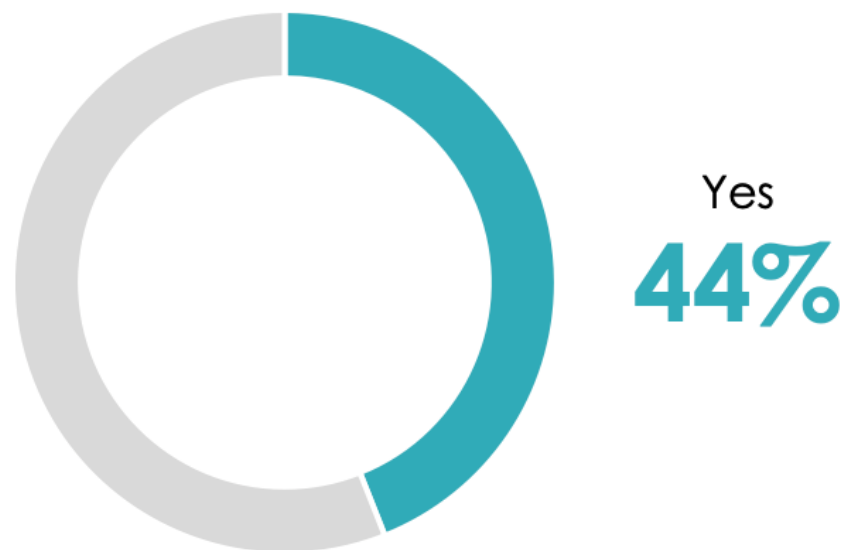
**VOLUNTARY
NOT LEGISLATED FOR**

Precautionary Allergen Labelling (PAL) Quantitative Research

Report of Findings

AWARENESS THAT PAL IS **VOLUNTARY** FOR FOOD MANUFACTURERS AND **NOT SPECIFICALLY
REGULATED BY HEALTH CANADA**

Base: Total sample (n=1080)

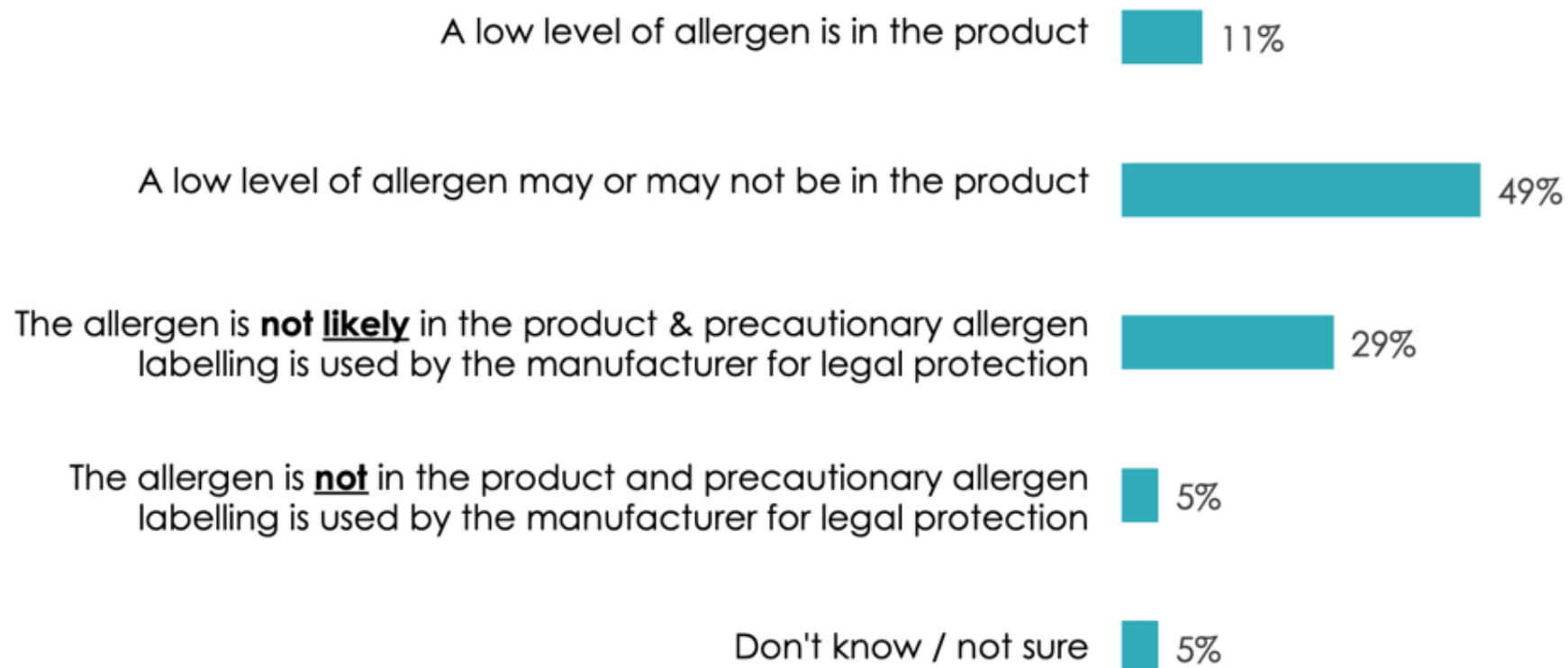


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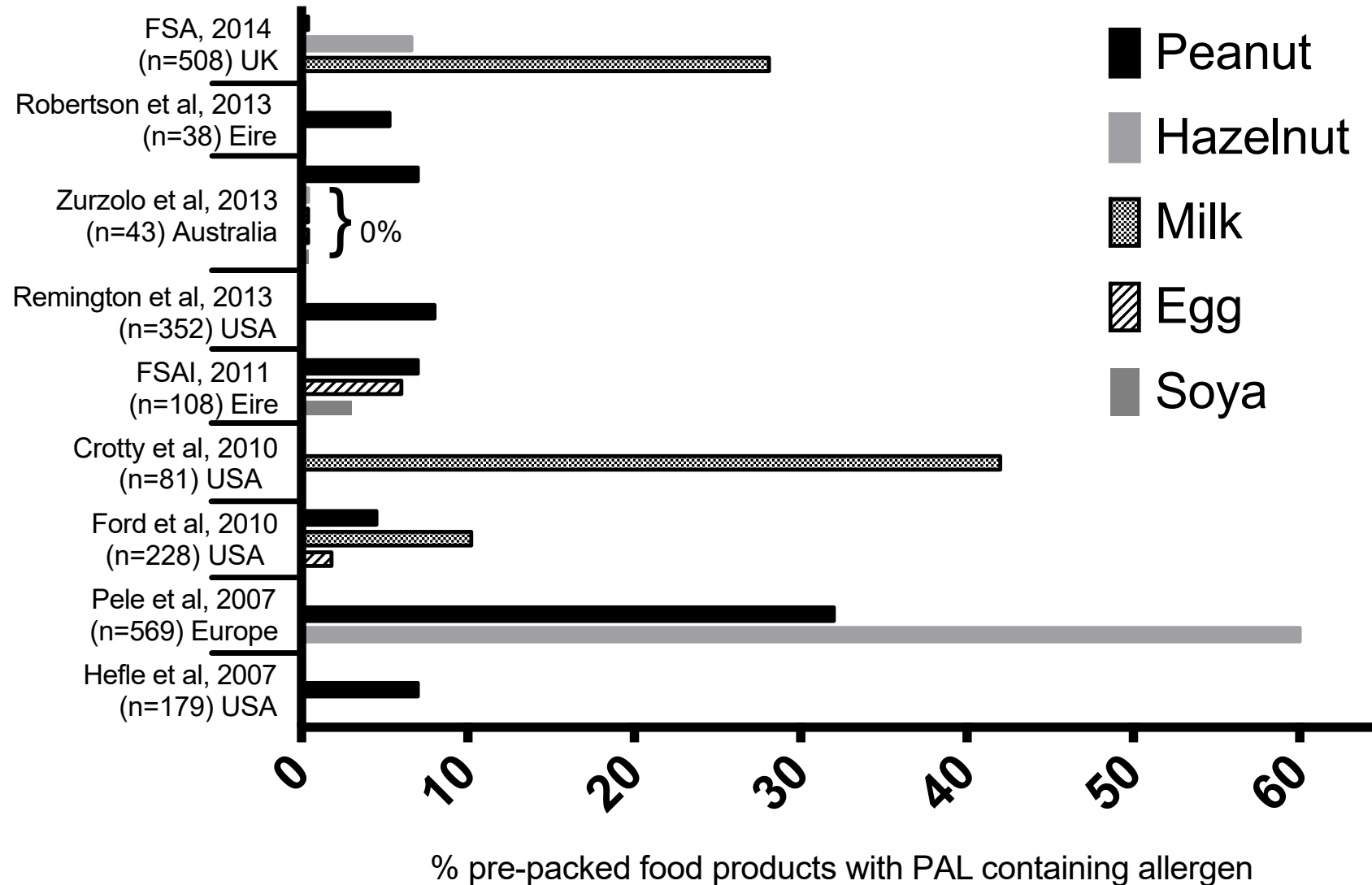
Report of Findings

INTREPRETATION OF PRECAUTIONARY ALLERGEN STATEMENTS

Base: Total sample (n=1080)



Do foods with PAL contain allergen?



Do foods without PAL contain allergen?

Study and allergens	% (No.) of food products with PAL	% (No.) of food products without PAL
Europe, 2007*		
Peanut	33% (109/333)	25% (52/211)
Hazelnut	60% (175/291)	31% (64/209)
USA, 2010		
Peanut	4% (5/112)	0% (0/120)
Egg	2% (1/57)	3% (3/117)
Cow's Milk	10% (6/59)	3% (4/134)
Eire, 2011		
Peanut	7% (5/75)	2% (2/106)
Egg	6% (1/18)	5% (5/106)
Soya	3% (1/30)	5% (5/106)
UK, 2014		
Peanut	0.4% (1/226)	0% (0/249)
Hazelnut	7% (15/228)	0% (0/266)
Cow's Milk	28% (16/57)	3% (6/181)

*This study assessed contamination in biscuits and cookies, which may be at higher risk of nut cross-contamination than other food products

What do Healthcare Professionals recommend?

Clinical Communications

Knowledge, practice, and views on precautionary allergen labeling for the management of patients with IgE-mediated food allergy—a survey of Australasian and UK health care professionals

Paul J. Turner, FRACP, PhD^{a,b},
Katrina J. Allen, FRACP, PhD^{c,d},
Sam Mehr, FRACP, MBBS^{d,e}, and
Dianne E. Campbell, FRACP, PhD^{a,d,e}

- Only 51% knew that PAL are voluntary and not regulated

TABLE I. Factors influencing the advice provided by health care professionals when advising food-allergic individuals with regard to avoidance of prepacked foods with precautionary allergen labeling (PAL)

Answer options	Factors that influence avoidance recommendations	
	Percent	Count
Type of allergen named in the PAL (eg, egg, cow's milk, nuts)	47.2%	75
Food to which the patient is allergic	57.9%	92
Type of food (eg, confectionery)	48.4%	77
Age of patient	16.4%	26
History of anaphylaxis	68.6%	109
History of allergic reaction to very small amount of allergen	78.0%	124
Asthma requiring preventer therapy	41.5%	66
Adrenaline autoinjector ownership	25.2%	40
No, I don't recommend avoidance	9.4%	15
Other (please specify)	6.9%	11

Do allergic individuals heed PAL?

	UK (n=184)	Australia (n=246)	USA (n=2729)	Netherlands (n=42)
“May contain nuts”	80% avoid	75% avoid	81% avoid	~90% avoid
“May contain traces of nuts”				
“Manufactured in a facility that also processes nuts”				
	Noimark et al. PAI 2009	Zurzolo et al. MJA 2013	Gupta et al JACI Prac 2021	Holleman et al. CEA 2021

Do allergic individuals heed PAL?

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“May contain nuts”	80% avoid	75% avoid	81% avoid	~90% avoid
“May contain traces of nuts”	60% avoid	45% avoid	86% avoid	~70% avoid
“Manufactured in a facility that also processes nuts”				
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Do allergic individuals heed PAL?

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“May contain nuts”	80% avoid	75% avoid	81% avoid	~90% avoid
“May contain traces of nuts”	60% avoid	45% avoid	86% avoid	~70% avoid
“Manufactured in a facility that also processes nuts”	40% avoid	35% avoid	50-80% avoid	~30% avoid
	Noimark et al. PAI 2009	Zurzolo et al. MJA 2013	Gupta et al JACI Prac 2021	Holleman et al. CEA 2021

Thus, PAL:

- Presence not related to actual risk
- Limits food choices unnecessarily
- Misinterpreted
- Increasingly ignored
- Inconsistent application:
 - Limits utility for food-allergic consumers

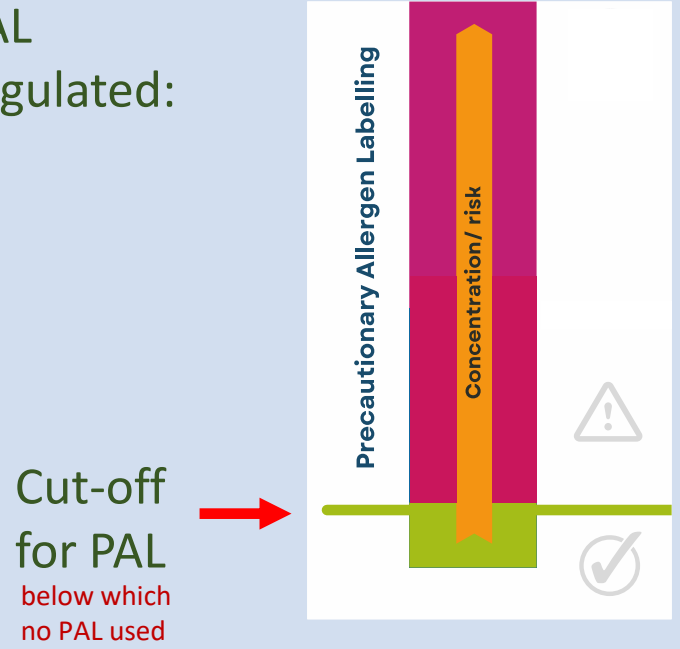
Maintain status quo

PAL is voluntary:

- If used, must be “truthful and not misleading”

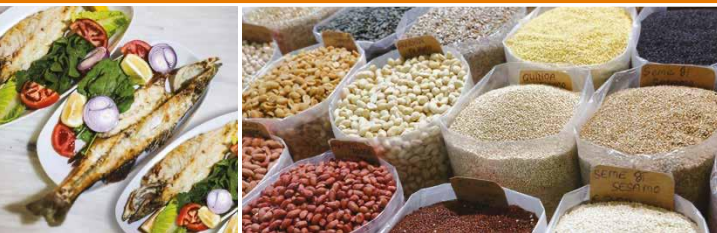
Most products have PAL
High variability in meaning

Maintain status quo	“Zero risk” approach	Regulated PAL
<p>PAL is voluntary:</p> <ul style="list-style-type: none"> If used, must be “truthful and not misleading” 	<p>PAL regulated and enforced:</p> <ul style="list-style-type: none"> If <u>any</u> risk (e.g. allergen is present in the factory), then PAL must be used (irrespective of the degree of risk or any controls in place) 	
<p>Most products have PAL</p> <p>High variability in meaning</p>	<p>Less variability</p> <p>Most products will have PAL (90% are made in facilities where priority allergens are used)</p>	

Maintain status quo	“Zero risk” approach	Regulated PAL
<p>PAL is voluntary:</p> <ul style="list-style-type: none"> If used, must be “truthful and not misleading” 	<p>PAL regulated and enforced:</p> <ul style="list-style-type: none"> If <u>any</u> risk (e.g. allergen is present in the factory), then PAL must be used (irrespective of the degree of risk or any controls in place) 	<p>PAL regulated:</p>  <p>Cut-off for PAL below which no PAL used</p>
<p>Most products have PAL</p> <p>High variability in meaning</p>	<p>Less variability</p> <p>Most products will have PAL (90% are made in facilities where priority allergens are used)</p>	<p>Less variability, less PAL?</p> <p>More transparency over the use of PAL?</p>



MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS PART 1: REVIEW AND VALIDATION OF CODEX ALIMENTARIUS PRIORITY ALLERGEN LIST THROUGH RISK ASSESSMENT

Current (GSLPF)	RECOMMENDED: Global (3+ regions)	+/- local	“Watch list”
Cereals containing gluten	Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains)		Buckwheat, oats, lupin
Crustacea	Crustacea		Insects
Egg	Egg		
Fish	Fish		
Peanut	Peanut		
Soya		Soya	
(Cow’s) milk	(Cow’s) milk		
Tree nuts	<i>Almond</i> , cashew, hazelnut, pecan, pistachio, walnut	Brazil nut, macadamia, pine nuts	
	Sesame	Mustard Celery	Pulses Kiwi fruit...

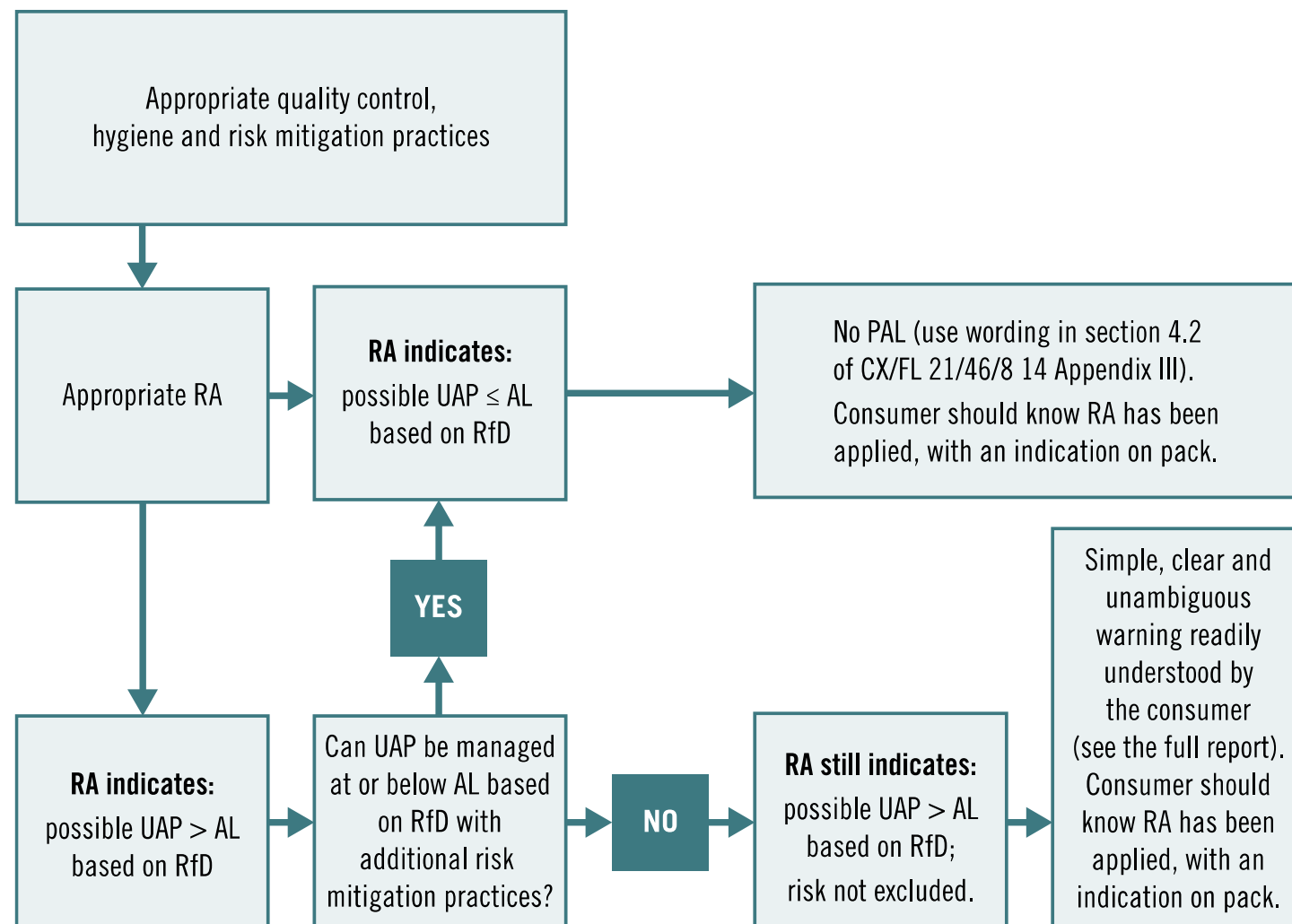


MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS PART 3: REVIEW AND ESTABLISH PRECAUTIONARY LABELLING IN FOODS OF THE PRIORITY ALLERGENS

FIGURE 1. OVERVIEW OF THE RECOMMENDED SINGLE PRECAUTIONARY ALLERGEN LABELLING (PAL) SYSTEM



Note: ^a. RA, risk assessment; ^b. UAP, unintended allergen presence; ^c. AL, action level; ^d. RfD, reference dose.



MEETING REPORT



RISK ASSESSMENT OF FOOD ALLERGENS

PART 2: REVIEW AND ESTABLISH THRESHOLD LEVELS IN FOODS FOR THE PRIORITY ALLERGENS

Global priority food allergens

Walnut, pecan, cashew, pistachio, almond

Egg, milk, peanut, sesame

Hazelnut

Fish, wheat

Crustacea

Foods which may require declaration in national
or regional legislation

Celery/celeriac

Soy

Oats

Food which may require declaration in national
or regional legislation

Brazil nuts, macadamia or Queensland nuts, pine nuts

Mustard

Lupin, buckwheat

RfD recommendation (mg total protein from the allergenic source)

1.0

2.0

3.0

5.0

200.0

RfD recommendation

1.0

10.0

Oat-specific RfD not appropriate

Value for risk management (when limited
data precluded formal RfD declaration)

1.0

1.0

10.0

EFA statement to the Chair of the Codex Committee on Food Labelling (CCFL)

In view of the 48th CCFL meeting, 27 October-1 November 2024, Quebec City, Canada

24 October 2024

“After consultations with our Food Allergy Working Group, with other patient organisations outside Europe, and with experts from the medical community and allergen risk assessors, EFA unequivocally backs the use of RfDs derived from a 5% eliciting dose (ED05).”

EFA statement to the Chair of the Codex Committee on Food Labelling (CCFL)

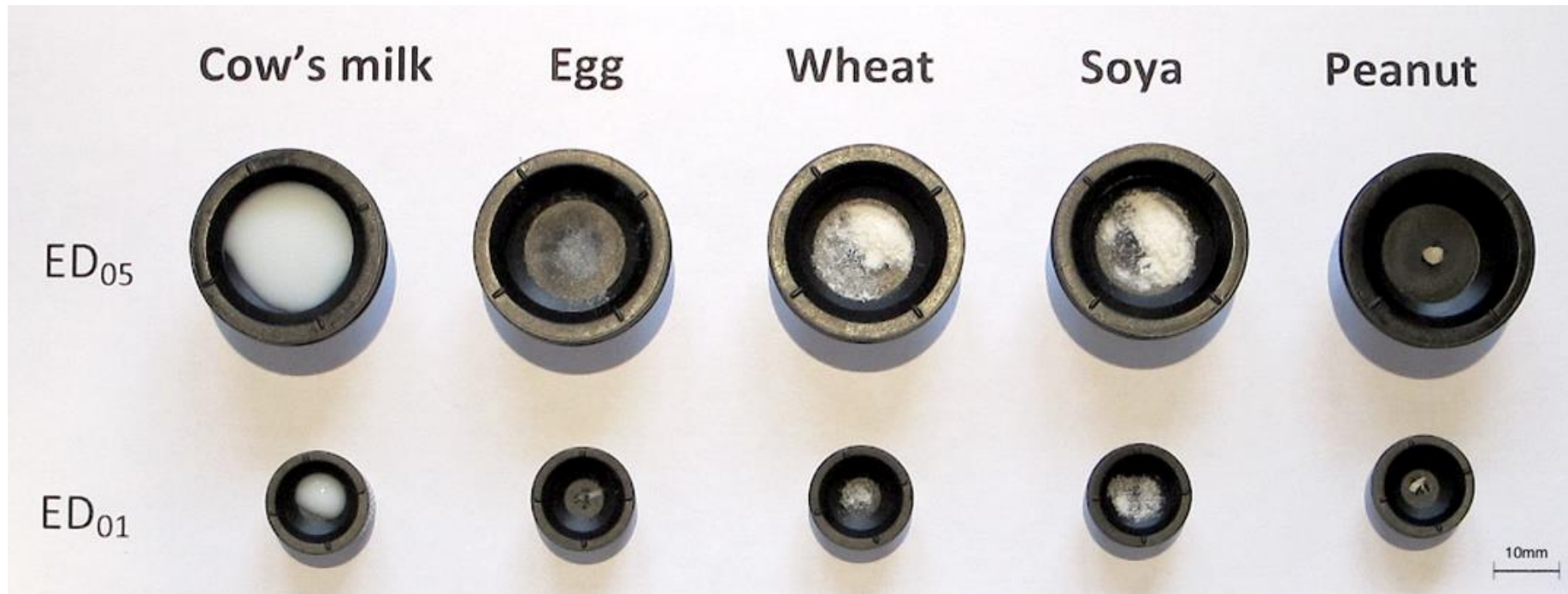
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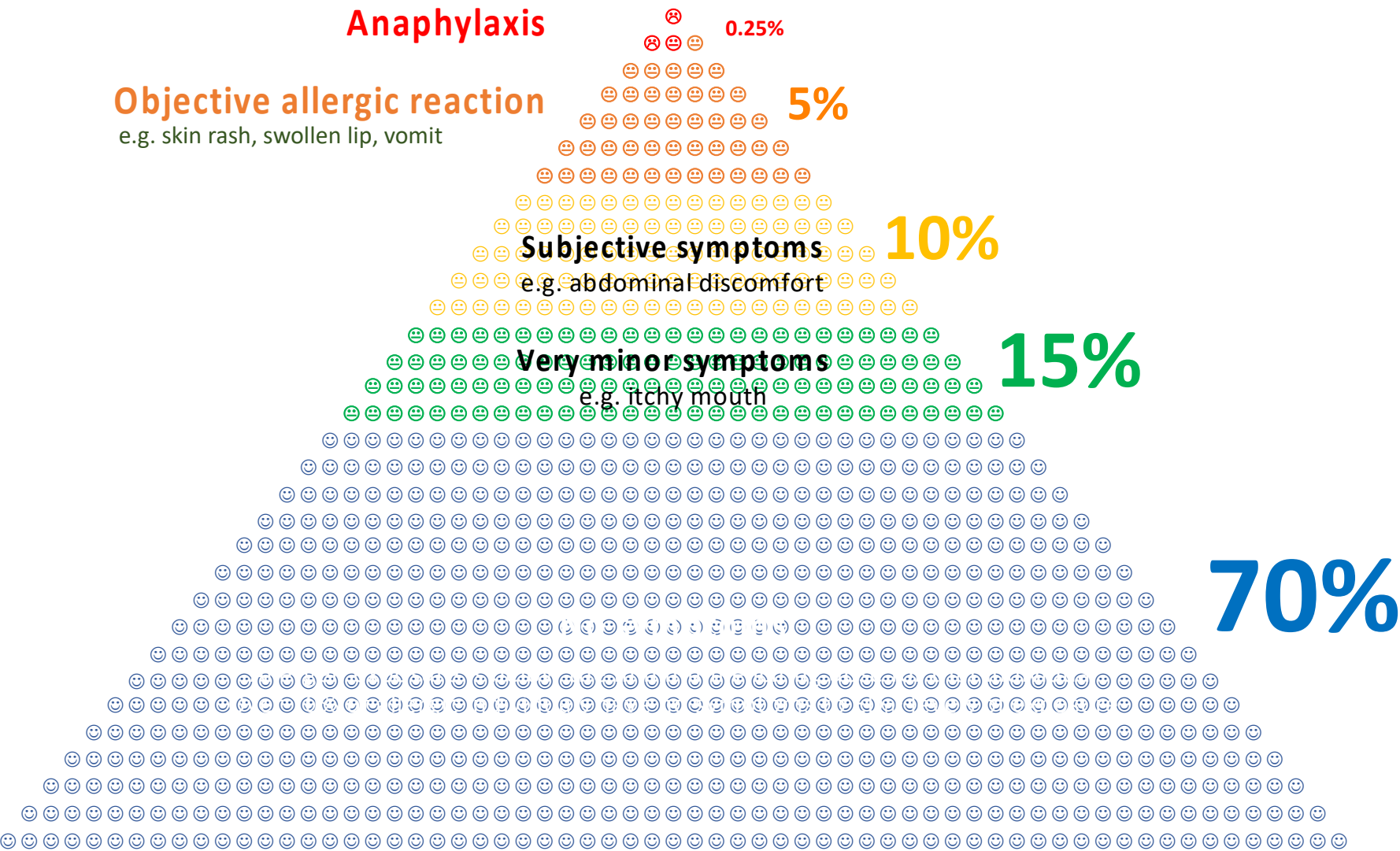
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Who am I to argue?

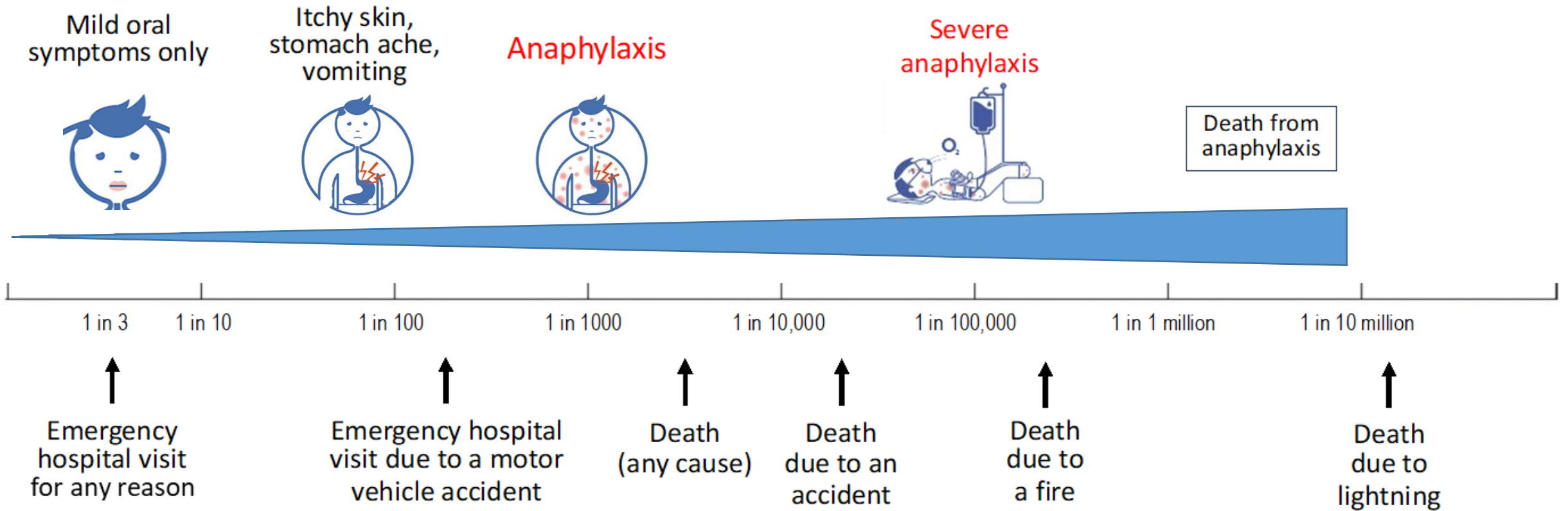
What happens if someone eats...



Following an ED₀₅ exposure:



To an ED₀₅ level of exposure:





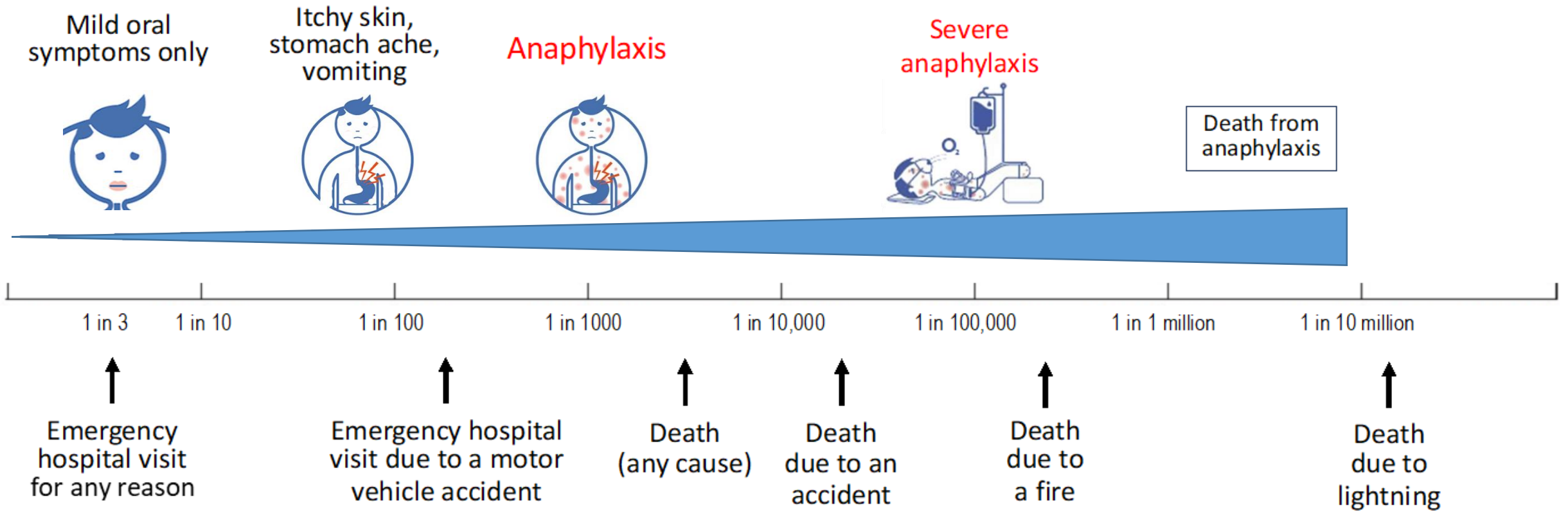
Assessment of the Codex report on food allergen thresholds

August 2023

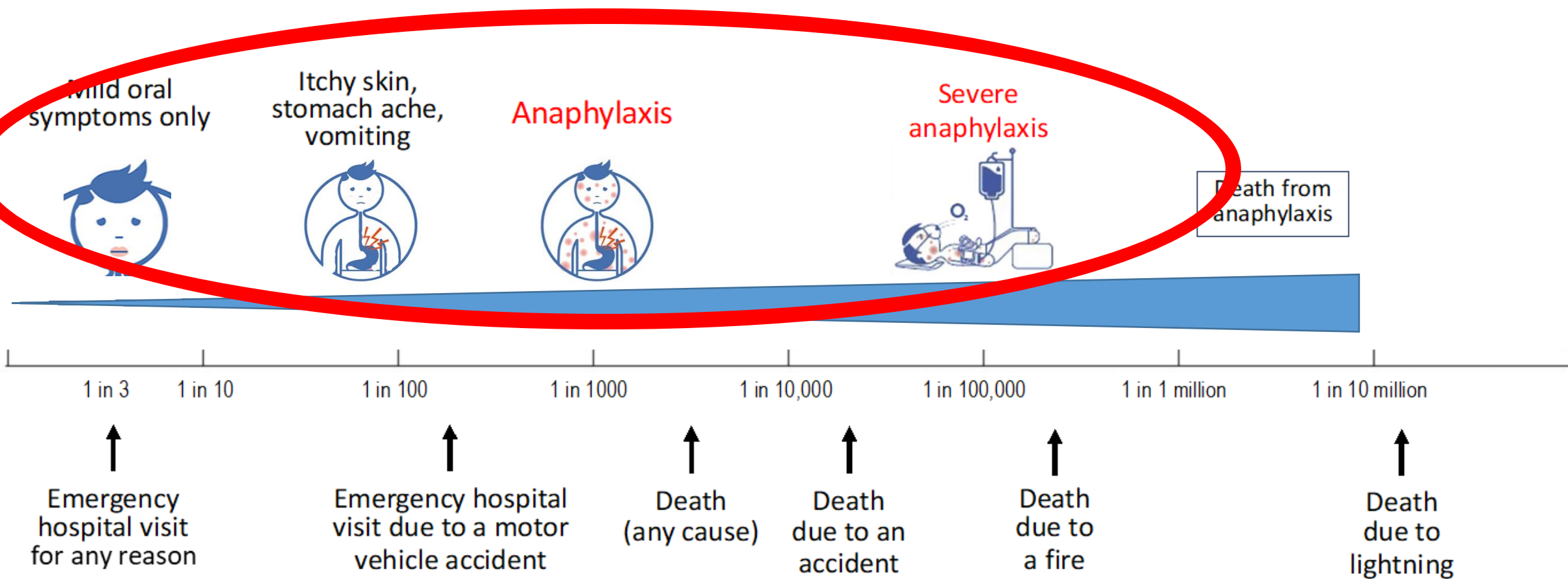
**Committee on Toxicity of
Chemicals in Food, Consumer
Products and the Environment**

The COT subgroup concluded that currently available evidence demonstrates that using reference doses based on ED_{05} , as opposed to ED_{01} values would significantly impact on public health. The COT subgroup recommends that the accuracy and reliability of derived ED values should be evaluated more rigorously if they are going to continue to form the basis for determination of reference vales for food allergens.

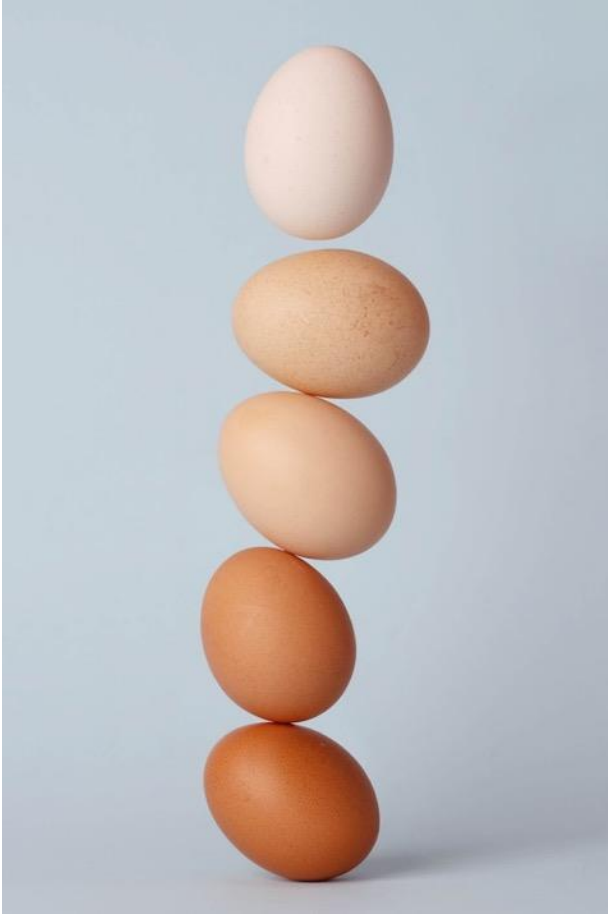
To an ED₀₅ level of exposure:



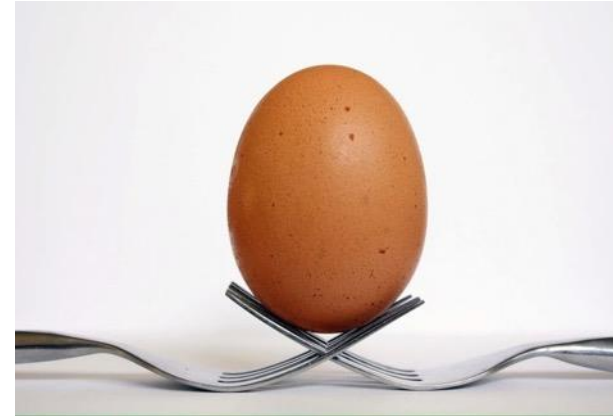
Food allergic consumers want to avoid *any* symptoms:

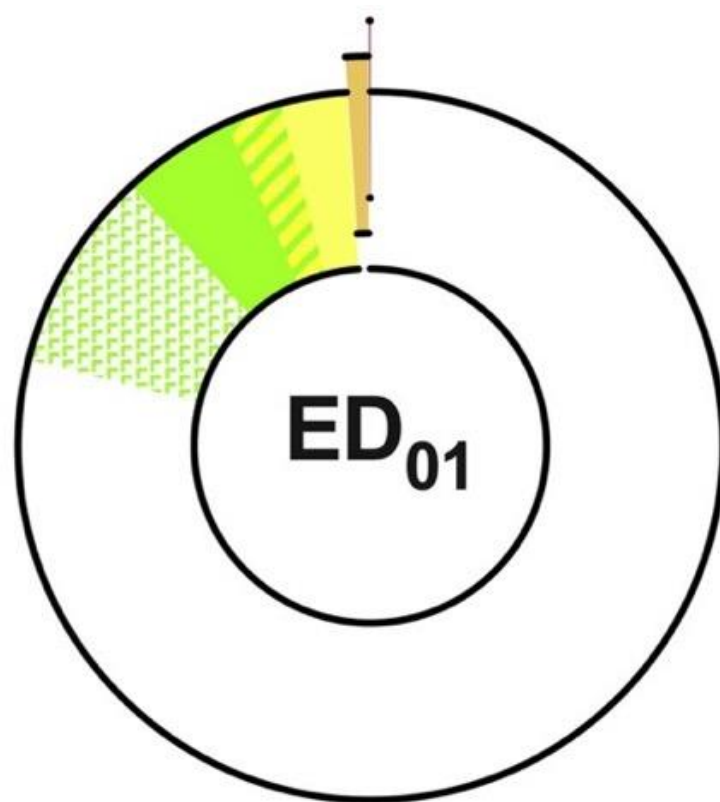
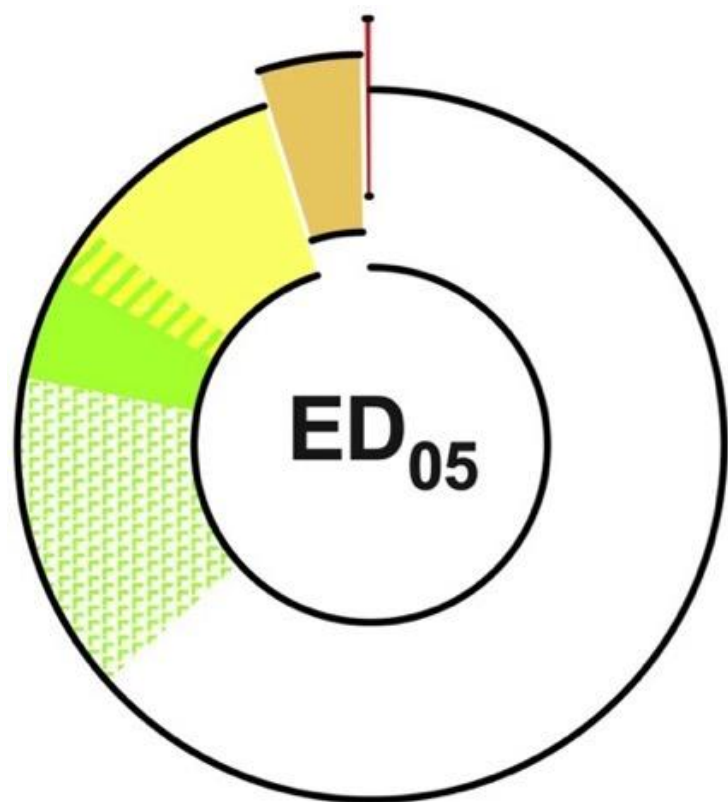







Five is 5 times greater than one... right?



>





-  No symptoms
-  Transient symptoms of OAS only
-  Subjective symptoms
-  Objective symptoms
-  Anaphylaxis

ED₀₅ versus ED₀₁

➤ 5% of allergic people would react

- 1 in 400 exposed will have anaphylaxis
= 25 per 100,000 people exposed

➤ Detectable with current methods

➤ Would reduce amount of PAL

- by around 90% for peanut,
- >50% for hazelnut and dairy (excl. chocolate)

➤ 1% would react

- 1 in 2000 exposed will have anaphylaxis
- 5 people per 100,000 exposed

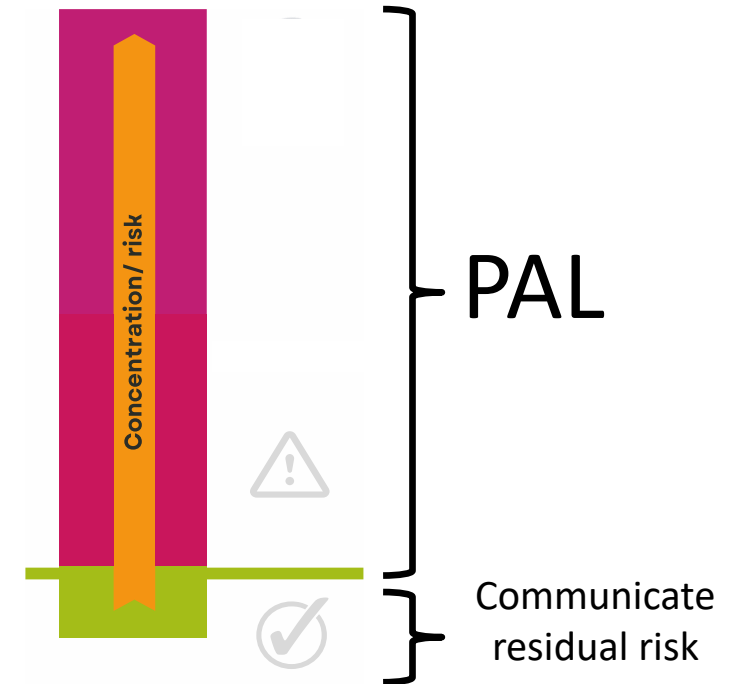
➤ NOT detectable with current analytical methods

➤ Could this lead to more PAL?

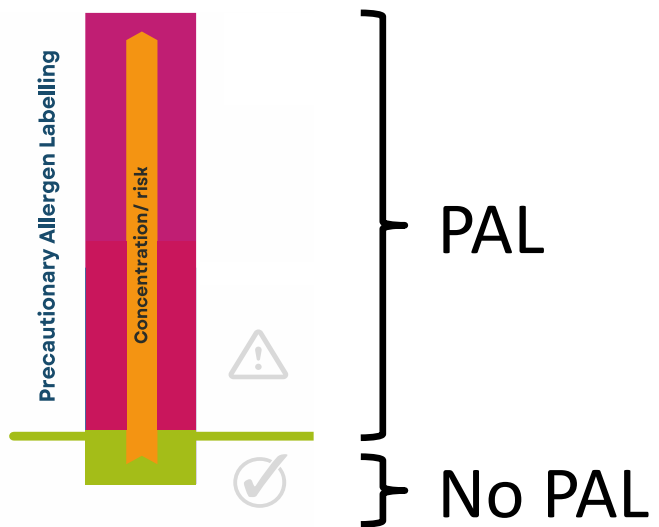


The patient voice

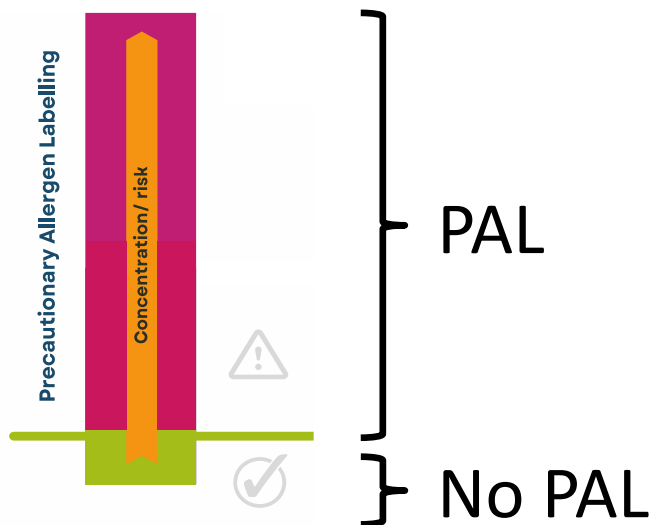
- Is ED_{05} acceptable?
- Would ED_{05} be “more acceptable” if:
 - we could identify lower-dose reactors?
 - there was a way of distinguishing foods with less than ED_{05} , but still detectable allergen?



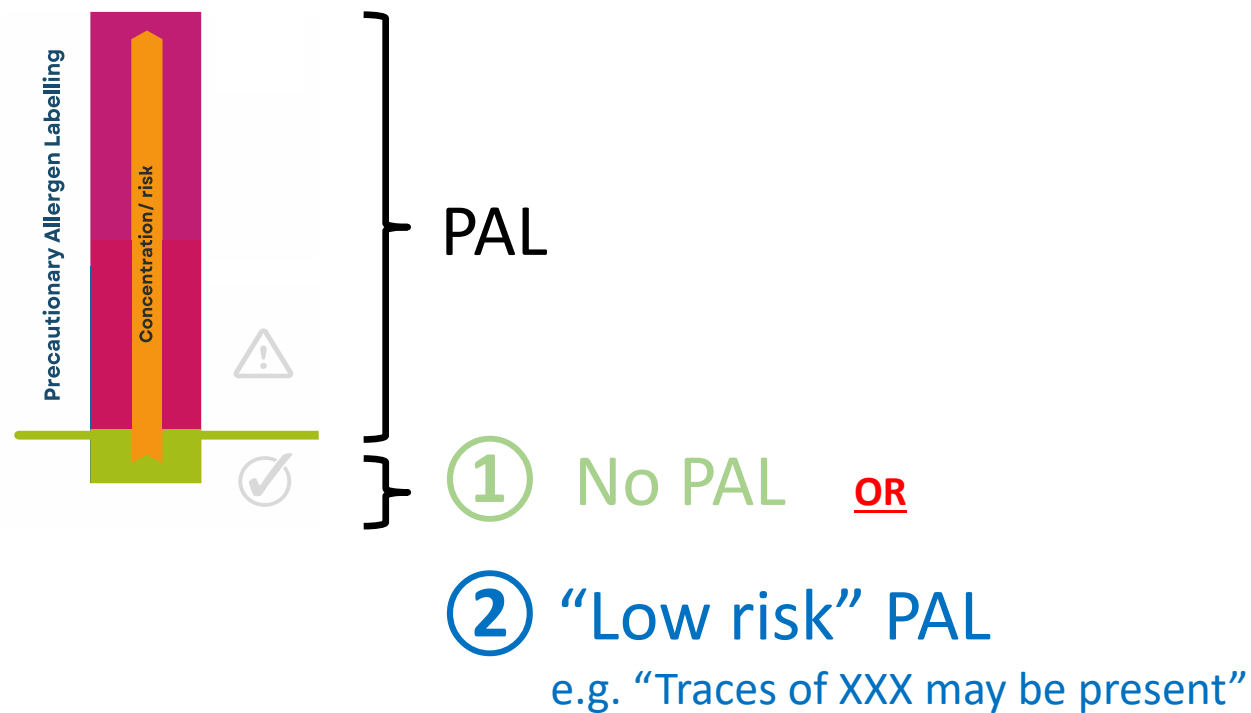
OPTION 1



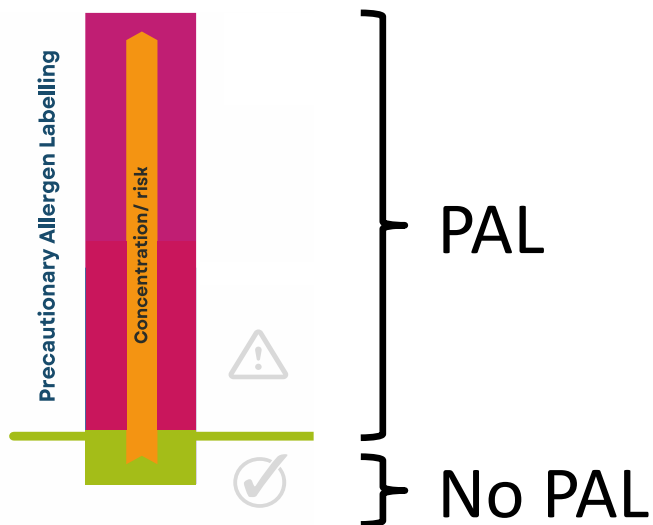
OPTION 1



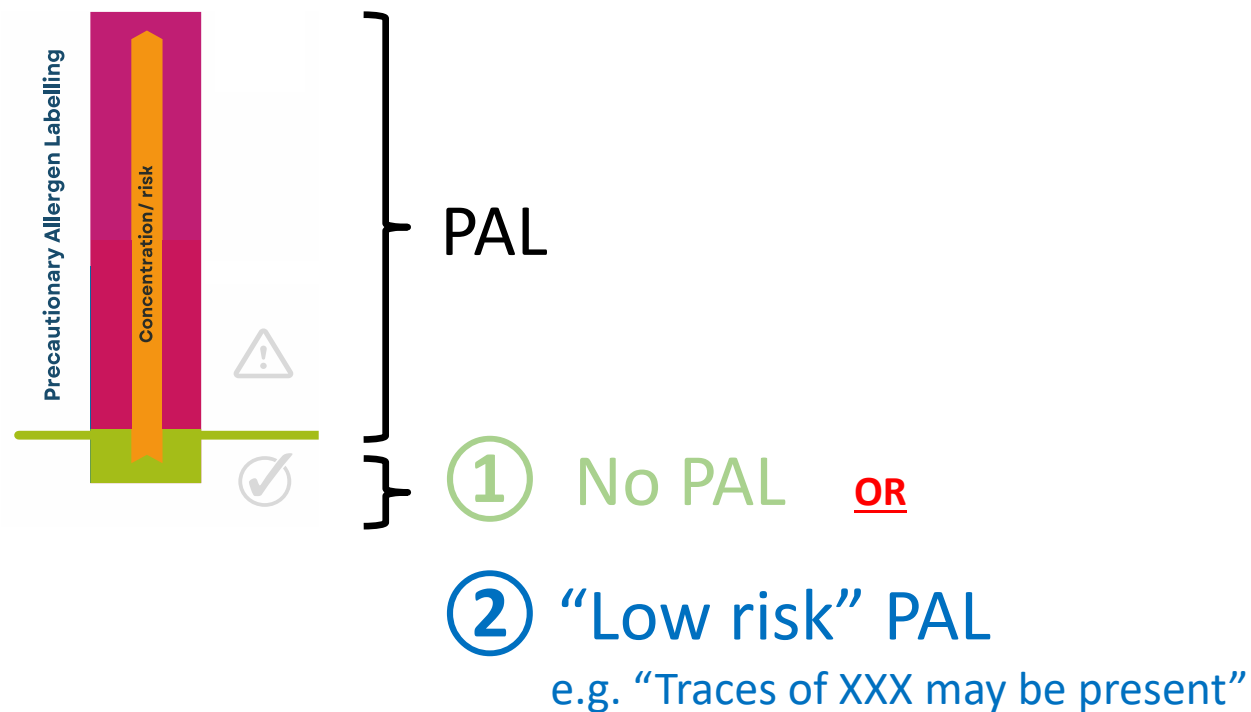
OPTION 2



OPTION 1



OPTION 2



OPTION 3

"May contain X mg peanut per serving"

We can test for people who react to $<ED_{05}$

- This can be done either using a single dose “challenge” in a clinic, or in the future, using a blood test.



What wording?

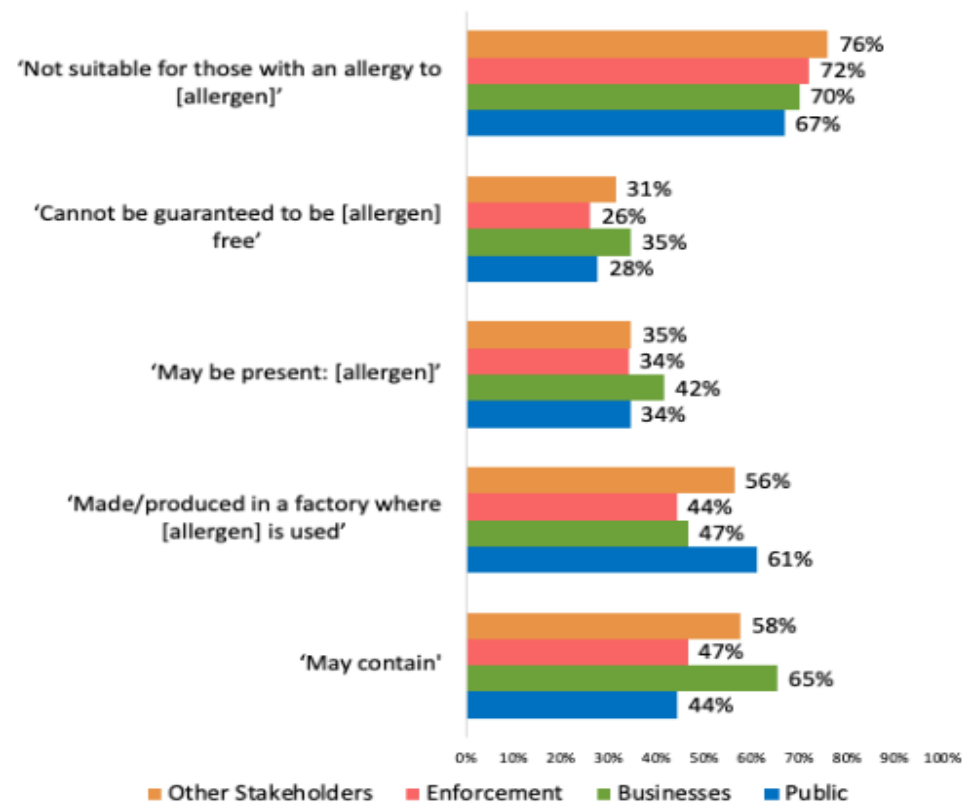


Precautionary Allergen Labelling (PAL) The 'may contain' Consultation

The consultation received 2,459 responses

'Not suitable for' is the preferred PAL statement wording

'Not suitable for...'
was the most
favoured wording
for PAL
statements
across all groups.

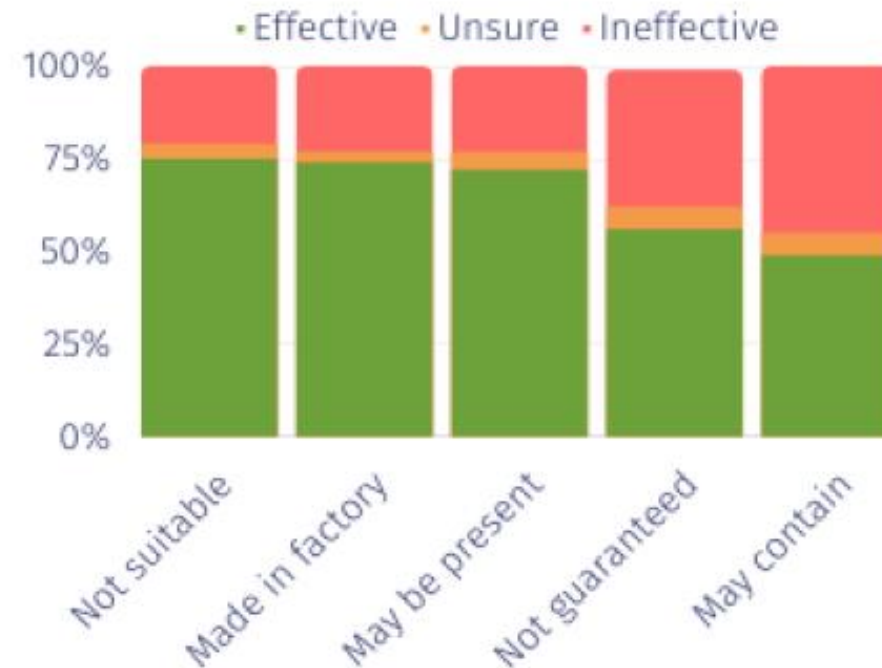


What wording?

Which PAL statements work best?

'Not suitable for...'
was the most favoured
phrase across all groups.

Businesses felt 'may
contain' worked best, while
the public supported use of
the phrase 'made in a
factory'.



Wording: cross-contamination



Precautionary Allergen Labelling (PAL)

The 'may contain' Consultation

Theme 1: Information Provision to Consumers

Cross-contamination wording on PAL

The majority of all groups (64% of businesses, 74% of enforcement, and 85% of the public) felt 'cross-contamination' most clearly described the risk an allergen was unintentionally in a food. All groups felt the following statements are effective:

- 'May contain [allergen] due to risk of cross-contamination' (74%)
- 'Risk of cross-contamination, as made in a factory where [allergen] is used' (73%)
- 'Not suitable for those with an allergy to [allergen] due to cross-contamination' (71%)

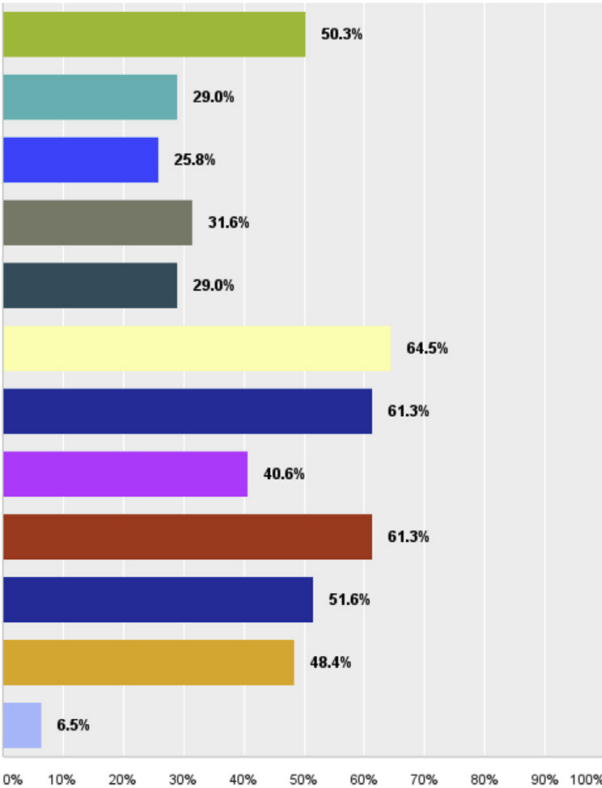
'Cannot be guaranteed to be [allergen] free due to cross-contamination' was not seen as effective by all groups except enforcement.

Knowledge, practice, and views on precautionary allergen labeling for the management of patients with IgE-mediated food allergy—a survey of Australasian and UK health care professionals

Paul J. Turner, FRACP, PhD^{a,b},
Katrina J. Allen, FRACP, PhD^{c,d},
Sam Mehr, FRACP, MBBS^{d,e}, and
Dianne E. Campbell, FRACP, PhD^{a,d,e}

J ALLERGY CLIN IMMUNOL PRACT
JANUARY/FEBRUARY 2016

Which of the following precautionary labelling statements DO YOU BELIEVE indicates a real risk of allergen cross-contamination?



Which ONE of the following statements do YOU BELIEVE is the **BEST wording** for precautionary allergen labelling?

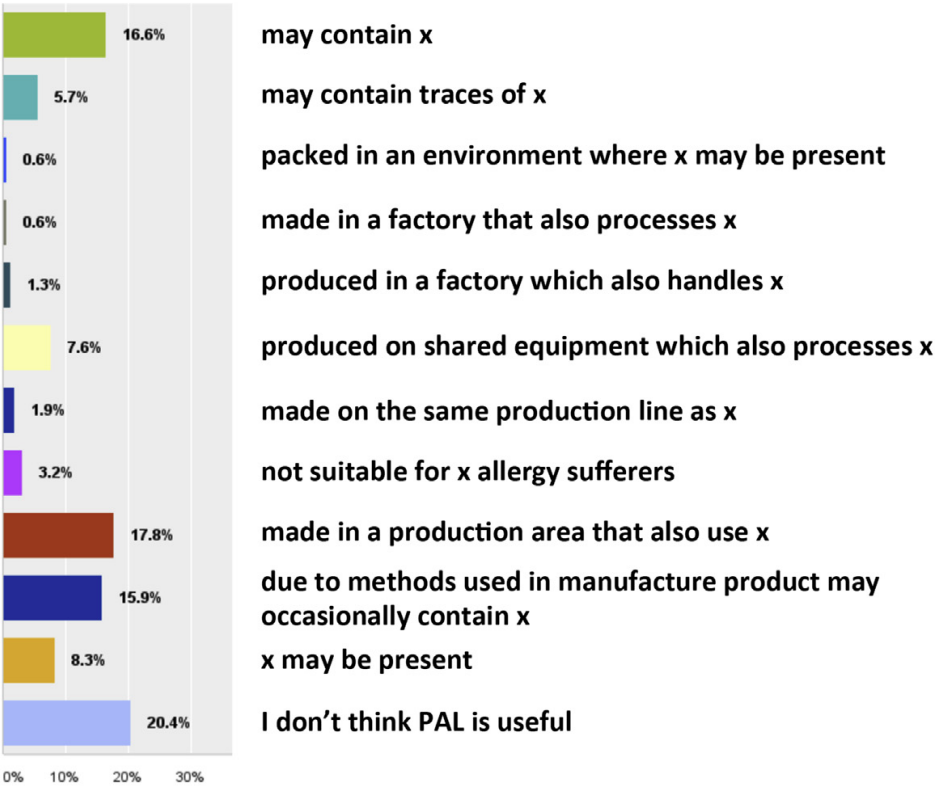
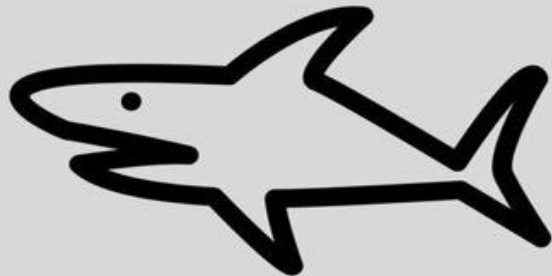


FIGURE 1. Discordance between which statements health care professionals believed indicated a real risk of allergen cross-contamination, and what they considered was the best wording for precautionary allergen labeling (PAL).

What about frequency of risk?

Hazard

Something that can potentially cause harm



Risk



= hazard + exposure

What about when the exposure is smaller and the risk lower?



What about frequency of risk ?

Frequency

How often may a food be contaminated?



Always



50%



10%



Almost
never

Is there a need to communicate how often a risk is present?

% RANKING #1 (MOST VALUABLE INFORMATION) ON LABEL

If cross-contamination was to occur, **what amount of the allergen is potentially in the product.**



What the **probability of the allergen being in the product** where it is not intended is.



Why the precautionary allergen label is being used.



What the manufacturer is doing to minimize the risk of unintentional allergen presence throughout the food manufacturing process.



Codex Recommendations on Food Allergens - will they work for Allergic Consumers?

Maybe



The challenge ahead...

Increase in anaphylaxis-related hospitalizations but no increase in fatalities: An analysis of United Kingdom national anaphylaxis data, 1992-2012

Paul J. Turner, FRACP, PhD,^{a,b} M. Hazel Gowland, BA,^c Vibha Sharma, FRCPCH,^d Despo Ierodiakonou, MD, PhD,^a Nigel Harper, FRCA,^d Tomaz Garcez, MRCP, FRCPATH,^d Richard Pumphrey, FRCPATH,^d and Robert J. Boyle, MBChB, PhD^a *London, Farnborough, and Manchester, United Kingdom, and Sydney, Australia*

UK Food-anaphylaxis fatalities:

- 27% caused by allergen in prepacked foods
 - none known to be due to PAL
- 59% due to products from catering establishments

