



The story of the definition of the gluten free thresholds

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Outline of the presentation:

1. Why do we need gluten free thresholds?
2. Chronology to have a regulation
3. The current situation and its benefits

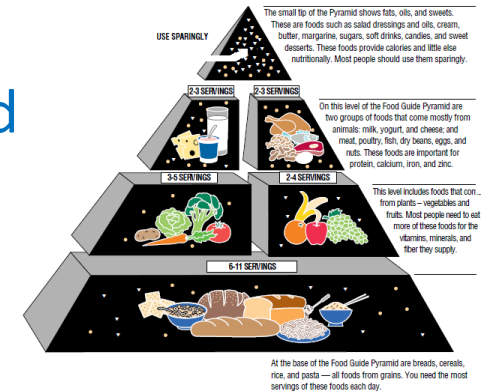


1. Why do we need gluten free thresholds?

- The only treatment available nowadays for those suffering from coeliac disease is to adhere to a strict gluten-free diet (GFD) for life.
- The GFD consists of:
 - Products which do not contain gluten by nature (i.e. fruits, vegetables, meat, fish, dairy products, rice, corn, etc.)
 - Products specifically made of gluten-free cereals (i.e. bread, pasta, pizza, cookies, etc..) also called **“GF substitutes”**.

1. Why do we need gluten free thresholds?

- **GF substitutes** have two main functions:
 1. They guarantee a balanced diet to celiacs:
 - cereals are the base of the food pyramid
 - They provide energy, vitamins, minerals and fiber.



2. They minimize the differences with the diet of non-celiacs

- Help integration and socialization,
- Prevent from committing transgression.



1. Why do we need gluten free thresholds?

- Where is the problem?

ZERO GLUTEN DOES NOT EXIST

Really?





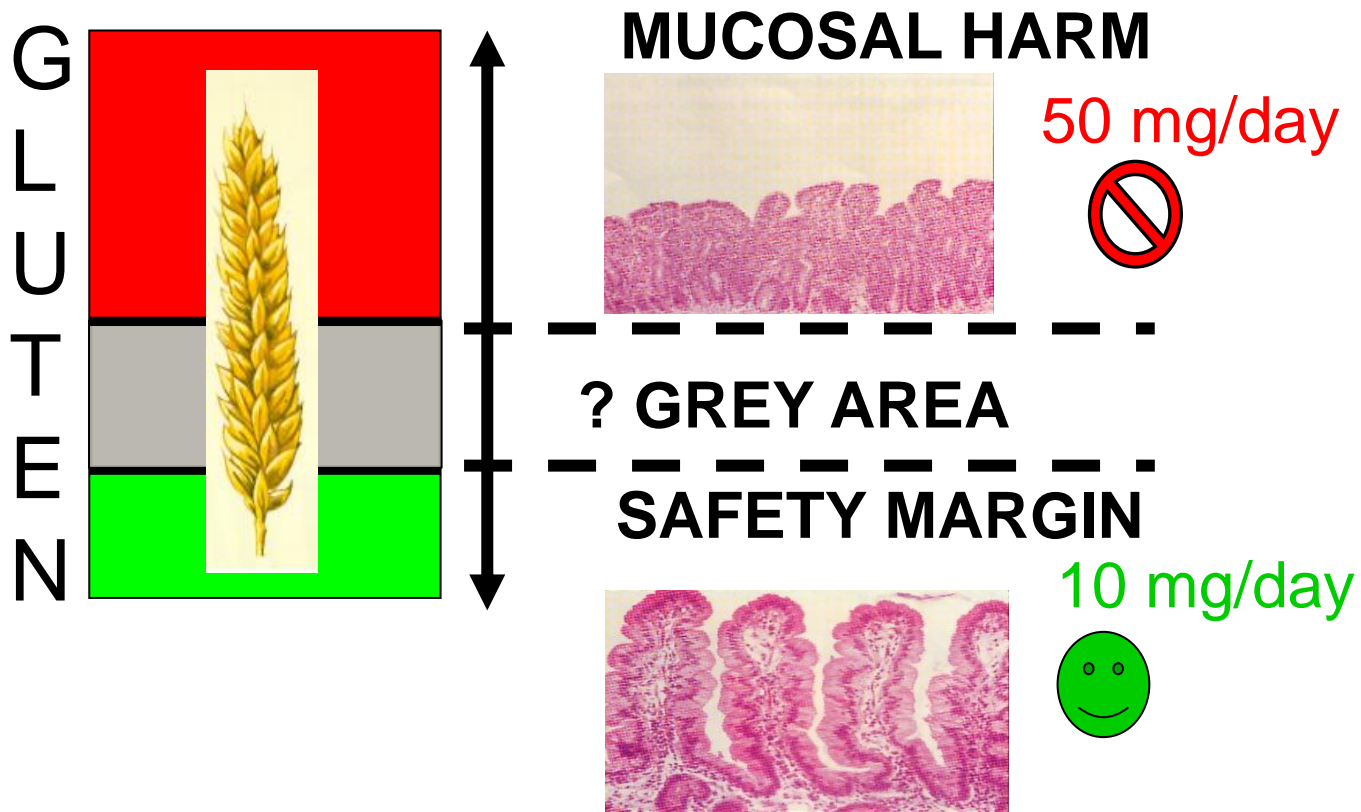
1. Why do we need gluten free thresholds?

Causes:

- Gluten contamination of grain cereals occurs during harvest, handling, transport and milling practices.
- Gluten containing cereals such as wheat starch are “purified” and used to produce gluten-free foods.

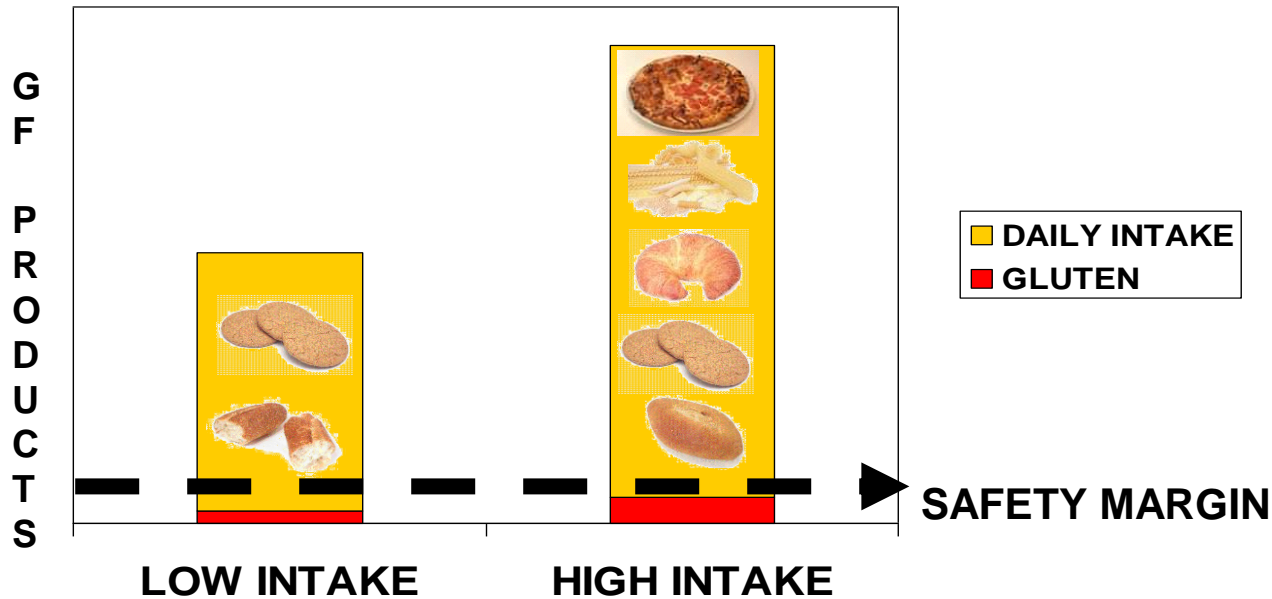
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- If **Zero gluten does not exist** how much can be tolerated?



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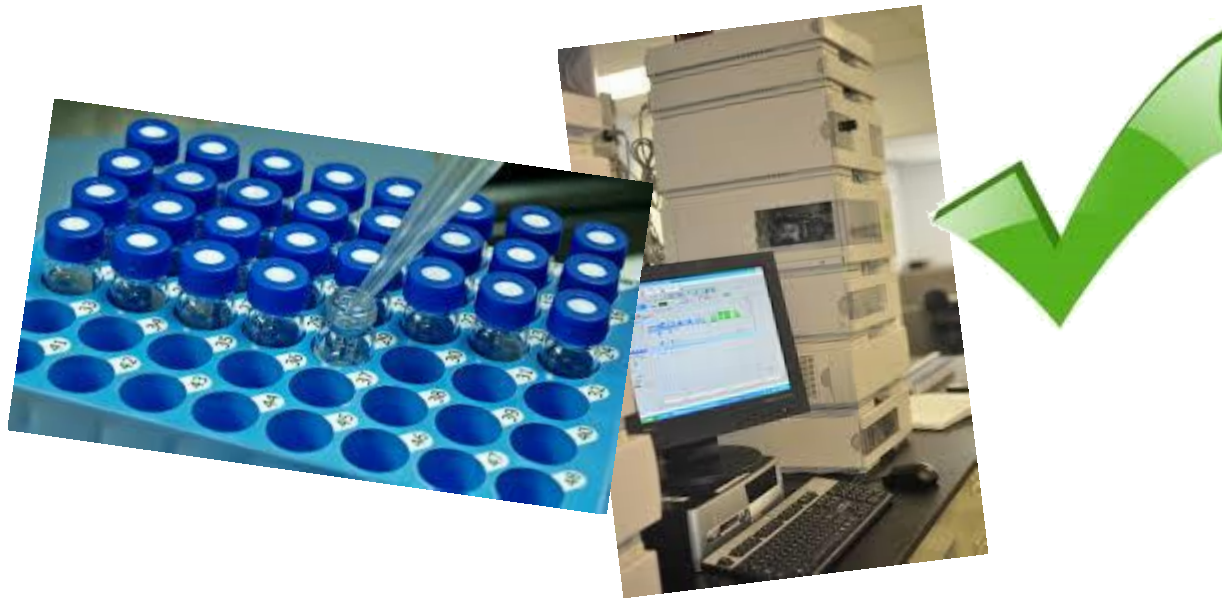


Gibert et al. Eur J Gastroenterol Hepatol 2006;18:1187–95.

1. Why do we need gluten free thresholds?

- If **Zero gluten does not exist** how much can be tolerated?

With a validated method of analysis



1. Why do we need gluten free thresholds?

- If **Zero gluten does not exist** how much can be tolerated?



2. Chronology to have a regulation



CODEX ALIMENTARIUS

1979	Adopted Codex standard for gluten-free foods	Codex standard 118
1983	Amended Codex standard for gluten-free foods	gluten-free 0.05 g nitrogen per 100 g (Kjeldahl method) TOTAL PROTEIN. UNSPECIFIC
1998	Proposed draft revised standard for gluten-free foods.	Dual threshold 1) 20 ppm gluten-free ingredients 2) 200 ppm (wheat starch)
2003	R5-Mendez ELISA method of analysis send for endorsement	Determines PROLAMINS (mainly Gliadin) SPECIFIC
2006	Endorsement of R5-ELISA as Method for the analysis of gluten residues in food	Type I Method – fully validated Limit of detection 3ppm
2008	Revised Codex standard for foods for special dietary use for persons intolerant to gluten.	Dual threshold: 1) 20 ppm -“gluten-free” 2) 100 ppm – national level
2015	Amendment Codex standard for foods for special dietary use for persons intolerant to gluten.	to include the term “khorasan wheat” (Kamut)

2. Chronology to have a regulation



EUROPE

EUROPE		
2003	Directive 2003/89/EC Indication of the ingredients present in foodstuffs. (amending Directive 2000/13/EC)	No thresholds defined, only qualitative declaration of allergens including GLUTEN.
2003 (Italy)	Ministero della Salute. Oggetto: Prodotti dietetici senza glutine e alimenti di uso corrente non contenenti fonti di glutine.	20 ppm
2004	European Food Safety Authority (EFSA) Opinion of the SPDPNA relating to the evaluation of allergenic foods for labelling purposes	Questioned the scientific basis for 200ppm Review of available clinical data
2009 (January 2012)	Regulation (EC) No 41/2009	Dual threshold: Gluten free 20 ppm Very low gluten 100 ppm
2013 (20 July 2016)	Regulation (EU) No 609/2013	No change in thresholds
2015	EFSA Scientific Opinion	Open to other methods of analysis. No changes on thresholds

2. Chronology to have a regulation



USA

2006	FDA/CFSAN. Approaches to establish thresholds for major food allergens and for gluten in food. Prepared by the Threshold Working Group	Currently published data can be used to draw a conclusion to temporarily establish a threshold for gluten.
2007	Proposed Rule: Food Labeling; Gluten-Free Labeling of Foods	Single threshold: 20 ppm Oats? Wheat starch
2011	FDA/CFSAN Health hazard assessment for gluten exposure in individuals with celiac disease: determination of tolerable daily intake levels and levels of concern for gluten.	Single threshold: 20 ppm
2013 (Aug 2014)	Final rule	Single threshold: 20 ppm Wheat starch Oats can be labelled GF if <20ppm Also, any unavoidable presence of gluten in the food must be less than 20 ppm.

2. Chronology to have a regulation

1983 – Codex
Standard

- UNSPECIFIC

1998 – Codex
Standard

- SPECIFIC
- DUAL THRESHOLDS: 20 and 200 ppm

2008 – Codex
Standard

- SPECIFIC
- DUAL THRESHOLDS: 20 and 100 ppm
- VALIDATED METHOD OF ANALYSIS R5-ELISA

2009
(January 2012)

- Regulation (EC) No 41/2009
- Specific for people intolerant to gluten
- DUAL THRESHOLDS: 20 and 100 ppm



3. The current situation and its benefits

1. We have a **Regulation** to define what is gluten-free
2. This provided manufacturers with a **legal framework** to label gluten-free
3. There are **more products** labelled GF
4. More products are **available** to coeliacs
5. “**very low gluten**” has never been used
6. It has forced manufacturers to produce **<20ppm**

3. The current situation and its benefits

Does zero gluten exist??

If I were to guess I would say

