

# Food Allergens: Concepts, Controls and Risk Management

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**Dr. Ashok Gupta: Jaipur, India**

**Dr. Padukurdu Mahesh: Mysore, India**

**And the American Academy of Allergy, Asthma and Immunology**

**26 September, 2012: ILSI-India, New Delhi, India**



[www.farrp.org](http://www.farrp.org)



# Outline

Risks from many microbes and chemicals in foods present a serious risk for all consumers

Risks of food allergy and celiac disease – to Specific Consumers

- Risks for consumers & companies
- Risk Management by consumers, companies & regulators

Details: ([An overview of a 2 day workshop](#))

- IgE mediated allergy & celiac disease (CD)
- Clinical Manifestations
- Prevalence, Natural History
- Thresholds
- Allergen management – Food Companies
- Labeling
- Detection
- [GOAL improvements for Indian consumers & exports](#)

# FARRP Workshop types – 2013 hopefully one - 2 day in India <http://farrp.unl.edu/home>

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## Food Allergens: Issues and Solutions for the Food Product Manufacturer

Two-day Workshop

Provides a foundation for understanding and controlling Allergens in the plant

Course Highlights:

- Scientific aspects of food allergies

- Food allergies from the consumer's perspective

- Allergen recalls and labeling laws

- Industry issues and solutions

- Strategies for allergen control

## Food Allergen Sanitation

One-day Workshop

Provides details on using an Allergen Control Program

Course Highlights

- Scientific Aspects of Food Allergies

- Food Industry Challenges

- HACCP and SSOPs in Allergen Control

- Industry Case Studies and Solutions

# Food Safety Assessment

RELATIVE SAFETY – All foods pose some risks

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## History of Safe Use and Adaptation

- ❑ **Wheat** must be avoided by those with **celiac disease** ~ 1% of the population in most countries
- ❑ **Allergic individuals (IgE mediated allergy)** must avoid consuming **their allergen-specific food** (1-6% of people)
- ❑ Most **legumes** must be **cooked to inactivate lectins and protease and amylase inhibitors**

## Our food uses are changing and we need to adapt

- Packaged Foods
- Restaurants
- More Diverse Foods



# Food Allergy (FA) and Celiac Disease (CD) – Growing Concerns & Perceived Risks

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- **Consumers - challenges**
  - Increasing prevalence of food allergy, some over-diagnosis
  - Some individuals with severe – life threatening, life-long risks
  - Complex foods, multiple sources
  - Unclear labeling, news reports & misinformation
- **Food Producers – challenges**
  - Liability, regulations, recalls
  - Labeling, sourcing, value added product competition
  - International trade
- **Regulators - challenges**
  - Consumer pressure
  - Uncertain scientific methods for risk evaluation
  - Complex detection issues
  - International trade - complexity
  - Large / small producers, restaurants, packaged foods

# Improving Allergen (FA) and Gluten (CD) Control requires Cooperation

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- Food Industry
- Governments
- Clinicians
- Food Scientists
- Allergic Consumers (usually through consumer education and help-groups)
- Testing Companies



# Confusion from Non-Immunological Adverse Reactions – that mimic food allergy

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## Toxic / Pharmacologic

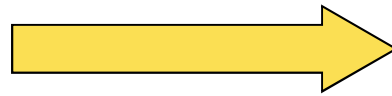
- **Bacterial food poisoning**
- **Scombroid fish poisoning** (tuna / mackerel & bacteria)
- **Histamine**
- Heavy metal poisoning
- Caffeine
- Alcohol

## Non-Toxic / Intolerance

- **Lactase deficiency and milk**
- Galactosemia
- Pancreatic insufficiency
- Gallbladder / liver disease
- Hiatal hernia
- Gustatory rhinitis
- Anorexia nervosa
- Idiosyncratic

# Immunological Adverse Food Reactions

IgE-Mediated allergy



Non-IgE Mediated  
Cell-Mediated

- **Systemic (Anaphylaxis)**
- **Oral Allergy Syndrome**
- **Immediate gastrointestinal allergy**
- **Asthma/rhinitis**
- **Urticaria**
- **Morbilliform rashes and flushing**
- **Contact urticaria**

**Mixed rxn**

- Eosinophilic esophagitis
- Eosinophilic gastritis
- Eosinophilic gastroenteritis
- Atopic dermatitis

- **Celiac Disease (food induced autoimmune disease)**
- Protein-Induced Enterocolitis (FPIES)
- Other Protein-Induced Enteropathy
- Eosinophilic proctitis
- Dermatitis herpetiformis
- Contact dermatitis



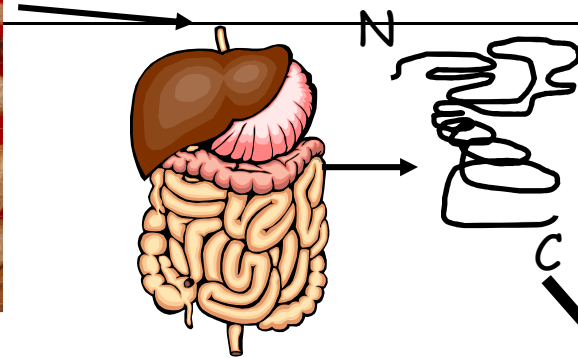
# Our Immune System

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- Has to differentiate between
  - Self and non-self
  - Food and symbiotic / beneficial microbes
  - Harmful bacteria, viruses, parasites (and cancers)
- Must be educated to be tolerant or to respond with immunity - memory
- Is imperfect, sometimes slow, but pretty good
- Genetics and environment interactions impact the outcomes

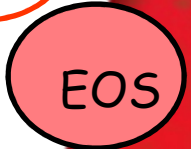
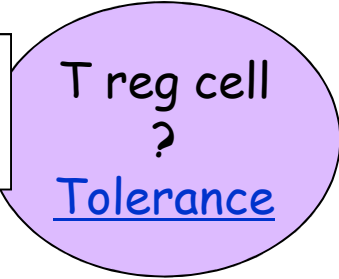
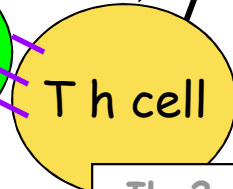
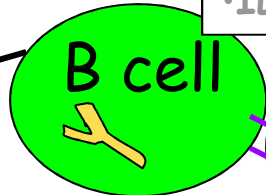
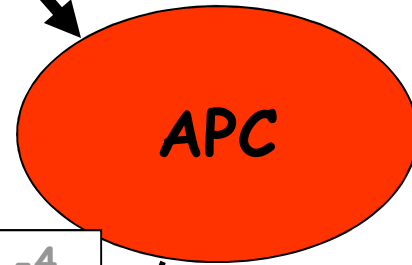
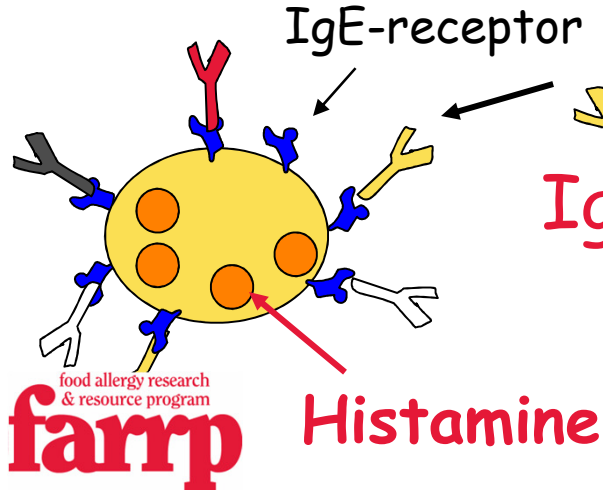


# IgE – allergy: Sensitization vs. Tolerance to foods



- Protein digestion
- Antigen (Ag) absorption
- Ag processing in DC, Mφ, B cells
- Ag presentation to T cells
- T cell and B cell memory

**Allergy**  
**Mast cell**



**Non-IgE-Mediated**

•IL-4  
•IL-13

•IFN $\gamma$   
•TNF- $\alpha$   
•IL-5

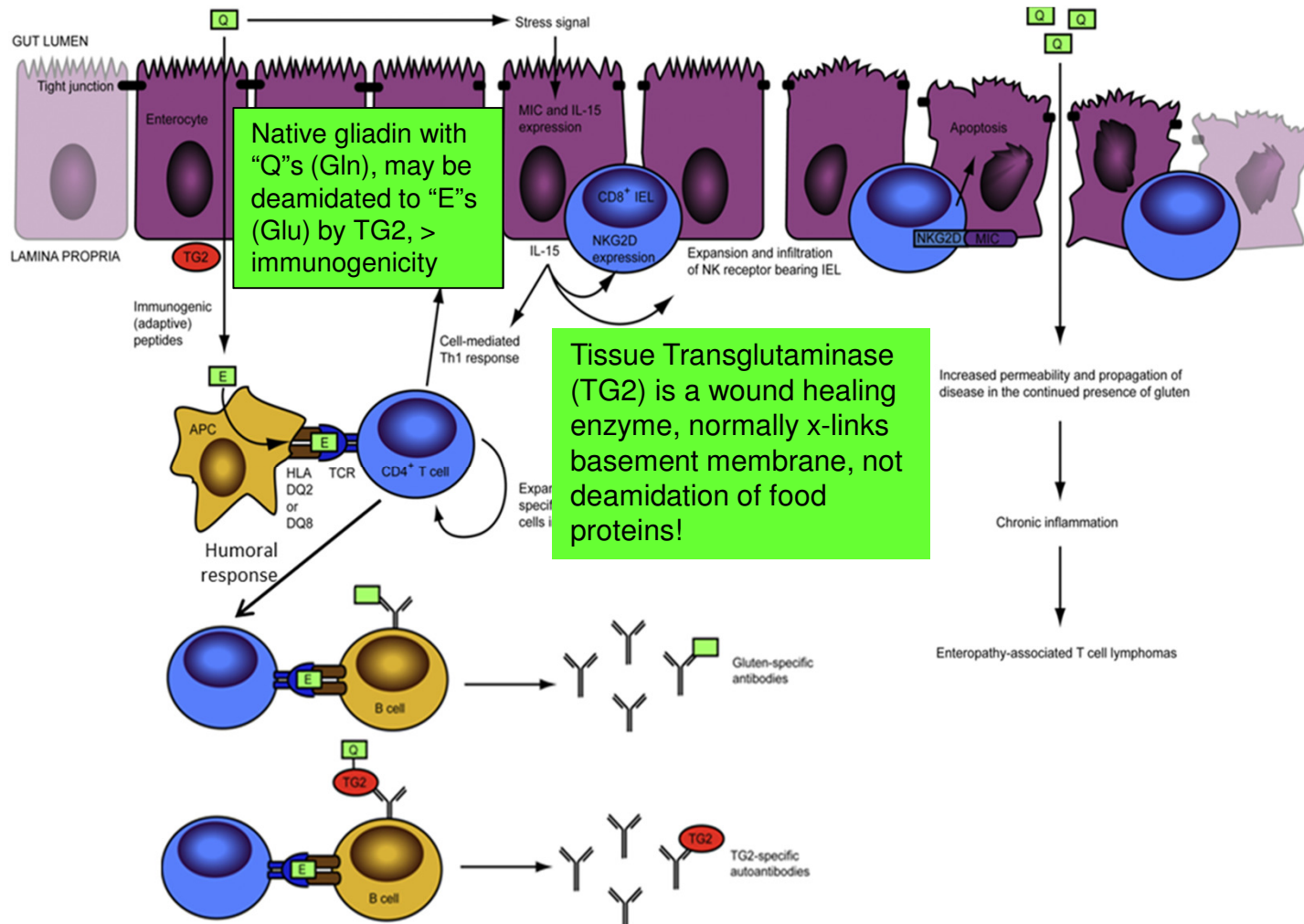
•IL-2  
or  
•TGFB

**IgE**

IgG  
or  
IgA

Tolerance

# Celiac Disease: T cell “allergy” to glutens of wheat - turns into Autoimmunity: Critical Genetic factor – MHC Class II, DQ 2.5 or DQ8



(Bethune and Khosla, 2008, PLOS Pathol)



# No Cures for Food Allergy or Celiac?

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Not in the near future.....therefore:

- AVOID the eliciting food....
- AVOID YOUR SPECIFIC Food ALLERGEN or GLUTEN...Always IF you are food allergic or have CD... in order to stay disease & symptom free!



# Celiac Disease (Sprue)

- Prevalence ~ 0.8% to 1.2% of people in the U.S. and India
- Genetics: at least one gene copy of one of two Major Histocompatibility Complex class 2 receptors (MHCII) HLA-DQ2.5 and HLA-DQ8 (>25% if all people, but 1% have celiac)....and other factors?
- Eliciting dose varies between CD patients
- Symptoms varied (body wasting, anemia, diarrhea, bone pain, etc.)
- Cereals with gluten: wheat, rye, barley, triticale, (and sometimes oats...possibly due to wheat contamination)....AVOID THESE

# Severe Case of CD from Dr. Ashok Gupta - Jaipur

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Vicky – 5 yrs. male

- Chronic Diarrhea
- Failure to thrive
- Rickets
- Multiple nutritional deficiencies
- Celiac Disease





## Celiac Disease with wheat gluten: variable effects

Almost normal small intestine, but eosinophils in tips of villi, mild inflammation



Severe celiac inflammation, flattened villi, malabsorption, wasting disease, autoimmune

# Foods celiac patients should avoid

Foods To Avoid		
wheat <ul style="list-style-type: none"> <li>including einkorn, emmer, spelt, kamut</li> <li>wheat starch, wheat bran, wheat germ, cracked wheat, hydrolyzed wheat protein</li> </ul>		barley rye triticale (a cross between wheat and rye)
Other Wheat Products		
bromated flour durum flour enriched flour farina	graham flour phosphated flour plain flour	self-rising flour semolina white flour
Processed Foods that May Contain Wheat, Barley, or Rye*		
bouillon cubes brown rice syrup candy chips/potato chips cold cuts, hot dogs, salami, sausage communion wafers	French fries gravy imitation fish matzo rice mixes sauces	seasoned tortilla chips self-basting turkey soups soy sauce vegetables in sauce

\* Most of these foods can be found gluten-free. When in doubt, check with the food manufacturer.

Source: Thompson T. *Celiac Disease Nutrition Guide*, 2nd ed. Chicago: American Dietetic Association; 2006. © American Dietetic Association. Adapted with permission. For a complete copy of the *Celiac*

Gluten:  
Gliadins  
and  
glutenins:

Specific  
peptides





# Gluten Testing: ELISA

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- “Gluten free” is the issue...ensuring and defining “free”
- Standard Canada, EU and maybe US = 20 ppm  
(20  $\mu\text{g}$  of gluten per g product)
  - Gluten is a complex collection of proteins...Therefore the 20 ppm Gluten is not an “absolute”
- Quantitative ELISAs by R-biopharm and Neogen both use R5, the new Romer kit uses anti-33mer peptide (G-12), Morinaga uses a total wheat assay
- Anti-gluten antibodies: n Ab: R5 antibody was made against peptide in Rye grain....on a mass basis 1 ppm of wheat gluten = 2.5 ppm of rye flour is 2, barley is less than 1, Einkorn, spelt and kamut are less
- There is not (yet) an international standard

# Gluten Free Starche alternatives Dr. Gupta

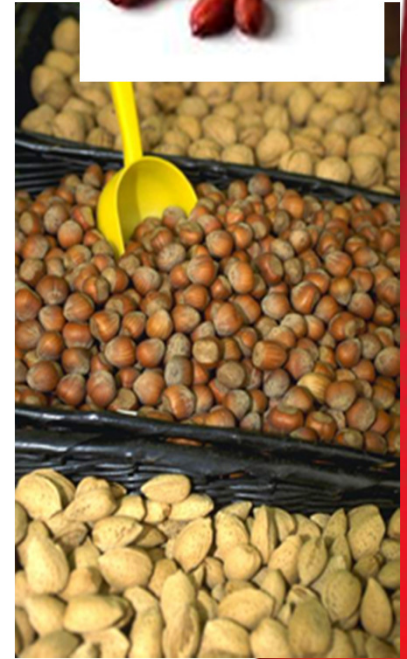
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- Rice
- Maize (corn)
- Sorghum (Jowar)
- Millet (Bajra)
- Amaranth
- Arrowroot
- Buckwheat
- Flax
- Oats (if pure), although some varieties??
- Potato
- Quinoa
- Tapioca
- Flours from nuts and beans



# IgE Mediated Food Allergy Sources

...but many foods are processed



# Soybeans are in many different foods in vastly different concentrations, amounts and forms....food processing

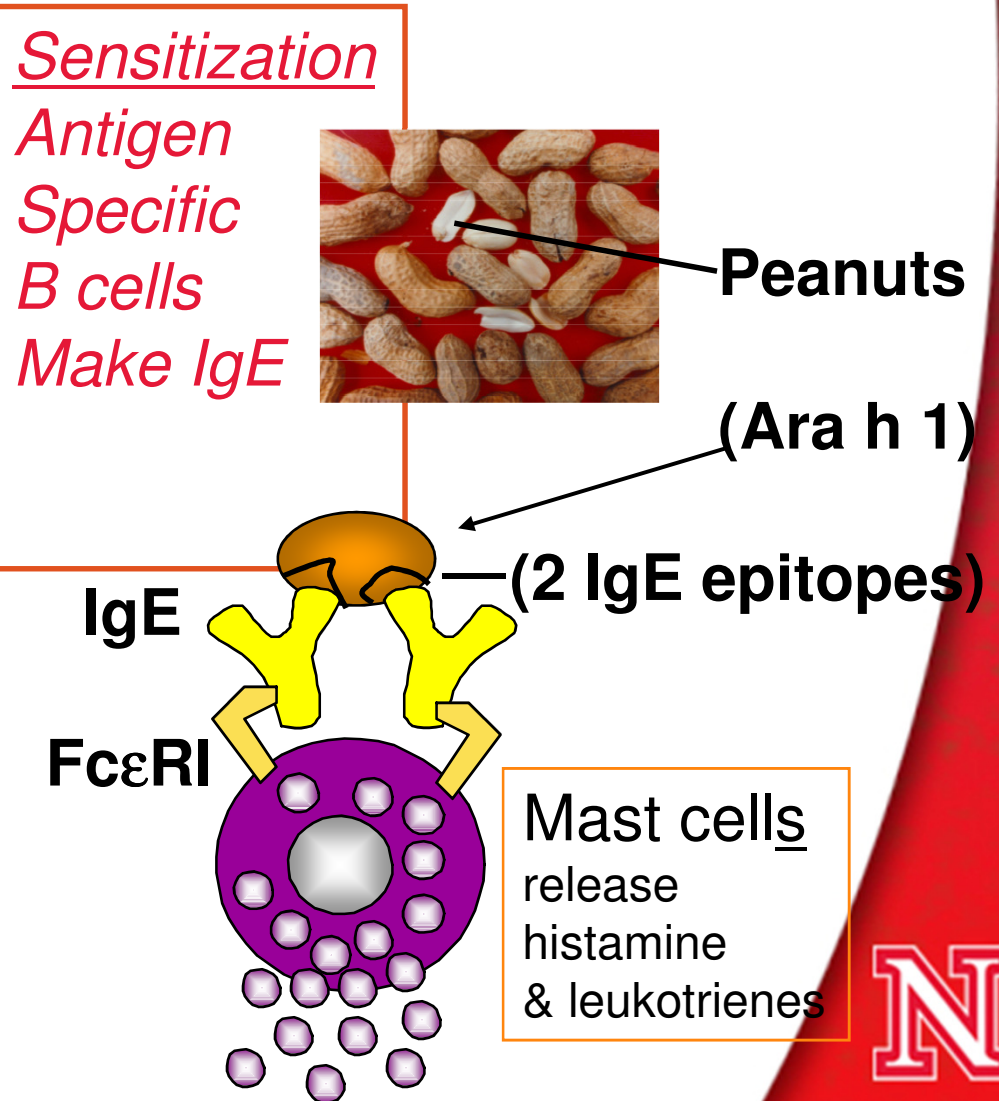


# Elicitation: Protein-specific IgE is the key mediator of specificity in Food Allergy

## IgE Mediated Symptoms

10 to 20 minutes after eating:

- hives
- angioedema
- asthma
- diarrhea/vomiting
- atopic dermatitis
- anaphylaxis



# What is IgE mediated food allergy – symptoms – can be quite severe



Angioedema  
Asthma  
Hives  
Vomit  
Diarrhea  
Hypotension



Sometimes  
mixed IgE, T-  
cell and  
eosinophil  
reactions



## Anaphylaxis... 15 minutes

→  
During a food  
challenge.  
Some risk



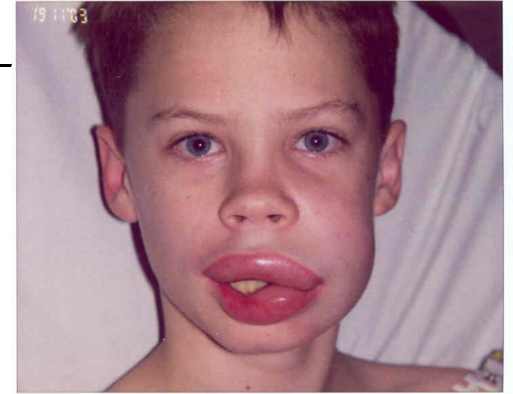
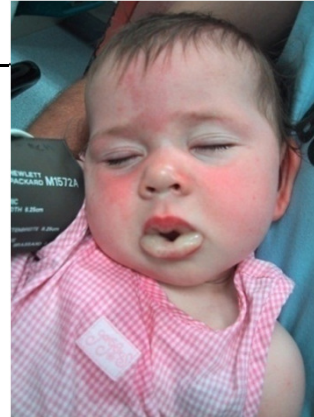
She did recover:  
Epinephrine, IV  
Other support  
Clear anaphylaxis

Could have died if  
this was not in the  
clinic

# Diagnosis of Food Allergies – often complex

## In Vivo

- Clinical history
- Elimination diet
- Skin Prick test can over-predict
  - Extract of food
  - Fresh food prick-prick
- Food challenge under appropriate CLINICAL conditions
  - Controlled setting
  - Open or blinded
  - Be PREPARED for anaphylaxis



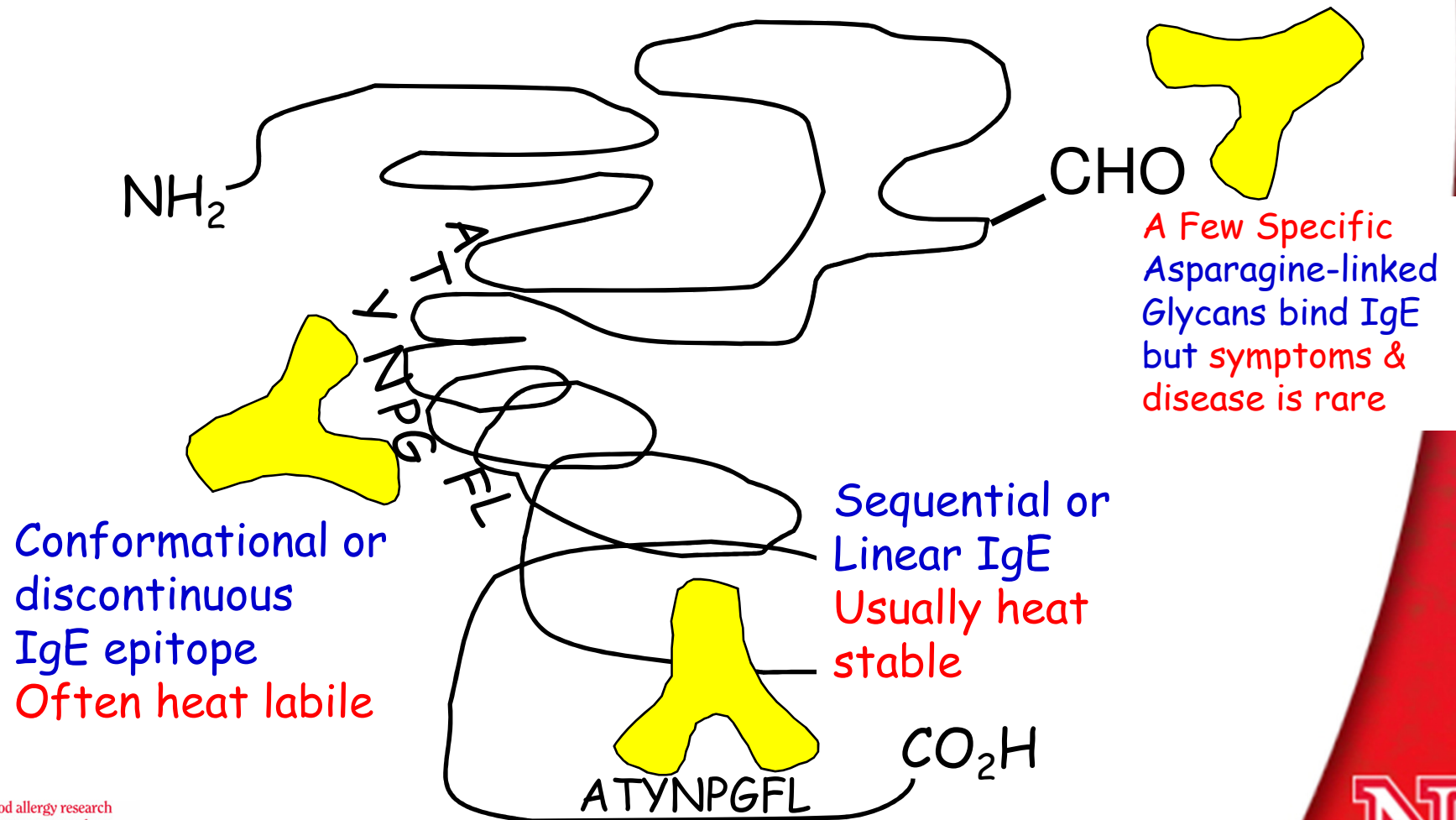
## In Vitro:

Specific IgE, useful but often over-predict & occasionally under-predicts



# Potential IgE Antibody Binding Epitopes:

Peptides - amino acids fixed in spatial arrangement – rarely to N-linked carbohydrate



# Natural History of IgE mediated Food Allergy



- Depends on food & person
- ~ 85% of cases of IgE mediated cow milk, soy, egg and wheat allergy remit by age 3 yrs
- **Non-IgE-mediated GI allergy**
  - Infant forms resolve in 1-3 years
  - Toddler / adult forms more persistent
- **FATAL reactions < 200 / year US (IgE mediated)**
  - Most Asthma + Food Allergy
  - Nearly 100% knew their allergen sensitivity
  - Hidden: in Restaurant > Home cooked-meal acquaintance > Packaged food
  - Peanuts > Tree nuts (together 90%) > Fish / shellfish > milk

Most did not use Epinephrine immediately

# Food Allergy Prevalence

(apparently increasing estimates from US population of 300 million)

- ❖ ~ 30% of people have allergies to inhaled allergens
- ❖ IgE mediated allergies (Type I) is the most common type
- ❖ Occurrence of **food allergy** in the US and Europe
  - ❖ 2-4% of adults
  - ❖ 4-8% of young children
  - ❖ Severe reactions relatively rare (U.S. estimates: ~120,000 Emergency Room visits, < 200 fatal reactions /year)
- ❖ Eight foods account for ~ 90% of food allergies & even minor ingredients require labels (US), 14 EU...some countries do not label:

Peanuts	Milk	(Wheat?)
Eggs	Fish	(Soybeans?)
Crustaceans	Tree nuts	

The EU adds lupine, celery root; mustard and sesame seeds

India should ? add chickpea, blackgram, lentil, pigeon pea?

# Known Allergenic Proteins

## Very few proteins represent major risks

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- **Peanuts (Groundnuts)**
  - Probably ~ 50 to 80+ deaths per year in the U.S.
  - 3 to 5 major allergens, 5 to 7 minor allergens
  - Hundreds of dietary proteins in seeds
- **Soybeans**
  - < 1 fatal reaction per year in the U.S.
  - 3 to 5 moderate allergens
  - Hundreds of dietary proteins in seeds
- **Cow's milk**
  - Few published reports of fatal reactions (e.g. Macdougall, 2002)
  - Caseins and beta-lactoglobulin dominant allergens, also alpha lactalbumin, minor allergens IgG, serum albumin
- **Fish**
  - Few reports of fatal reactions, but strong reactions common
  - 1 major allergen (parvalbumin), 2 to 4 minor allergens

# Allergens Common in India: Observations

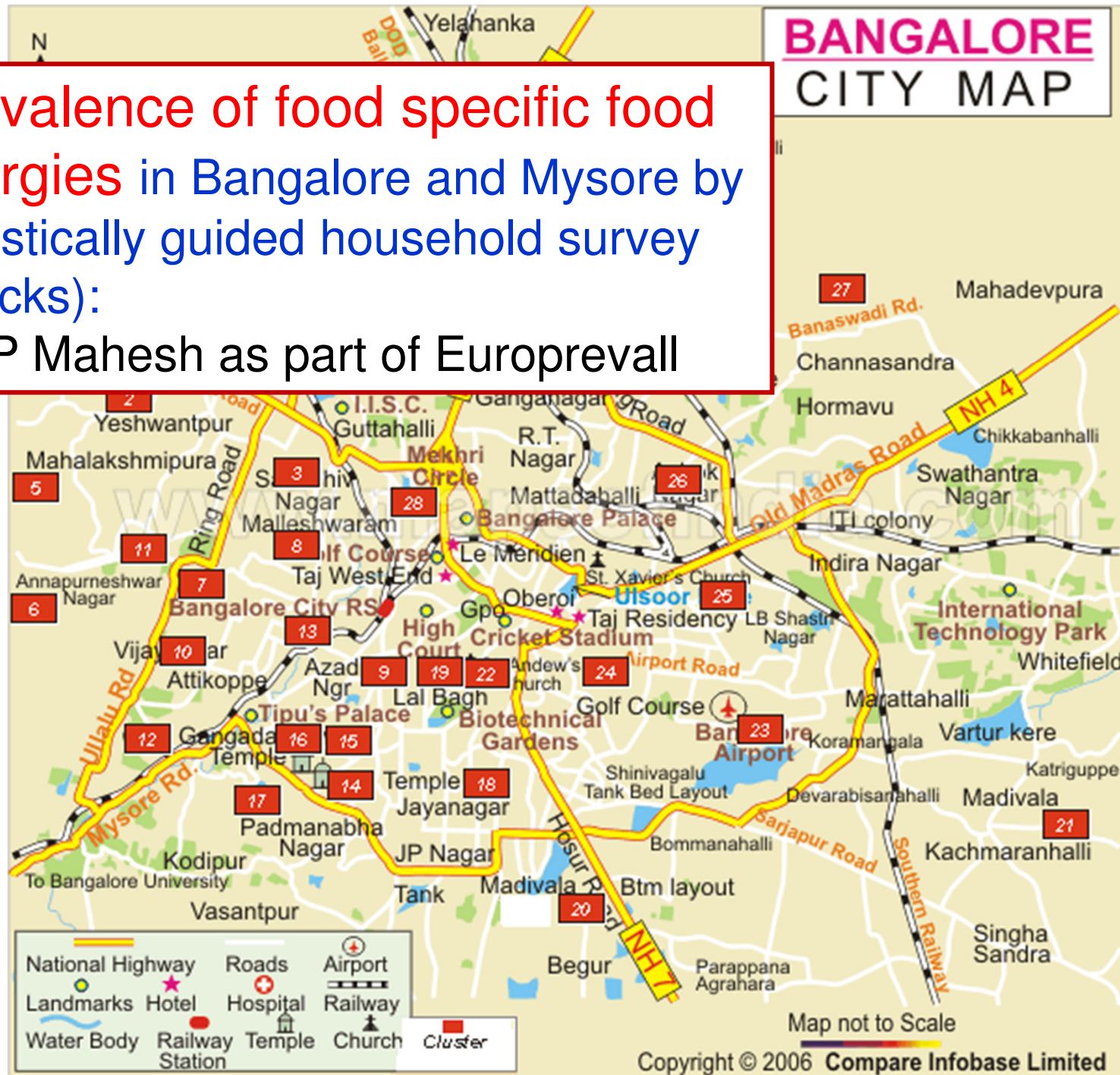
Dr. Ashok Gupta, Jaipur

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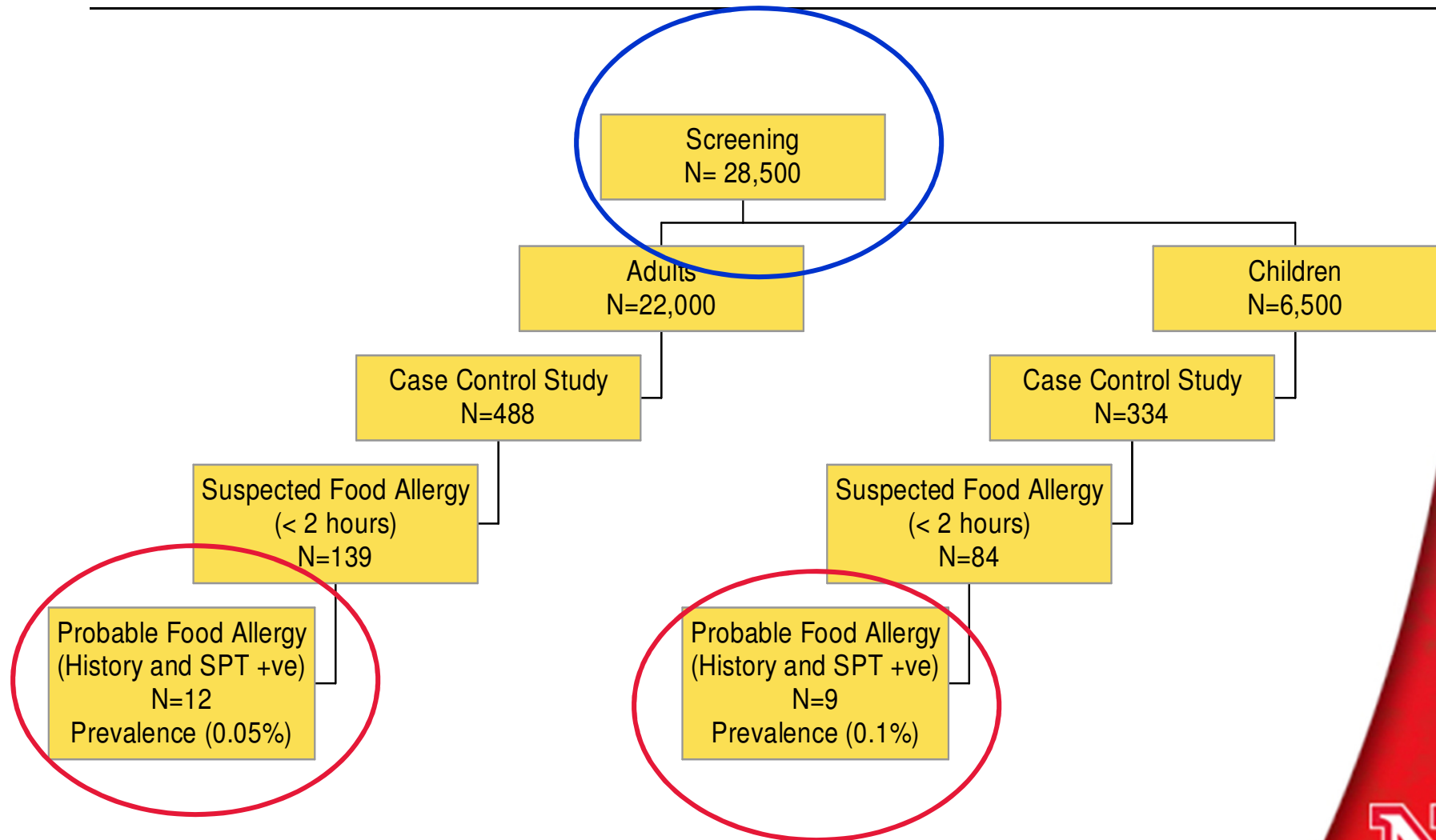
- Any food can be allergenic, but few commonly cause allergies
- Patterns of common allergens differ across regions and cultures
- Dairy, eggs, peanuts, tree nuts such as walnuts, almonds and cashews, fish, shellfish, soya, wheat, sesame top the list
- Incidence of allergies to milk, eggs and wheat less frequent than in the West
- Dals (pulses) such as chickpeas more common
- Allergy to rice has been reported - unusual



Prevalence of food specific food allergies in Bangalore and Mysore by statistically guided household survey (Blocks):  
Dr. P Mahesh as part of Europrevall



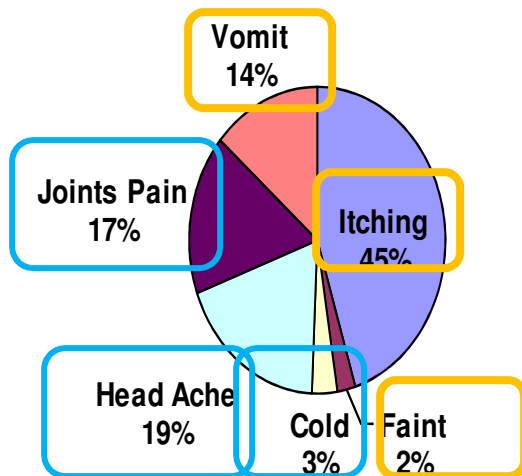
# Prevalence – survey of Food Allergy in India by Dr. Mahesh – Final # may be too low



# Symptoms scored as + Bangalore

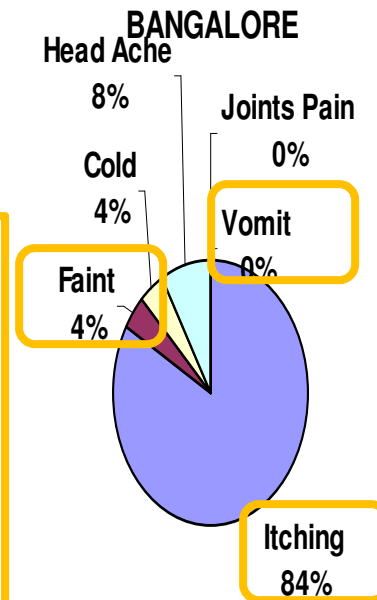
## Likely Over estimated by Q & A

CLINICAL PRESENTATION OF FOOD RELATED SYMPTOMS IN ADULTS IN BANGALORE



Unlikely to be allergy symptom

CLINICAL PRESENTATION OF FOOD RELATED SYMPTOMS IN CHILDREN IN BANGALORE



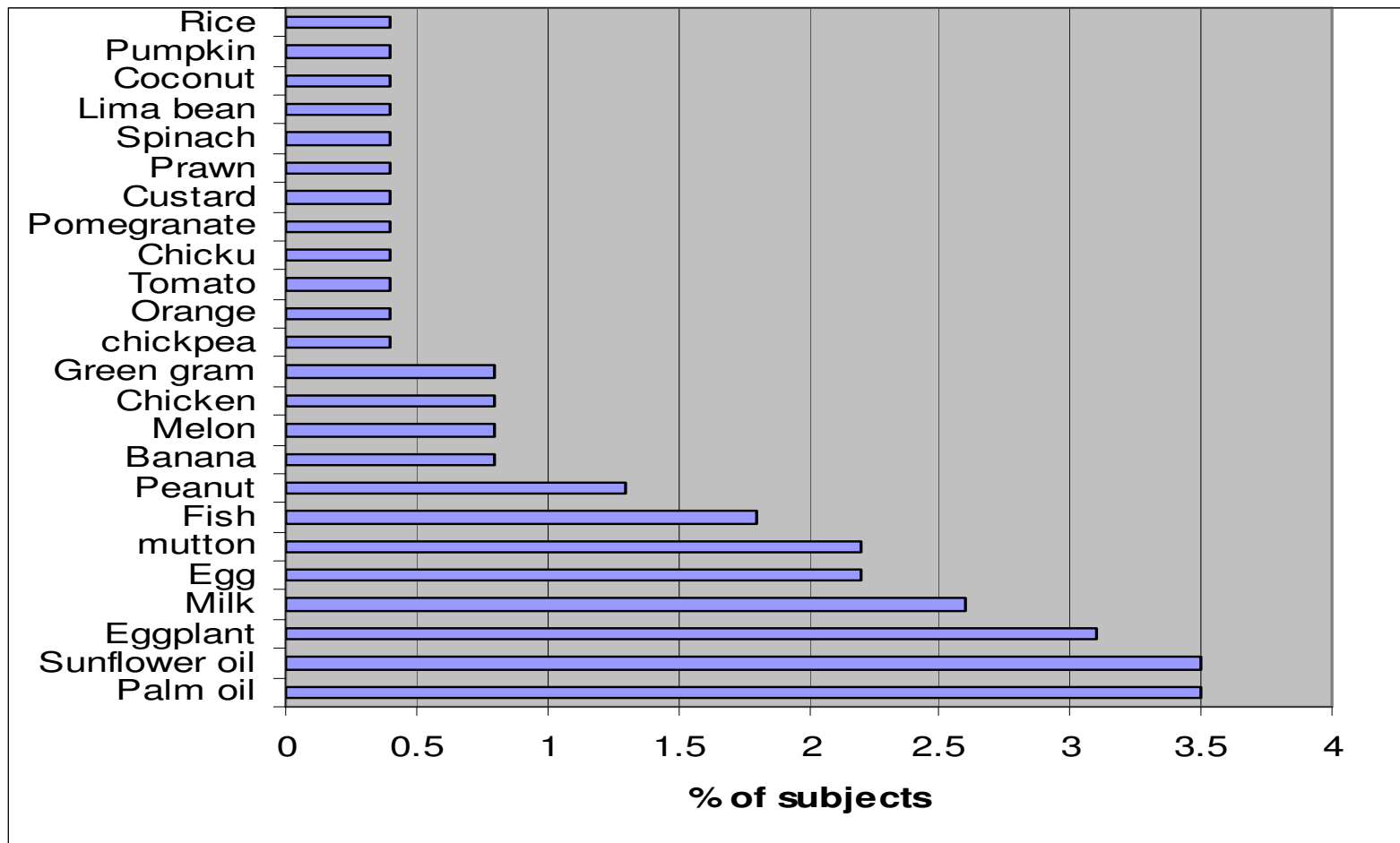
Might be symptoms of food allergic reactions:  
Faint ~ hypotension  
Vomit  
Itch ~ hives or urticaria  
But easily other cause / effects possible





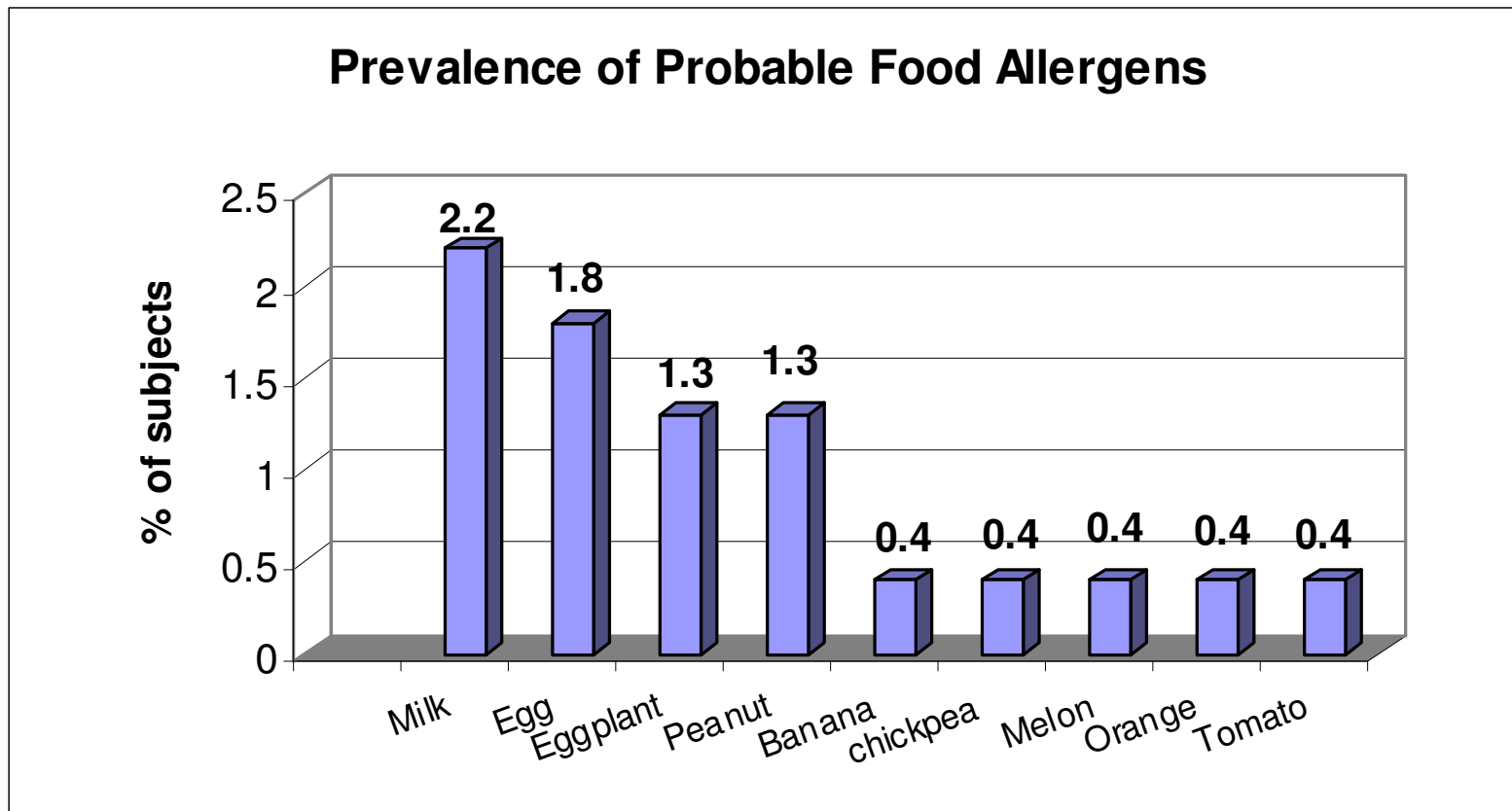
# Prevalence of “food allergens” reported based on history (< 2 hours after consumption):

A number of these, like Palm oil are not likely allergens!



# Prevalence of Probable Food Allergens

(n=223): (History & Skin Prick Test positive) Dr. Mahesh

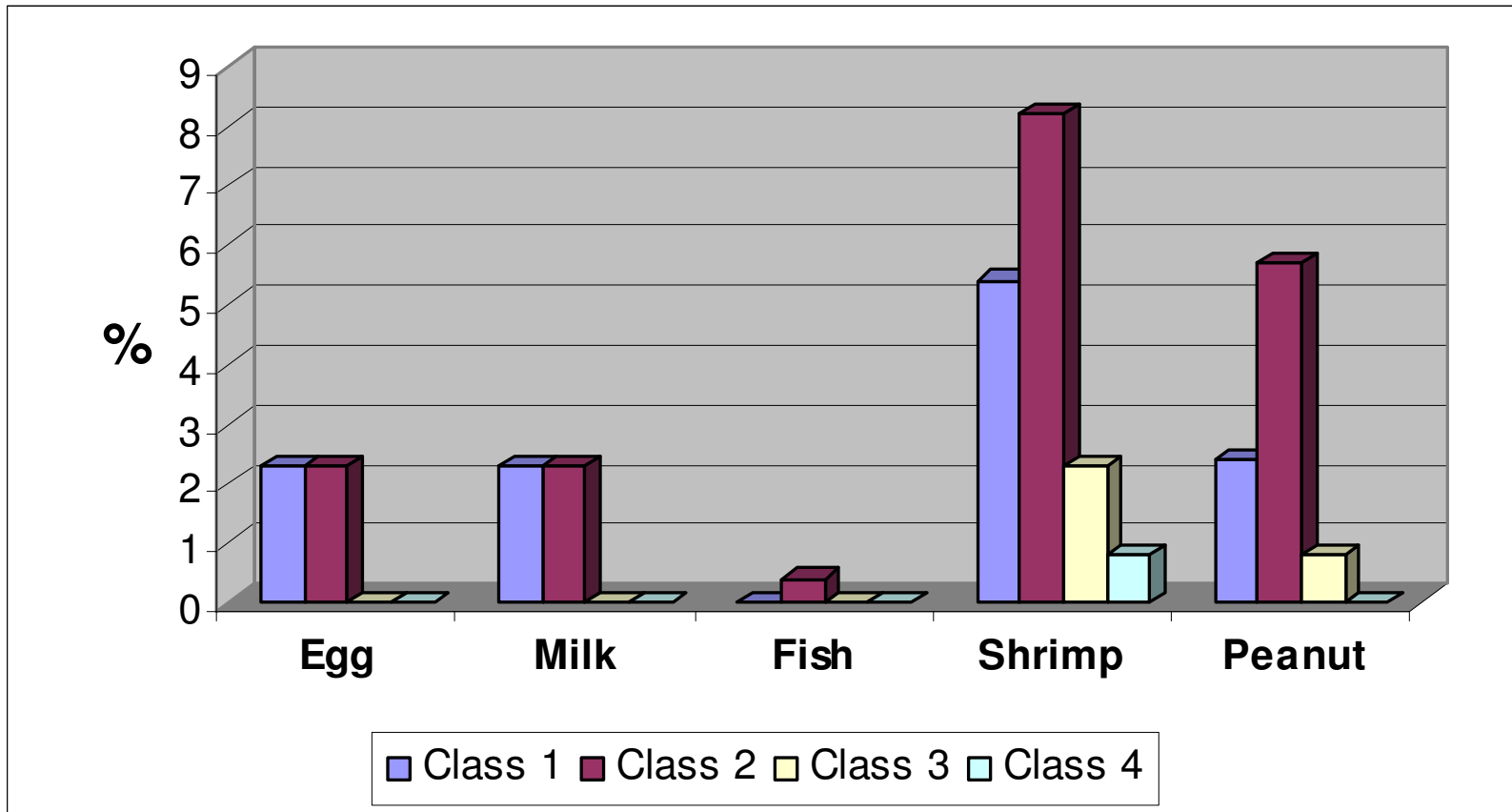


# Bangalore, Specific IgE ImmunoCAP®

## Specific IgE can help in diagnosis, but?

Dr. Mahesh

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# Observations food allergy India

Dr. Mahesh, MD

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- Prevalence of Food Allergy is very low in India
- Even in Case control studies, there is poor correlation between patient's history and sensitization patterns (SPT and IgE)
- Patients commonly consume foods they are sensitized to without symptoms of food allergy.



# Observations Food Allergy India

RE Goodman, PhD...second hand observations

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- Few Indian clinicians are trained in food allergy
- Pediatricians and pulmonary doctors see different types of patients and allergens
- Food allergy in India is < in US, most of EU, Korea and Japan
- However, similar types of foods are likely important food allergens
- As income rises and lifestyles change to “typical middle income” houses, foods, water and medicines, the relative prevalence of FA is increasing!
- Visitors to India including Indians from abroad, are coming with food allergies to ground nut and other common food allergies – they are at risk



## Allergens are OK in processed food if food is clearly labeled ...but

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- Intended ingredients, if not labeled put allergic consumers at risk
- Unintended contamination...is just as risky
  - Some are uniformly distributed (milk, wheat)
  - Some are in big chunks (peanut)...hard to detect and can present huge risk
  - Some present little risk (rare serious reactions, very low levels, highly heat labile)
  - Some present huge risks

# Labeling for Allergenic Foods

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- Whole ingredients must be labeled
- Processed ingredients (e.g. oils, lecithin) must be labeled as to source if from major allergenic foods (peanut (groundnut), soybean, fish, milk)
- WHAT LANGUAGE(S) or SYMBOLS WOULD WORK FOR INDIA?
- Use “May Contain” or other similar labeling strategies judiciously and ONLY in situations where contamination is
  - uncontrollable
  - sporadic
  - potentially hazardous
  - Maybe a common need currently for India?

**Cross-Reactions are common for some foods, mostly due to very closely related or sources, but also nearly identical proteins**

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Within a given food group:

**Crustaceans:** shrimp, crab, lobster, crawfish, krill

**Boney fish:** perch, bass, cod, haddock

**Legumes:** peanut, lupine, peas, soybeans; rare, but a few cases

**Pitted fruits:** peach, apricot, cherry

For some with unrelated foods:

Apples, cherry, soybean with birch pollen

Banana, kiwi, and chestnut with latex



# **Advisory Labeling** (“may contain, or packed on shared equipment”) **Update 2005**

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- Advisory labeling is increasingly used; 2005 FARRP study – 7% of all cookies have peanut as an ingredient, but 49% have advisory labelling for peanut
- Proliferation of labeling statement formats
- Different companies have different criteria for advisory labeling
- Many “may contain” foods have 5 ppm allergen, but some have 2,000 ppm
- How much IS too much?

# The science: Dose of Peanut Causing Reactions in Highly Sensitized Subjects

(Barbara Ballmer-Weber, MD)



0.2mg

0.4mg

1.0mg

5.0mg

25mg

100mg

400mg

↑  
OAS

↑  
emesis, urticaria, dyspnea

Hourihane et al. JACI 1997



# Current Situation

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- Public health authorities have not (yet) established regulatory thresholds for peanut or any allergens
- Only for gluten (for celiac disease)...20 ppm
- U.S. Food Allergen Labeling and Consumer Protection Act (FALCPA)
  - there is an “undefined” threshold ...any detect is considered bad)
- The safety concern is for **NON - LABELED allergen** ... which is appropriate
- And for food choices availability to allergic consumers....if everything says “may contain”

# FDA Threshold Working Group

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- Outlined 4 potential approaches :
  1. Analytical methods-based (Limit of Detection or LOQ = fixed) has been the norm
  2. Legal, arbitrary (Federal law...e.g. exemptions)
  3. Safety assessment-based: Based on Lowest Observed Adverse Effect Level for most potent allergen LOAEL (or NoOAEL)
  4. **Quantitative Risk assessment-based (Judged best, based on LOAEL or NOAEL, statistical dose response, statistics...difficult)**

*Journal of Food Protection, Vol. 71, No. 5, 2008,  
Pages 1043–1088*

# The FARRP Approach Thresholds and Risk

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- Mined individual NOAEL and LOAEL data from the existing published clinical literature for peanut thresholds

Taylor SL, Crevel RWR, Sheffield D, Kabourek J, Baumert J. 2009.

Threshold dose for peanut: risk characterization based upon published results from challenges of peanut-allergic individuals. Food Chem. Toxicol. 47:1198-1204.

- Also mined data from Dr. Moneret-Vautrin's clinical data (Nancy, France)

Taylor SL, Moneret-Vautrin DA, Crevel RWR, Sheffield D, Morisset M, Dumont P, Remington BC, Baumert JL. 2010. Threshold dose for peanut: risk characterization based upon diagnostic oral challenges of a series of 286 peanut-allergic individuals. Food Chem. Toxicol. 48:814-819.

- Key Collaborators: Unilever (Rene Crevel and David Sheffield); FARRP colleagues (Steve Taylor, Jamie Kabourek, and Ben Remington) and ILSI-North America



# Regulatory Action Level for Peanut...could be set like this?

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- Example – use the 95% lowest confidence interval on the  $ED_{05}$  – 3.6 mg of whole peanut
  - Could apply an extra (conservative) uncertainty factor of 10-fold (for most “sensitive consumers”..debatable). Yields action level of 0.36 mg of whole peanut
- 0.36 mg of peanut in a 50 g serving of food = 7.2 ppm
- Of the 450 individuals, only 0.87% would be predicted to react at 0.36 mg and all would be predicted to have very mild, transitory, objective reactions
- Experimental doses: The most sensitive reacted at 0.4 mg of peanut in the Nancy clinic; none reacted at 0.1 mg.

# Outcome of oral food challenges in children in relation to symptom-eliciting allergen dose and allergen-specific IgE

C. Rolinck-Werninghaus<sup>1</sup>, B. Niggemann<sup>1,2</sup>, L. Grabenhenrich<sup>3</sup>, U. Wahn<sup>1</sup> & K. Beyer<sup>1</sup>

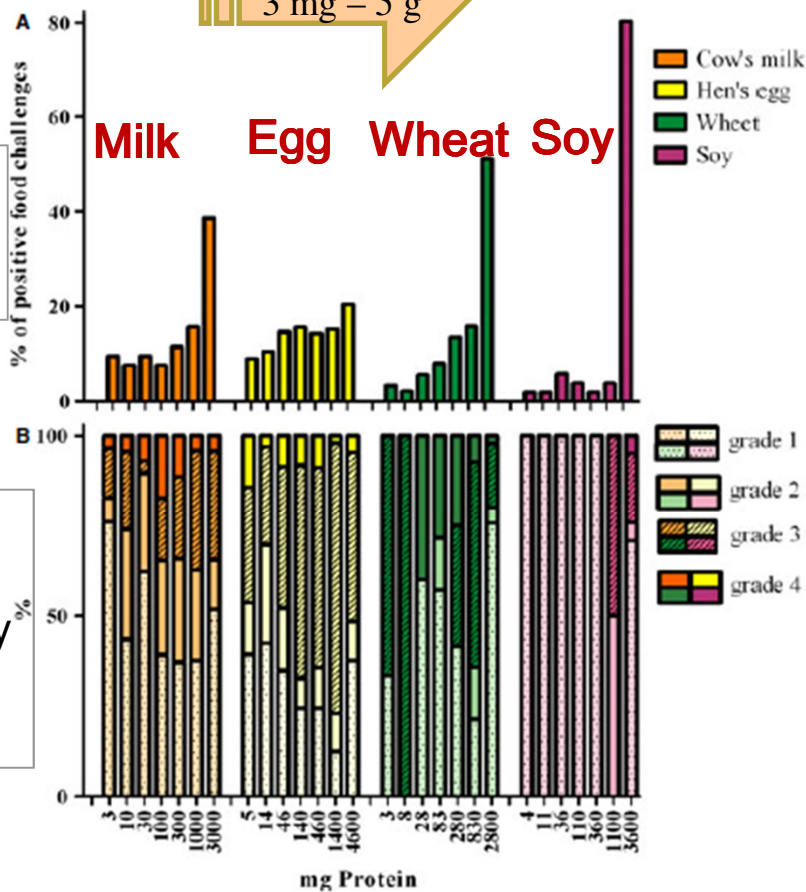
<sup>1</sup>Department of Pediatric Pneumology and Immunology, University Children's Hospital Charité of Humboldt University; <sup>2</sup>Pediatric Allergy and Pneumology, German Red Cross Hospital Westend; <sup>3</sup>Institute of Social Medicine, Epidemiology and Health Economics, Charité University Medical Centre, Berlin, Germany

To cite this article: Rolinck-Werninghaus C, Niggemann B, Grabenhenrich L, Wahn U, Beyer K. Outcome of oral food challenges in children in relation to symptom-eliciting allergen dose and allergen-specific IgE. *Journal of Allergy and Clinical Immunology* 2010;125:100-106.

Dose  
3 mg – 5 g

% Subjects Reacting At dose

% Subjects Reacting With severity Graded At dose



Quite similar patterns to peanut thresholds from an EU group for four allergenic foods

Figure 1 (A) Distribution of positive food challenges to seven allergen dose steps (approximately 3 mg to 5 g protein). (B) Distribution of severity of clinical reactions by dose steps.





# Management: Infant Formulas for Milk Allergic Infants

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- Cow's milk protein - extensive hydrolysates
  - >90% tolerance in IgE-Cow Milk Allergic infants
- Partial hydrolysates
  - Not hypoallergenic!
- Elemental amino acid-based formulas
  - Lack allergenicity

# US List of Allergenic Ingredients (and products thereof) – (black= that MUST be labeled (by species) under FALCPA

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- **Wheat**
- **Crustaceans**
- **Fish**
- **Peanuts**
- **Soybeans**
- **Milk**
- **Eggs**
- **Tree nuts (e.g. almonds, pecans, walnuts)**

By species is a problem....(in black)

How many commercial fish are correctly identified?

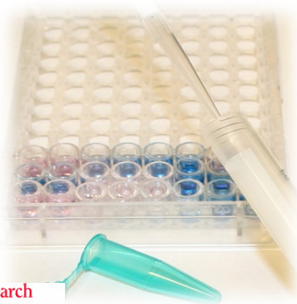
How many crustaceans?

How many tree nuts are really commonly allergenic?

# Detection of Allergenic Residues

- ELISAs are the preferred method for in the food industry
  - Specific – detects protein(s) from source; not always specific for allergenic protein
  - Available for many of the major allergens
  - Sensitive (low ppm limits of detection; 2.5 ppm)
  - Can be used in the plant for quick assessment (10 minutes -1 hour assay time)
- Quantitative and qualitative formats

Quantitative Microwell ELISAs



Qualitative Microwell ELISAs



Qualitative Lateral Flow ELISAs



# FARRP Confidential Analytical Testing: ELISAs

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## Fully Developed

- Peanut
- Milk
- Egg
- Processed Soy
- Soy Flour
- Almond
- Hazelnut
- Shrimp  
Tropomyosin
- Lupine
- Sesame
- Gluten/Gliadin  
(wheat, barley, rye)
- Buckwheat\*
- Walnut\*
- Mustard
- Clam\*
- Pecan\*
- Cashew\*

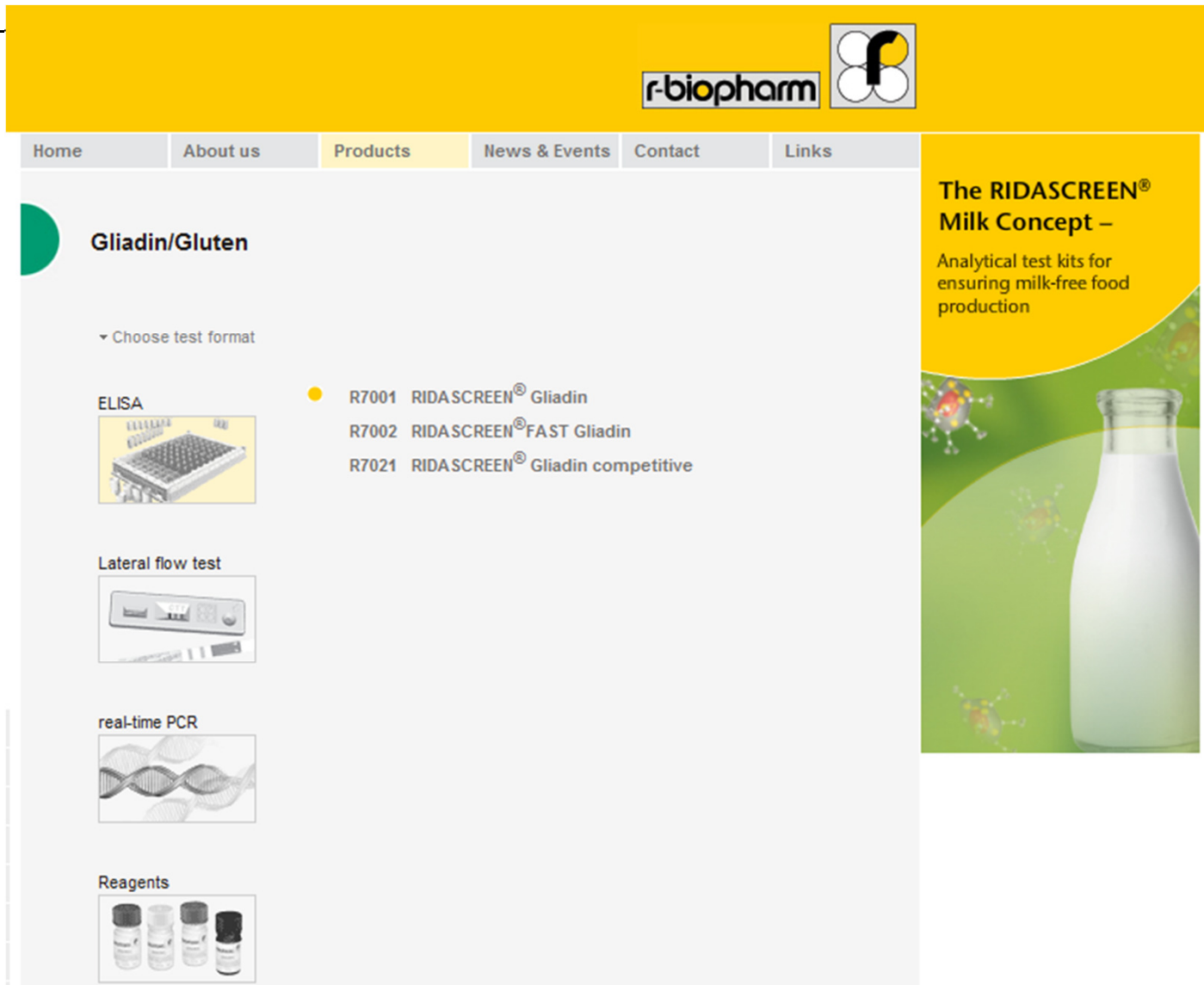
\*In-house ELISAs

## In Development

- Pistachio\*\*
- Fish

\*\*in use for analysis

# rBiopharm Allergen and Gluten tests available in India



The screenshot displays the rBiopharm website interface. At the top, the r-biopharm logo is visible. Below the logo is a navigation menu with the following items: Home, About us, Products, News & Events, Contact, and Links. The main content area is titled "Gliadin/Gluten" and features a dropdown menu labeled "Choose test format". Under this menu, four test formats are listed: ELISA, Lateral flow test, real-time PCR, and Reagents. The ELISA section is highlighted with a yellow dot and includes a list of three products: R7001 RIDASCREEN® Gliadin, R7002 RIDASCREEN® FAST Gliadin, and R7021 RIDASCREEN® Gliadin competitive. To the right of the main content area, there is a promotional banner for "The RIDASCREEN® Milk Concept – Analytical test kits for ensuring milk-free food production". The banner features a glass bottle of milk and a green background with molecular structures.

**r-biopharm**

Home About us **Products** News & Events Contact Links

## Gliadin/Gluten

▼ Choose test format

**ELISA**

- R7001 RIDASCREEN® Gliadin
- R7002 RIDASCREEN® FAST Gliadin
- R7021 RIDASCREEN® Gliadin competitive

**Lateral flow test**

**real-time PCR**

**Reagents**

**The RIDASCREEN® Milk Concept –**  
Analytical test kits for ensuring milk-free food production



# NEOGEN Corporation Allergen and Gluten (India?)



HOME | FOOD SAFETY | ACUMEDIA | GENESEEK | ANIMAL SAFETY | LIFE SCIENCES | TOXICOLOGY

- Food Safety Home

---

- Acumedia
- Dehydrated Culture Media

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- Dairy Analysis ▶
- Drug Residues ▶
- Food Adulterations ▶
- Food Allergens ▶
- Foodborne Pathogens ▶
- General Microbiology ▶
- GMO ▶
- Natural Toxins ▶
- Pesticide Residues ▶
- Sanitation ▶
- Seafood Analysis ▶
- Species Identification ▶
- Plant Disease ▶
- Water & Liquid Microbial Testing ▶

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- Equipment & Software ▶

---

- Products By Industry ▶
- Industry Newsletters ▶

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- C of A Search
- Check Sample Program
- MSDS List
- Tradeshows

---

- ORDER

## Food Safety Food Allergen Testing

Neogen offers screening and quantitative food allergen test kits to detect **almond, egg, gliadin/gluten, hazelnut, lupine, casein, β-Lactoglobulin (BLG), total milk, mustard, peanut, sesame, crustacea, soy, and walnut** residues. Neogen's food allergen tests can detect the target allergen in ingredients, liquids, clean-in-place rinses, finished foods, and on environmental surfaces.



[Click here to view our Food Allergen Handbook](#)



Neogen's **Alert®** for food allergen kits are screening tests that compare up to 5 samples at a time against a known level of allergen. The tests provide visible results that clearly show whether a sample contains more or less of a food allergen than the control provided.



Neogen greatly expanded the number and variety of rapid food allergen test kits it offers with the **BioKits** food allergen test product line. The **BioKits** microwell assay test kits are available for the quantification of allergens in foods and environmental surfaces in the low parts per million level (ppm).



Neogen's **Reveal®** for food allergen kit is an easy-to-use and interpret **strip test** that screens samples for food allergen at 5 ppm in 10 minutes or less. If the test detects at least 5 ppm, two lines will form on the simple test device. The formation of only one line indicates a negative test result.



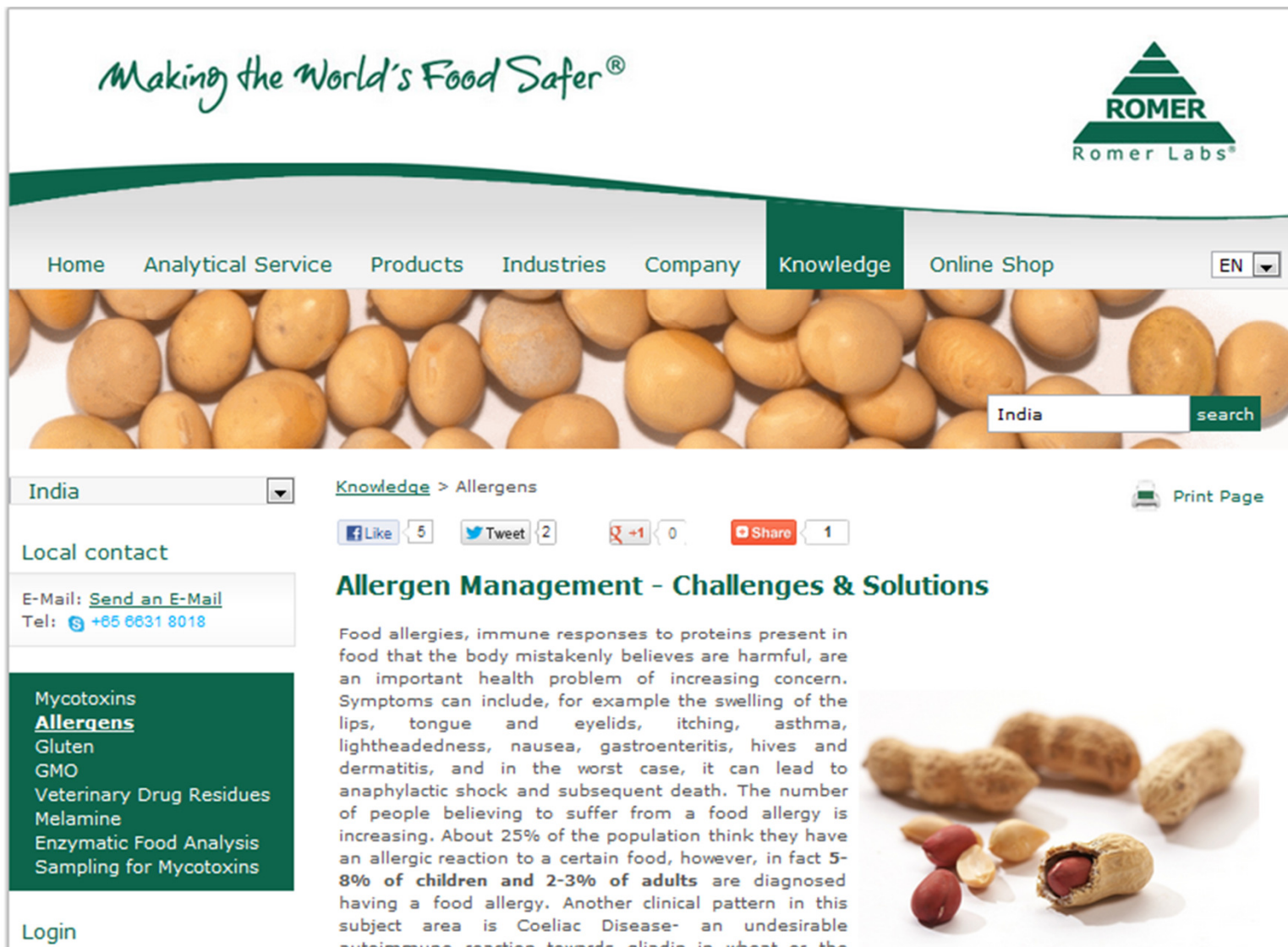
Neogen **Reveal 3-D** food allergen kits are easy-to-use and interpret strip tests that screen samples for the detection of trace levels of specific food allergens in 10 minutes or less. The unique **Reveal 3-D** tests allow for rapid screening for the presence of low levels of allergen in CIP rinses and environments swabs virtually anywhere. The ten **Reveal 3-D** allergen tests utilize a 3-line readout: a control line confirms the method has been performed successfully and two further lines differentiate low & high levels of detection.



Neogen's **Veratox®** for food allergen kits are quantitative tests that compare up to 19 samples at a time against 5 test controls. Through the use of a microwell reader, the tests provide accurate sample results in parts per million.



# RomerLabs Allergen and Gluten (India?)



*Making the World's Food Safer®*

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Romer Labs®

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India search

India

Local contact

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Tel: [+65 6631 8018](#)

Mycotoxins  
**Allergens**  
Gluten  
GMO  
Veterinary Drug Residues  
Melamine  
Enzymatic Food Analysis  
Sampling for Mycotoxins


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## Allergen Management - Challenges & Solutions

Food allergies, immune responses to proteins present in food that the body mistakenly believes are harmful, are an important health problem of increasing concern. Symptoms can include, for example the swelling of the lips, tongue and eyelids, itching, asthma, lightheadedness, nausea, gastroenteritis, hives and dermatitis, and in the worst case, it can lead to anaphylactic shock and subsequent death. The number of people believing to suffer from a food allergy is increasing. About 25% of the population think they have an allergic reaction to a certain food, however, in fact **5-8% of children and 2-3% of adults** are diagnosed having a food allergy. Another clinical pattern in this subject area is Coeliac Disease- an undesirable subimmune reaction towards gliadin in wheat or the



# Morinaga Allergen and Gluten kits (India?)



## Food Allergen Lateral Flow Kits

The innovative food allergen lateral flow kits, which can effectively detect allergen protein in both processed and unprocessed foods, have been developed. The kits are also suitable for production line examination by swab testing. The kits use an innovative new extraction solution to achieve a high recovery of the target allergen protein in both processed and unprocessed foods.

- Food Safety Kits
  - Food Allergen ELISA Kits
  - Food Allergen Lateral Flow Kits
  - Morinaga Acrylamide EIA Kit





# All ELISAs Are Not Created Equal

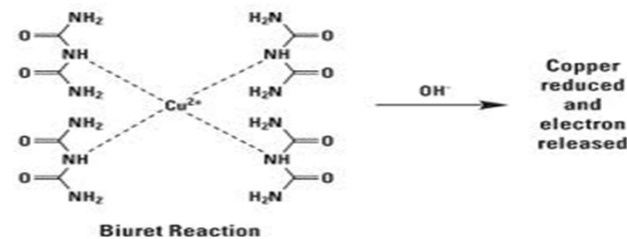
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- Specificity
- Sensitivity
- Format
- Quantitative vs. Qualitative
- Extraction buffer appropriate for matrix and proteins
- Standards
- Validation by company and in your lab

# General Protein Tests help in managing production line sanitation

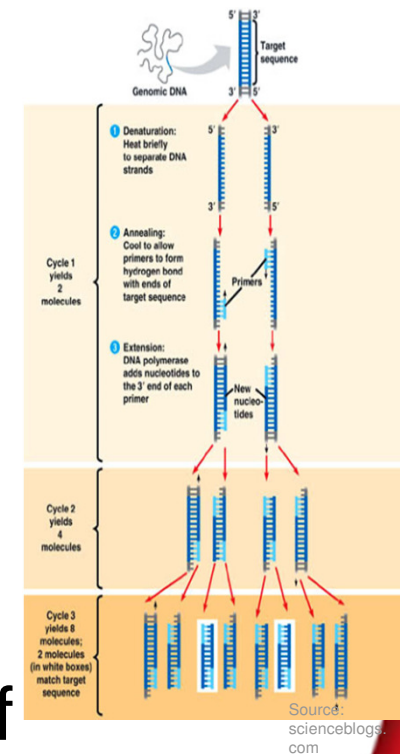
- 3M™ Clean-Trace™ Surface Protein
  - Swab method for detection of protein
  - Based on biuret/BCA reaction
- Detects protein regardless of source but not specific for allergenic source of protein
- Detection limits not low enough for allergen detection
  - limit of detection: 3-20 µg protein
- May not correlate to allergen

ELISAs



# PCR Methodology

- Specific – to the source but not to the allergenic proteins
- Sensitive (very)
- Semi-quantitative
- Depends on specific DNA primers
- Available for many allergenic food sources
- Rapid detection and can be adapted for multiple screens (e.g. detection of several tree nuts)



# Limitations of PCR

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- Foods that cannot be differentiated by PCR
  - Beef / milk
  - Egg / chicken
- DNA differentially distributed as compared to proteins
  - Ex. DNA in low abundance in milk, egg white, and in some protein concentrates and isolates
  - Protein levels are in high quantities in these products
  - Could give rise to false negative results
- Food matrix and processing can negatively impact the extraction and detection

# Picking the Best Test Method

## General Comments

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- Lateral flow allergen-specific antibody strips are usually specific and quick, but not quantitative
- Surrogate testing (protein, ATP) can be helpful in some cases
- ATP is not an allergenic protein
- Protein swabs measure general protein and not protein from the allergenic source
- PCR measures DNA and not protein

# Status of Allergen Testing in U.S.

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- Many companies are testing for allergen residues – in process
- ELISA or lateral flow-type immunoassays are the preferred methods
- Some do in-house testing, others use contract labs
- Most companies are not testing finished product except under unusual circumstances
  - Are testing to validate sanitation methods
    - environmental swabbing
    - push-through materials
  - Some testing of finished product advised after sanitation methods are validated

# FARRP Workshops – 2013 hopefully in India <http://farrp.unl.edu/home>

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## Food Allergens: Issues and Solutions for the Food Product Manufacturer

Two-day Workshop

Provides a foundation for understanding and controlling Allergens in the plant

Course Highlights:

- Scientific aspects of food allergies

- Food allergies from the consumer's perspective

- Allergen recalls and labeling laws

- Industry issues and solutions

- Strategies for allergen control

## Food Allergen Sanitation

One-day Workshop

Provides details on using an Allergen Control Program

Course Highlights

- Scientific Aspects of Food Allergies

- Food Industry Challenges

- HACCP and SSOPs in Allergen Control

- Industry Case Studies and Solutions

## Food Industry: Where Substantial Risks of Contamination Exist, Controls are Needed

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- Research and Development – what allergenic ingredients are necessary
- Engineering and System Design – easy clean-up, minimize waste and “missed” carry-over
- Raw Materials – Are supplies clean?  
Wheat in oats? Mustard in soy?  
Peanuts in spices?
- Labeling and Packaging



# Appropriate Actions to Protect the Consumer (and the company)

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- Dedicate lines for major allergens (ideal)
- Dedicated lines for “allergen” free (ideal)
- Clean sufficiently & consistently
- Some matrices (chocolate) are difficult to clean and difficult to test
- Segregate allergenic raw materials & products
- Clear labeling of bulk materials
- Avoid unnecessary use of common allergenic “micro-ingredients” (peanut flavoring)

# Food Company Purchasing Strategies

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- Maintain records on allergenic raw materials
- Segregate and label allergens as they come in the door
- Be careful about batch printing of labels
- Train suppliers
- Audit suppliers
- Test supplies if there is evidence or suspicion of possible mixing or contamination

# Potential Risks in Restaurants

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- Using same utensils/containers
- Using same frying oil (for fish and potato)
- Lack of restaurant labeling (big problem)
- Un-informed waiters / cooking staff
- “Creative” recipe formulation
- Table-side cooking
- Buffets....many allergic consumers should avoid!

# What proteins are allergens?

## Allergenonline Homepage version 12 (Feb 2012)

<http://www.allergenonline.org>

UNIVERSITY OF NEBRASKA-LINCOLN

UNL > AllergenOnline > Home

### AllergenOnline

Home of the farm allergen protein database.

Navigation

- Home
- About AllergenOnline
- Contact us
- Browse the Database
- Version History
- Sequence Search Allergen Database
- Search Algorithm Help
- Related Links

FAO Home

Celiac Disease Novel Protein Risk Assessment tool

**New trial**

Welcome to AllergenOnline.org

AllergenOnline provides access to a peer reviewed allergen list and sequence searchable database intended for the identification of proteins that may present a potential risk of allergenic cross-reactivity. This website was designed to help in assessing the safety of proteins that may be introduced into foods through genetic engineering or through food processing methods. The objective is to identify proteins that may require additional tests, such as serum IgE binding, basophil histamine release or in vivo challenge to evaluate potential cross-reactivity.

The database is updated annually. Version 4 was released on a public website in 2004. The database is freely accessible with the intent of providing a simple and useful tool that may be useful in food safety evaluations.

Features and Tools Available.

*Sequence search routines for food safety*

- We continue provide simple amino acid search routines to allow you to compare a protein sequence with the sequences in the current AllergenOnline database, which is updated on an annual basis. This is intended primarily for evaluating new proteins in Genetically Modified crops or in Novel Foods.
- Search for full-length alignments by FASTA:** The most predictive search is the overall FASTA alignment (see FASTA Help Page), with identity matches greater than 50% indicating possible cross-reactivity (Aalberse, 2000).
- Search for 80 amino acid alignments by FASTA:** A precautionary search using a sliding window of 80 amino acid segments of each protein to find identities greater than 35% (according to CODEX Alimentarius guidelines, 2003).
- Search for 8 amino acid exact match:** An 8-amino acid short-sequence identity search is provided since some regulatory authorities demand results of this extremely precautionary search. Our scientific opinion

Latest News:

New Version	
Version #	12
Peer Reviewed Sequences	1603
taxonomic-protein groups	603
Released On	Feb 7, 2012

