

# Safety of Genetically Modified Foods

**By:** Dr. Milad Rouhi  
& Azin Kolahdouz-Nasiri

***HEALTH RISKS***  
***ASSOCIATED***  
***WITH GM FOODS!***





**TOXIC EFFECTS**

**GENETICAL RISKS**

**ALLERGIC REACTIONS**





## Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize

Gilles-Eric Seralini<sup>a,\*</sup>, Emilie Clair<sup>a</sup>, Robin Mesnage<sup>a</sup>, Steeve Gress<sup>a</sup>, Nicolas Desbordes<sup>a</sup>, Manuela Malatesta<sup>b</sup>, Didier Hennequin<sup>c</sup>, Joël Spiroux de Vendômois<sup>a</sup>

<sup>a</sup> University of Caen, Institute of Biology, CRIGEN and Risk Pole, MISH-CNRS, EA 2608, Esplanade de la Paix, Caen Cedex 3, 14032, France

<sup>b</sup> University of Verona, Department of Neurological, Neuropsychological, Morphological and Motor Sciences, Verona 37139, Italy

<sup>c</sup> University of Caen, UR ABTE, EA 4651, Bd Maréchal Juin, Caen Cedex 14032, France

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### ABSTRACT

The health effects of a Roundup-tolerant genetically modified maize (from 11% in the diet), cultivated with or without Roundup, and Roundup alone (from 0.1 ppb in water), were studied 2 years in rats. In females, all treated groups died 2–3 times more than controls, and more rapidly. This difference was visible in 3 male groups fed GMO. All results were hormone and sex dependent, and the pathological profiles were comparable. Female developed large mammary tumors almost always more often than and before controls, the pituitary was the second most disabled organ; the sex hormonal balance was modified by GMO and Roundup treatments. In treated males, liver congestions and necrosis were 2.5–5.5 times higher. This pathology was confirmed by optic and transmission electron microscopy. Marked and severe kidney neoplasias were also generally 1.3–2.3 greater. Males presented 4 times more large palpable lesions than controls which occurred up to 600 days earlier. Biochemistry data confirmed very significant kidney chronic deficiencies; for all treatments and both sexes, 76% of the altered parameters were kidney related. These results can be explained by the non linear endocrine-disrupting effects of Roundup, but also by the overexpression of the transgene in the GMO and its metabolic consequences.

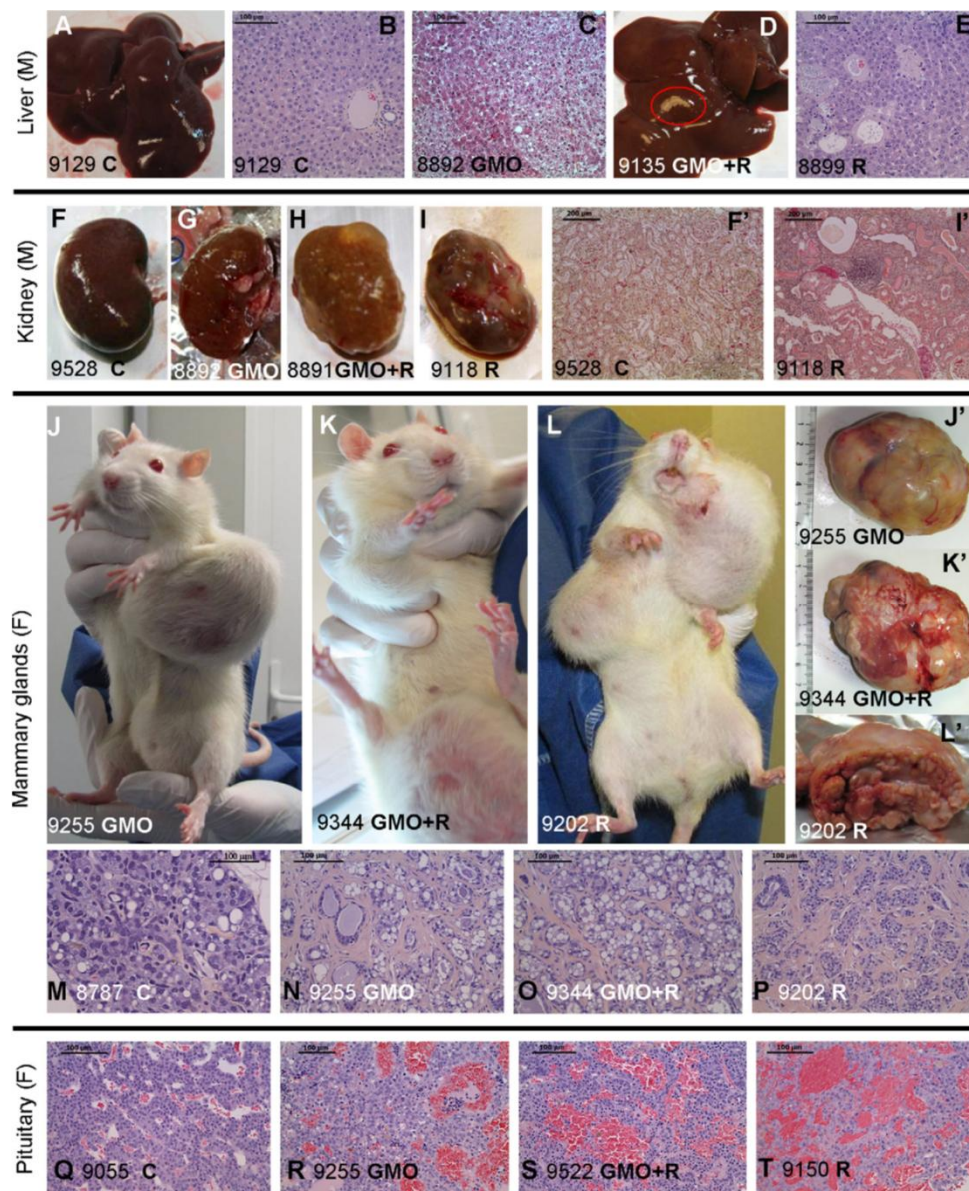
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### 1. Introduction

There is an ongoing international debate as to the necessary length of mammalian toxicity studies in relation to the consumption of genetically modified (GM) plants including regular metabolic analyses (Seralini et al., 2011). Currently, no regulatory authority requests mandatory chronic animal feeding studies to be performed for edible and formulated pesticides. However, several studies consisting of 90 day rat feeding trials have been conducted by the biotech industry. These investigations mostly concern GM soy and maize that are rendered either herbi-

cide tolerant (to Roundup (R) in 80% of cases), or engineered to produce a modified *Bt* toxin insecticide, or both. As a result these GM crops contain new pesticide residues for which new maximal residual levels (MRL) have been established in some countries.

If the petitioners conclude in general that there is no major change in genetically modified organism (GMO) subchronic toxicity studies (Domingo and Giné Bordonaba, 2011; Hammond et al., 2004, 2006a,b), significant disturbances have been found and may be interpreted differently (Seralini et al., 2009; Spiroux de Vendômois et al., 2010). Detailed analyses have revealed alterations in kidney and liver functions that may be the signs of early chronic diet intoxication, possibly explained at least in part by pesticide residues in the GM feed (Seralini et al., 2007; Spiroux de Vendômois et al., 2009). Indeed, it has been demonstrated that R concentrations in the range of  $10^3$  times below the MRL induced endocrine disturbances in human cells (Gasnier et al., 2009) and toxic effects thereafter (Benachour and Seralini, 2009), including *in vivo* (Romano et al., 2012). After several months of consumption of an R-tolerant soy, the liver and pancreas of mice were affected, as highlighted by disturbances in sub-nuclear structure (Malatesta et al., 2008a, 2002a,b). Furthermore, this toxic effect was reproduced by the application of R herbicide directly to hepatocytes in culture (Malatesta et al., 2008b).



Abbreviations: GM, genetically modified; R, Roundup; MRL, maximal residual levels; GMO, genetically modified organism; OECD, Organization for Economic Co-operation and Development; GT, glutamyl-transferase; PCA, principal component analysis; PLS, partial least-squares; OPLS, orthogonal partial least-squares; NIPALS, Nonlinear Iterative Partial Least Squares; OPLS-DA, Orthogonal Partial Least Squares Discriminant Analysis; G, glycogen; L, lipid droplet; N, nucleus; R, rough endoplasmic reticulum (on microscopy pictures only); U, urinary; UEx, excreted in urine during 24 h; APPT, Activated Partial Thromboplastin Time; MCV, Mean Corpuscular Volume; PT, Prothrombin Time; RBC, Red Blood Cells; ALT, alanine aminotransferase; MCHC, Mean Corpuscular Hemoglobin Concentration; A/G, Albumin/Globulin ratio; WBC, White Blood Cells; AST, aspartate aminotransferase.

\* Corresponding author. Tel.: +33 (0)231565684; fax: +33 (0)231565320.

E-mail address: [crigen@unicaen.fr](mailto:crigen@unicaen.fr) (G.-E. Seralini).

***RESISTANCE TO  
ANTIBIOTICS!***



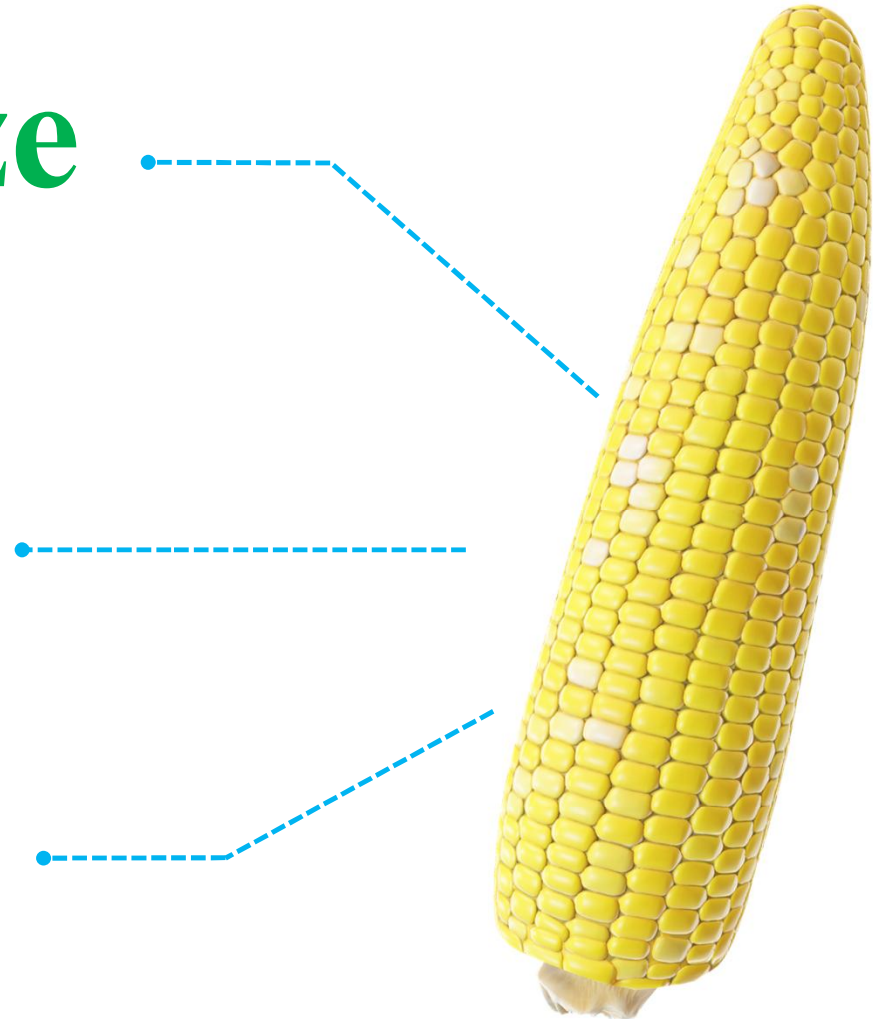
# Starlink maize



**The protein was Resistant to digestion**



**Did not cause any allergic reactions**





# Transgenic soybeans

Enriched in the amino acid methionine

The gene isolated from Brazil nuts



**2S albumin Brazil nut protein**



***ECOLOGICAL RISKS  
ASSOCIATED WITH  
GM FOOD!***





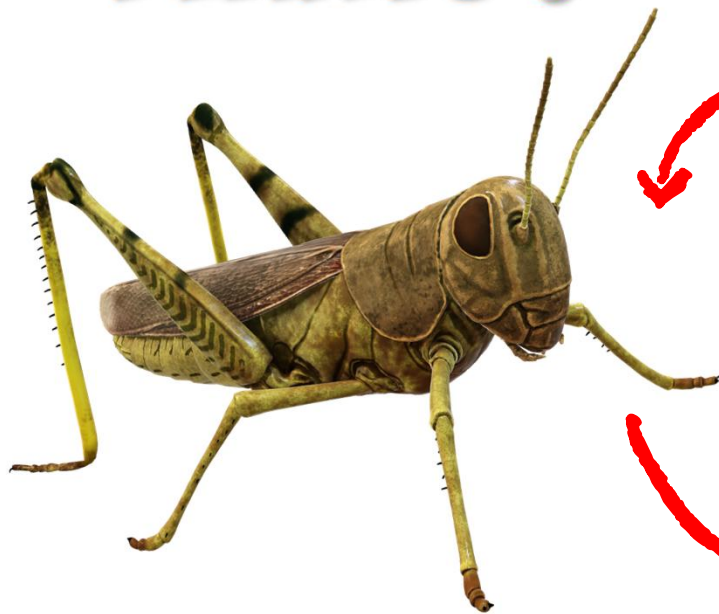


**AquAdvantage  
salmon**



**FIRST GM ANIMAL THAT  
RECEIVED FDA APPROVAL!**

# PEST RESISTANT PLANTS!

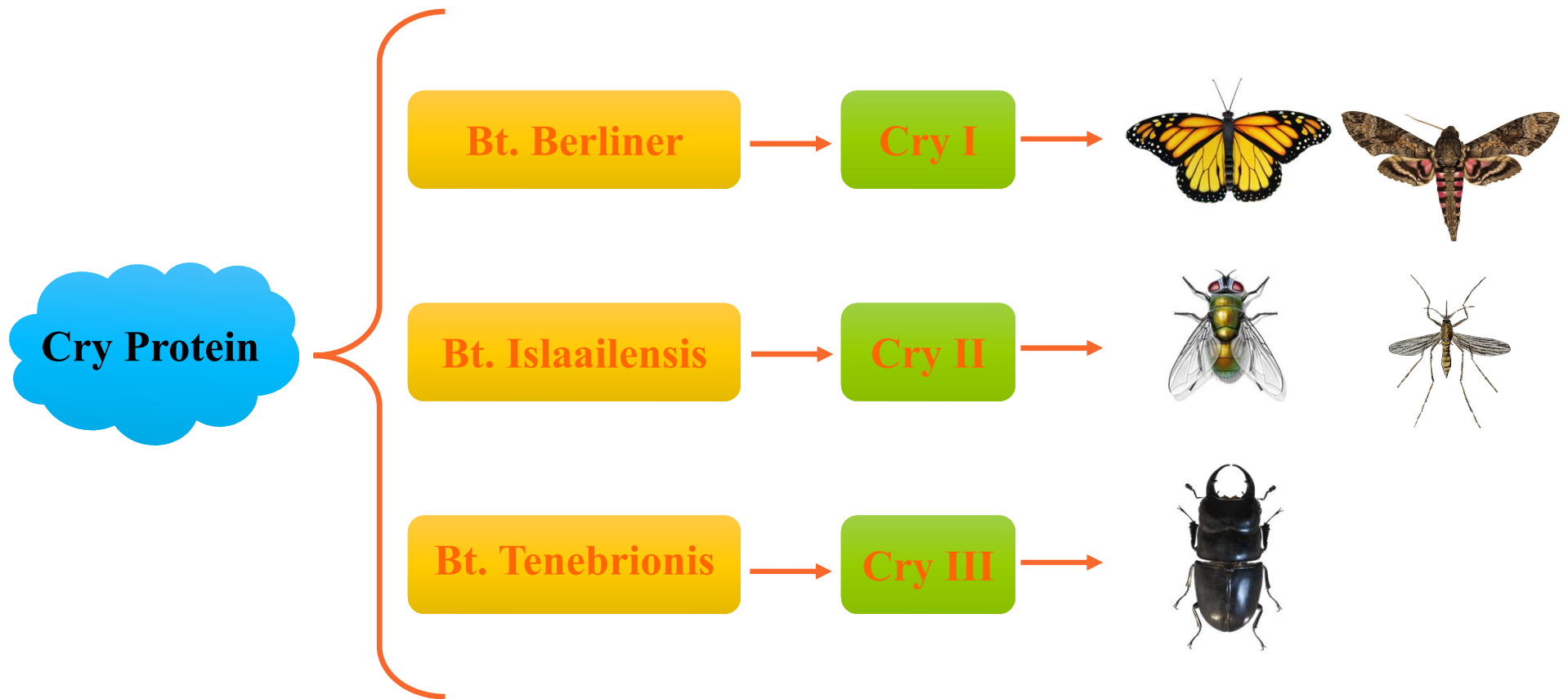


Cry Proteins

**Bacillus  
thuringiensis**

Endotoxin!



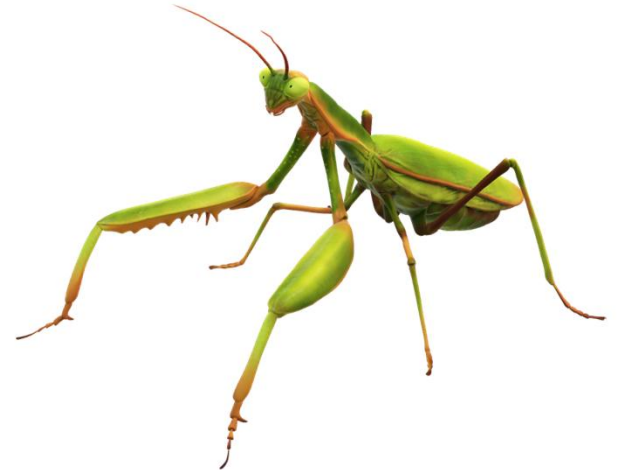




# **PEST RESISTANT PLANTS**



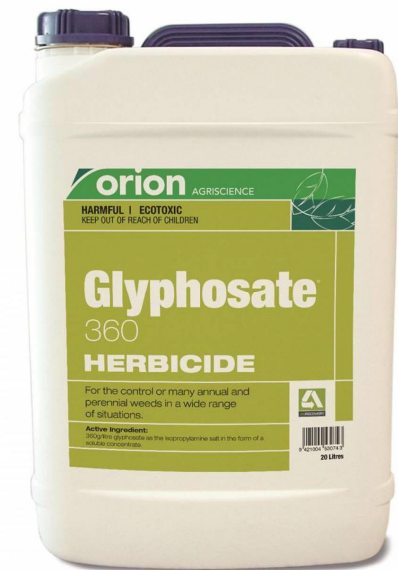
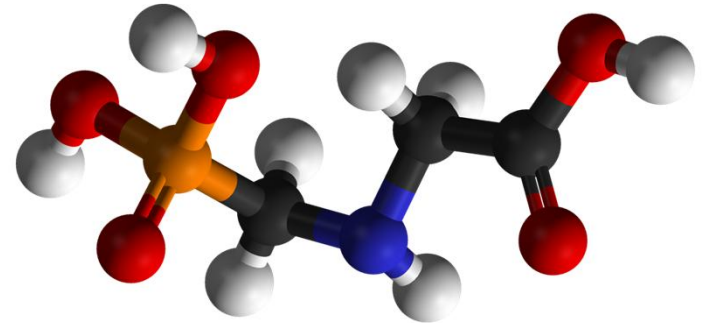
**NATURE *CHOOSES* THE  
MORE RESILIENT ONE !**





***DISRUPTION OF  
FOOD WEB ...***

**THE *USE OF*  
PESTICIDES WILL  
INCREASE!**





The moth *Helicoverpa zea*



**THIS PHENOMENON WAS  
SOLVED TEMPORARILY BY  
A STRATEGY NAMED  
"REFUGE" ✓**



# Safety Evaluation

# Screening



## FDA “Substantial Equivalence”

a new product must be the same as the non-genetically engineered crop except for the traits that were enhanced, added, or removed through genetic engineering.



## Safety Evaluation



**TOXICOLOGICAL  
STUDIES ?**

**YES !**

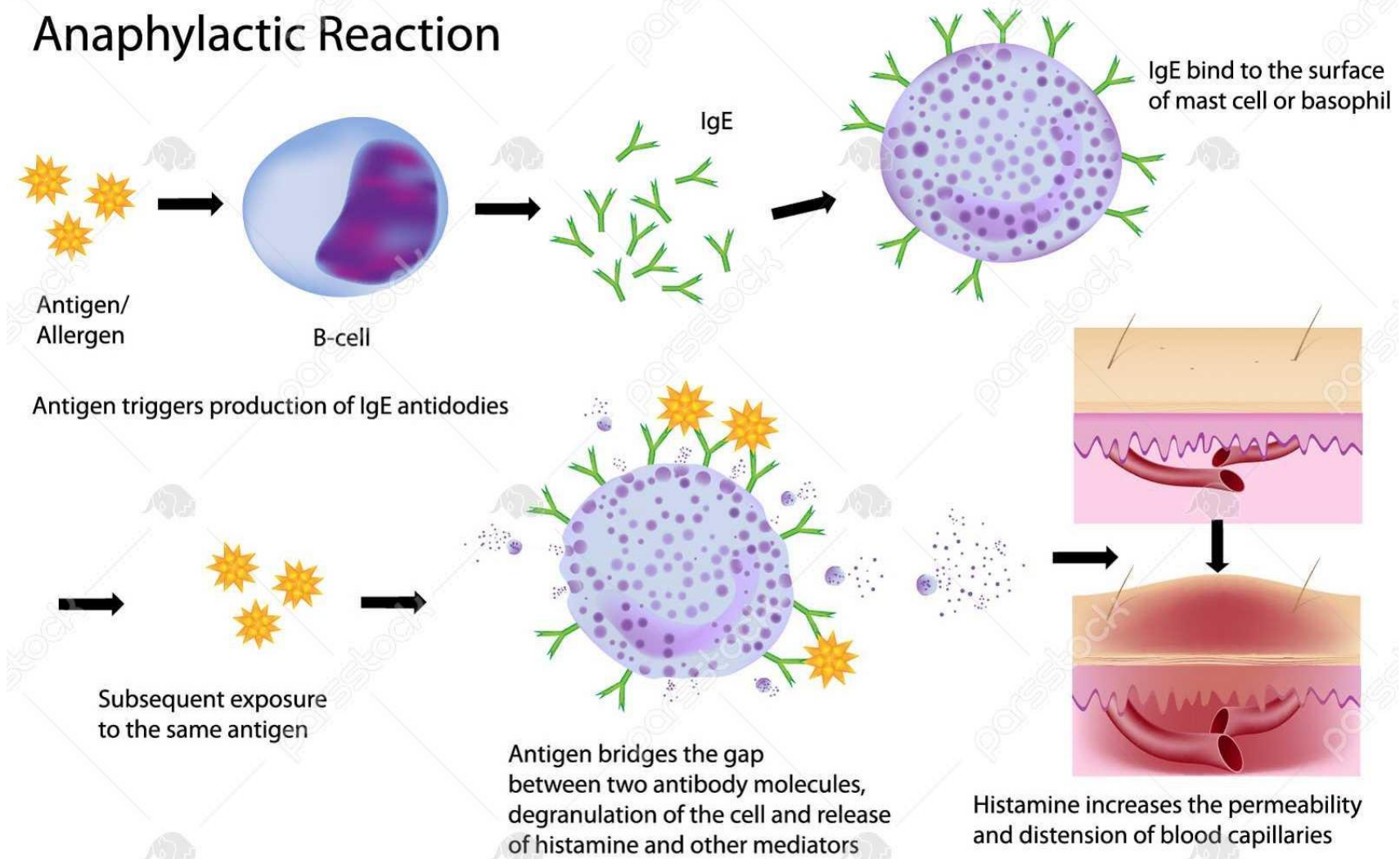
- Sub-chronic trial ✓
- Cohort studies ✓

**ASSESSING THE  
ALLERGENICITY  
OF GM FOODS!**



# Mechanism of Allergy

## Anaphylactic Reaction





# *IS SOURCE OF GENE* **ALLERGENIC?**



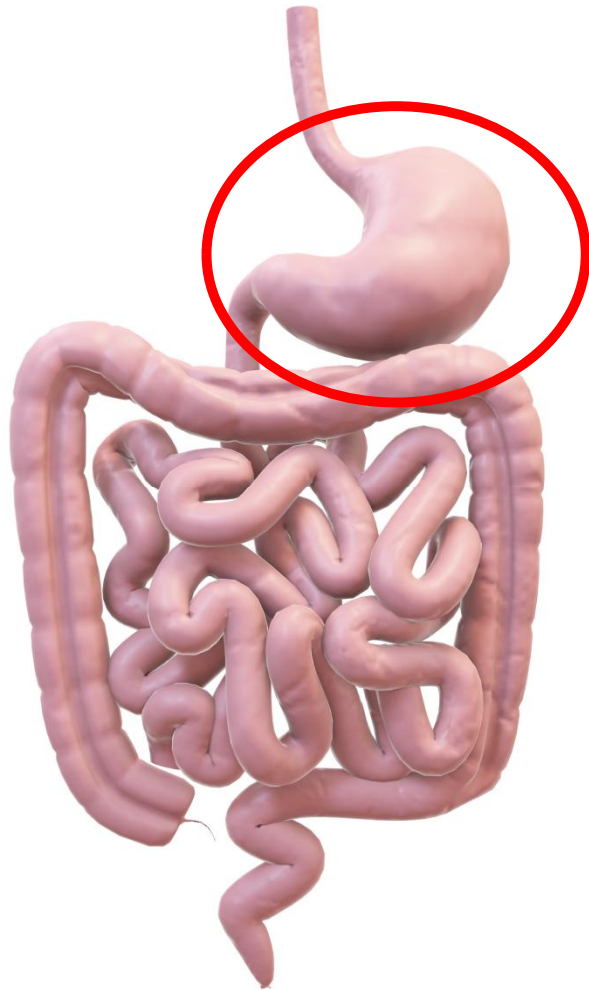
**EGG SOY BEAN WHEAT**  
**PEANUTS SHELLFISH**  
**FISH**



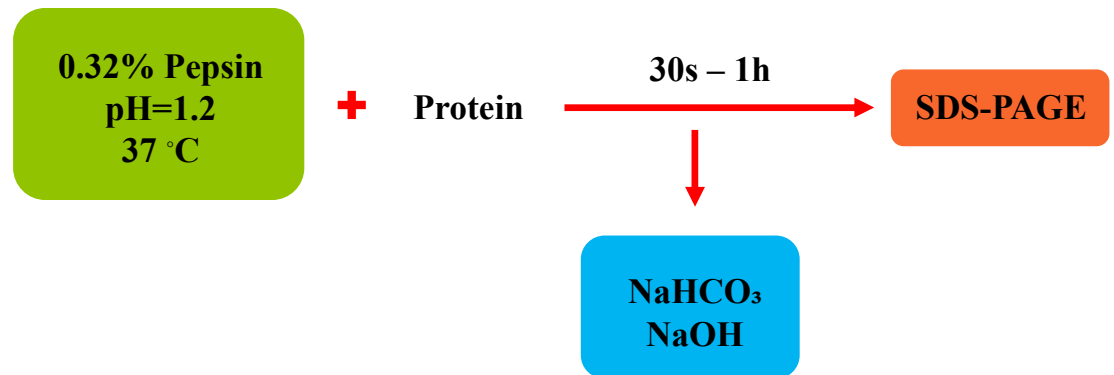
# **SEQUENCE HOMOLOGIES AND STRUCTURAL SIMILARITIES**

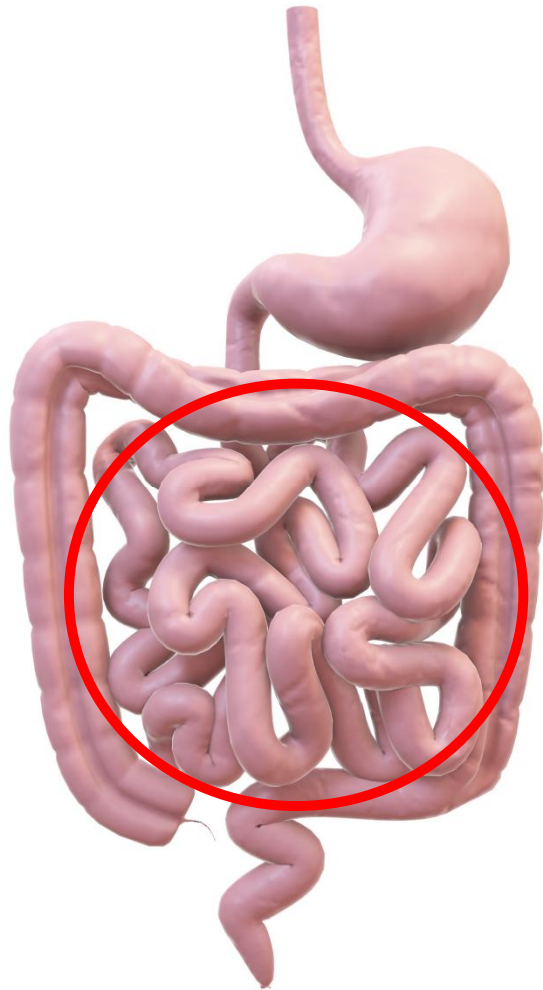
Allergen Online  
SDAP



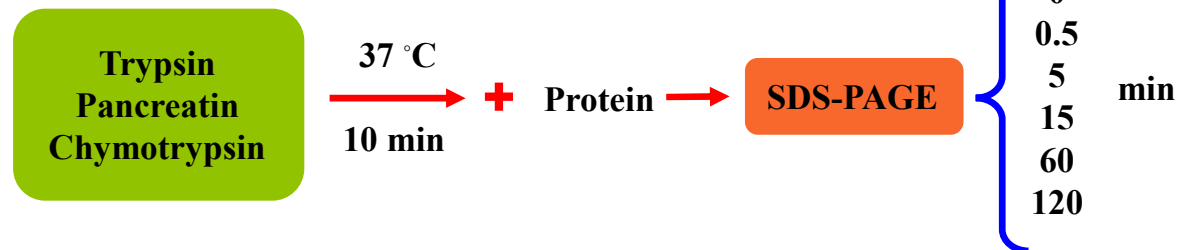


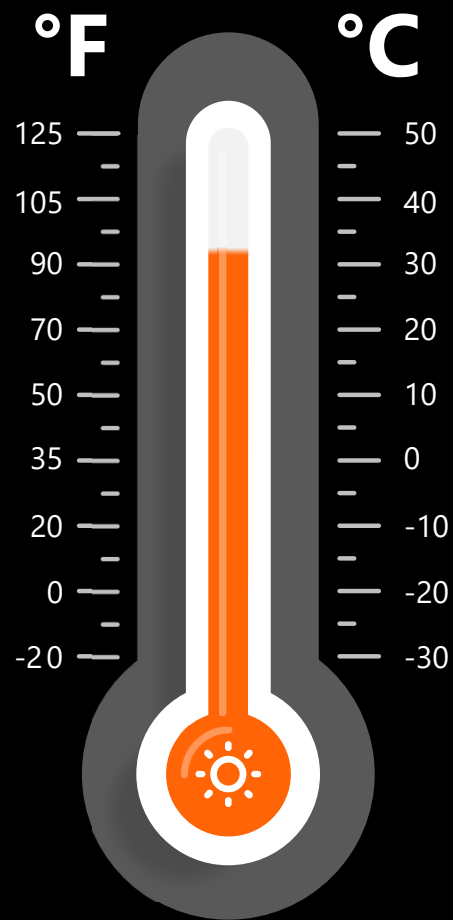
# Simulated gastric fluid (SGF) assay



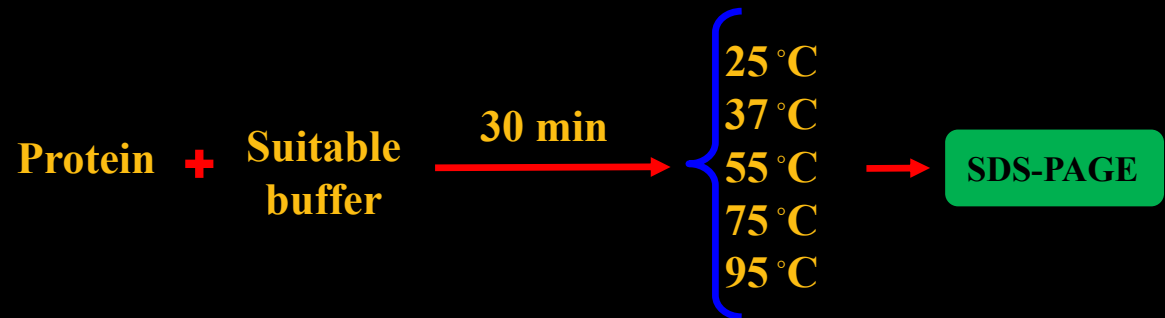


# Simulated Intestinal fluid (SGF) assay



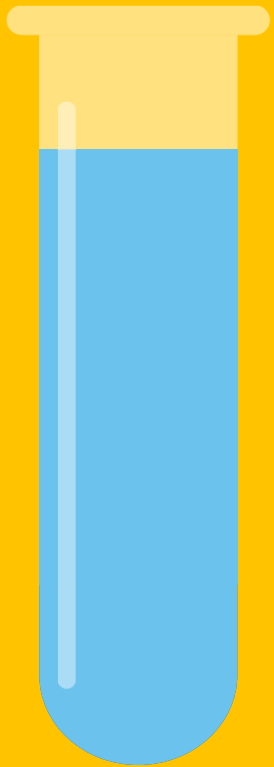


# Thermal treatment assay

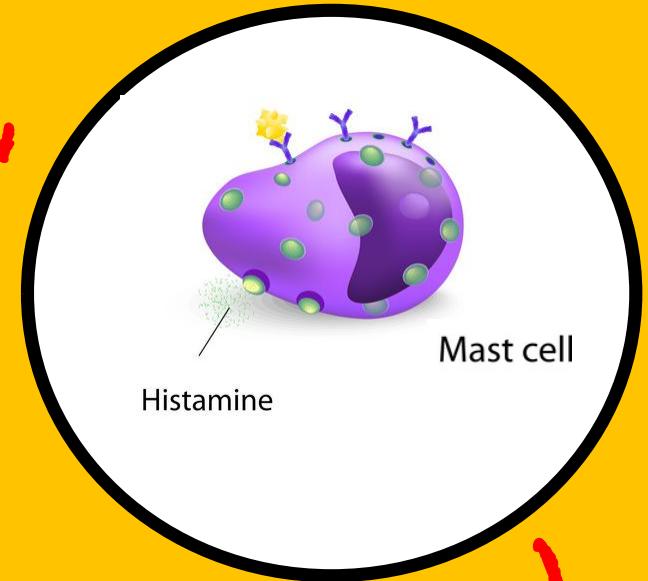




# Serological test

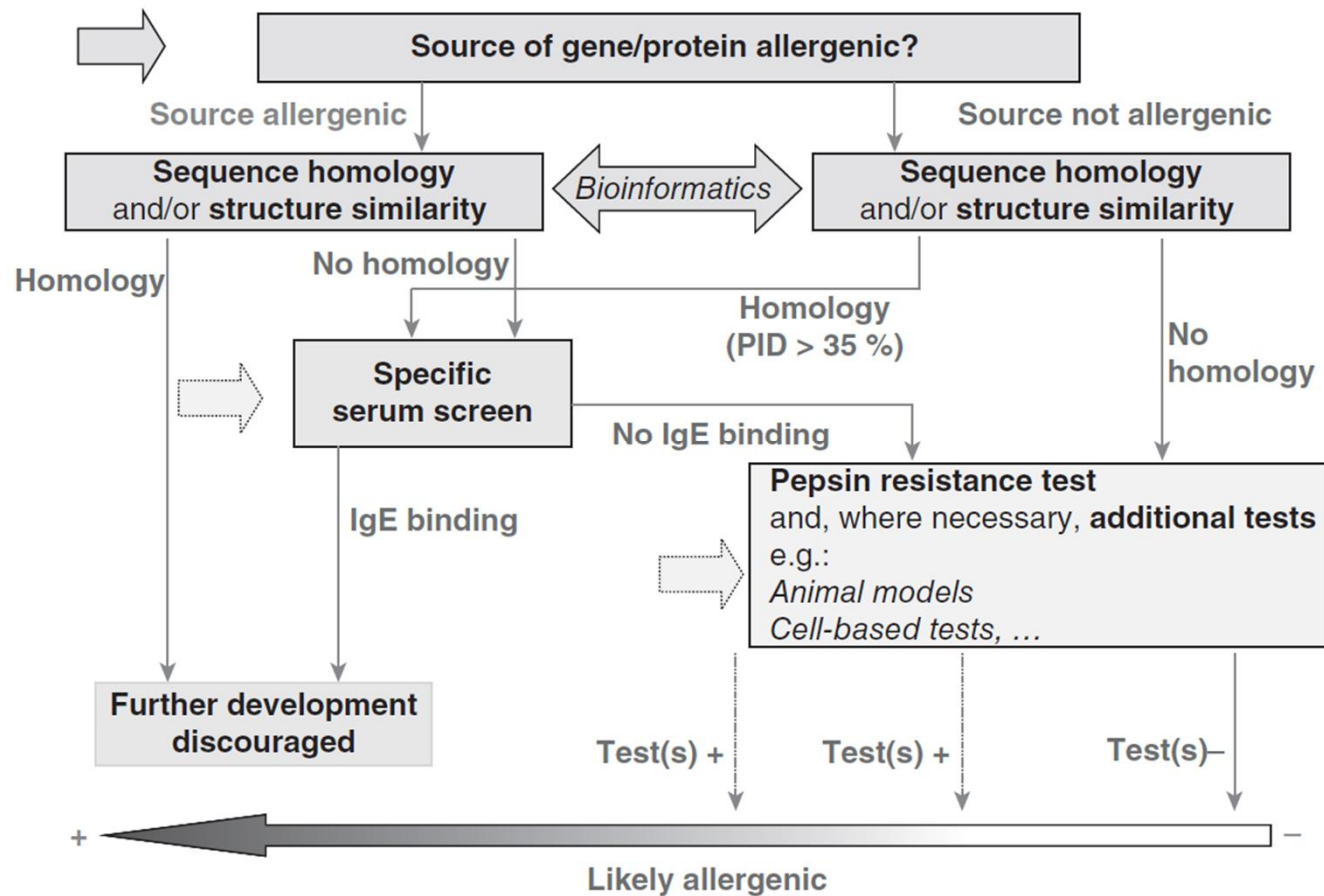


**IS THERE ANY  
INCREASE?**








**~~X~~ ALLERGEN!**

**YES!**



## Some of approved GM crops

Crops	GM traits	Trade name
	Viral disease resistance	N/A
	antibiotic resistance modified starch/carbohydrate reduced acrylamide potential	Atlantic New Leaf™ potato Innate™ G/H Potato
	Delayed ripening/senescence antibiotic resistance	FLAVR SAVR™
	Viral disease resistance	N/A
	glyphosate herbicide tolerance Sulfonyleurea herbicide tolerance drought stress tolerance	Agrisure® Duracade™ Enogen™

Convention on Biological Diversity

SIGN IN EN ?

**BCH** BIOSAFETY CLEARING-HOUSE

HOME ABOUT SEARCH SUBMIT COUNTRY PROFILES HELP FORUMS PROTOCOL

CBD / BCH / Registries / LMO registry

### Living Modified Organism (LMO) Registry

The LMO Registry provides summary information on all living modified organisms registered in the BCH, including transformation events, genetic modifications and the [unique identification code](#) (if available) for each record. Links to all decisions and risk assessment reports that refer to these organisms are accessible through the records in the registry.

Total records: 898 Export

Record ID	Unique identification	Identity & transformation event	Organism	Description
<a href="#">BCH-LMO-SCBD-114444-1</a>	AAT-709AA-4	<b>Pod Borer-resistant cowpea</b> AAT709A	Vigna unguiculata Cowpea, Black eyed pea	Resistance to diseases and pests - Insects - Lepidoptera (butterflies and moths), Resistance to antibiotics - Kanamycin
<a href="#">BCH-LMO-SCBD-14752-6</a>	ACS-BN011-5	<b>Navigator™ canola</b> Oxy-235	Brassica napus Turnip, Rapeseed, Canola Plant, Oilseed Rape, Rape, BRANA	Resistance to herbicides - Bromoxynil
<a href="#">BCH-LMO-SCBD-15101-6</a>	ACS-BN010-4	<b>Falcon™ rapeseed</b> GS40/90pHoe6/Ac	Brassica napus Turnip, Rapeseed, Canola Plant, Oilseed Rape, Rape, BRANA	Resistance to herbicides - Glufosinate
<a href="#">BCH-LMO-SCBD-14753-6</a>	ACS-BN001-4	<b>InVigor™ canola</b> RF1 (B93-101)	Brassica napus Turnip, Rapeseed, Canola Plant, Oilseed Rape, Rape, BRANA	Resistance to herbicides - Glufosinate, Resistance to antibiotics - Kanamycin, Changes in physiology and/or production - Fertility restoration

Registries

- LMO Registry
- Organism Registry
- Genetic Element Registry

Rectangle Scan

?



## The Cartagena Protocol

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. It was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003.

### AIA procedure



# What now???



What now??? → It's OK✓





## References:

1. Zhang C, Wohlhueter R, Zhang H. Genetically modified foods: A critical review of their promise and problems. *Food Science and Human Wellness*. 2016;5(3):116-23.
2. Dadgarnejad M, Kouser S, Moslemi M. Genetically modified foods: promises, challenges and safety assessments. *Applied Food Biotechnology*. 2017;4(4):193-202.
3. Dunn SE, Vicini JL, Glenn KC, Fleischer DM, Greenhawt MJ. The allergenicity of genetically modified foods from genetically engineered crops: a narrative and systematic review. *Annals of Allergy, Asthma & Immunology*. 2017;119(3):214-22. e3.
4. Wal J-M. Assessing and managing allergenicity of genetically modified (GM) foods. *Handbook of Food Allergen Detection and Control*: Elsevier; 2015. p. 161-78.
5. Dwivedi PD, Das M, Kumar S, Verma AK. Safety assessment of food derived from genetically modified crops. *Animal Biotechnology*: Elsevier; 2020. p. 655-73.



The left side of the slide features a series of overlapping, semi-transparent blue geometric shapes. These shapes include various polygons, rounded rectangles, and organic, blob-like forms in different shades of blue, ranging from a deep navy to a bright cyan. They are arranged in a dynamic, layered composition that extends from the top left towards the center of the slide.

# **THANK YOU!**

Any questions?