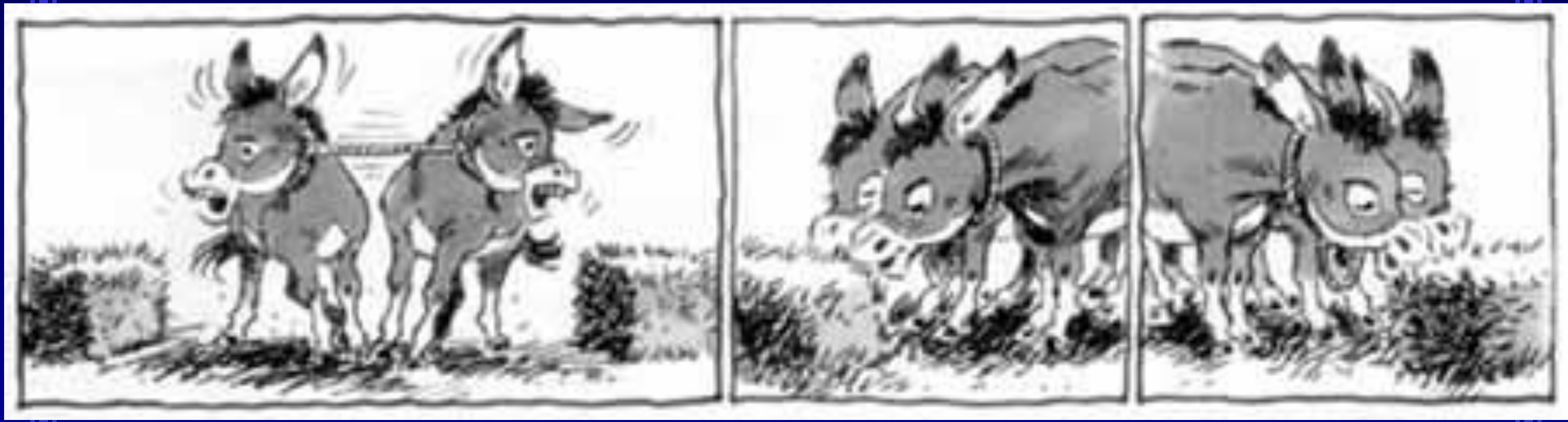
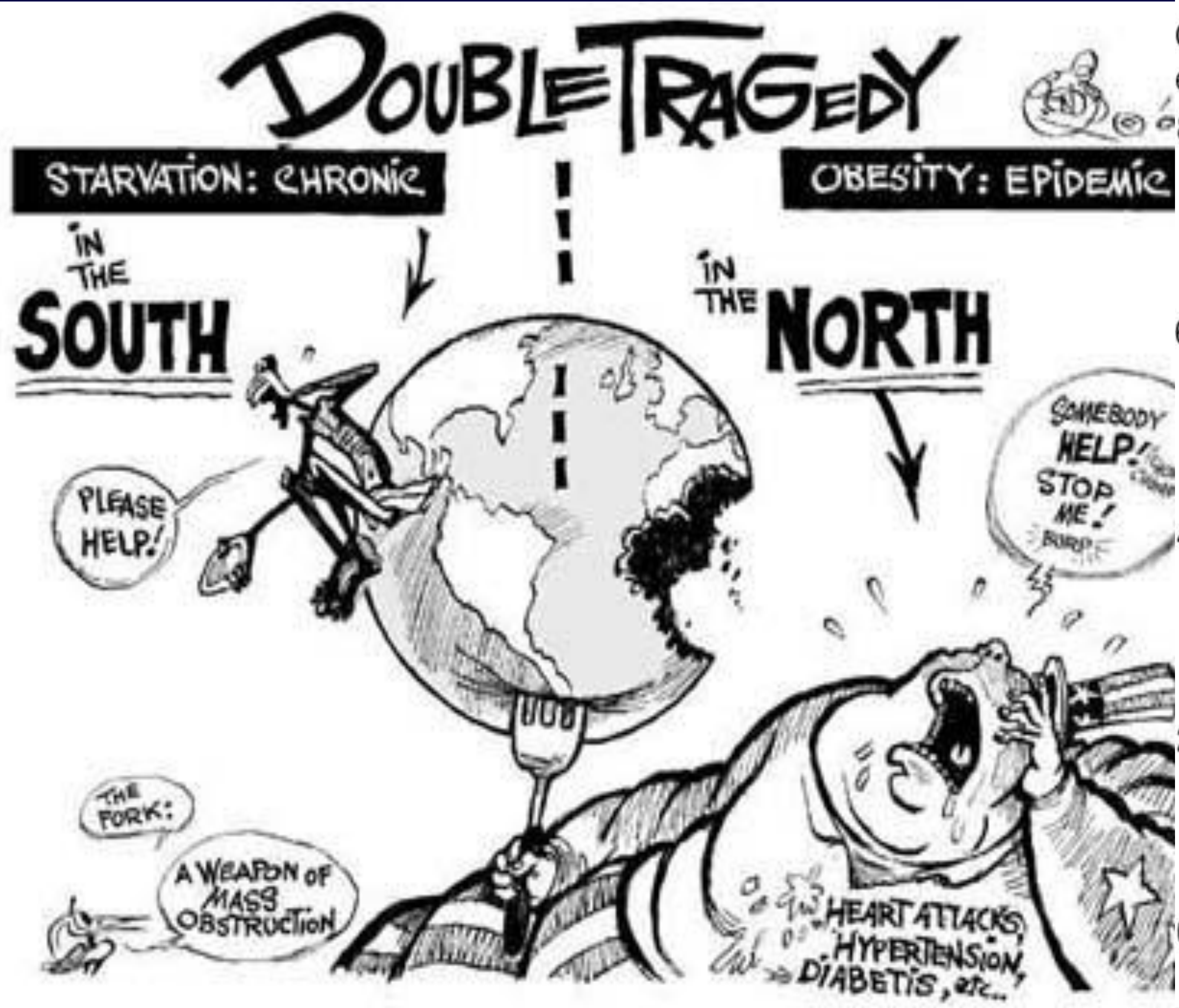
Why we all need to get along!

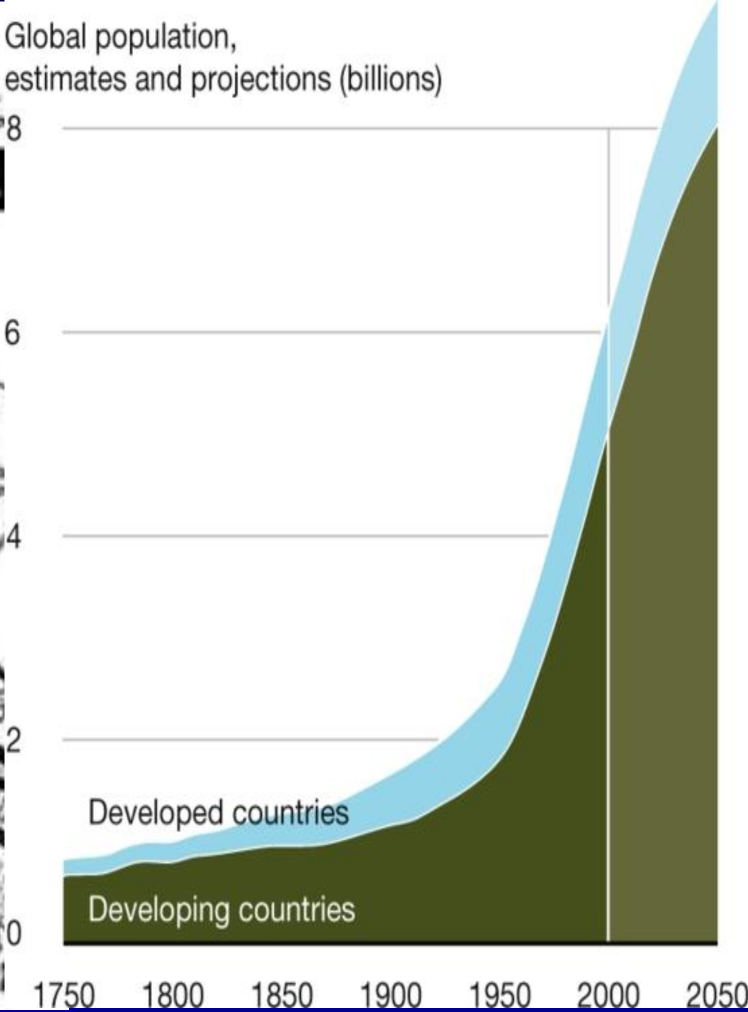
Use all the tools in the toolbox



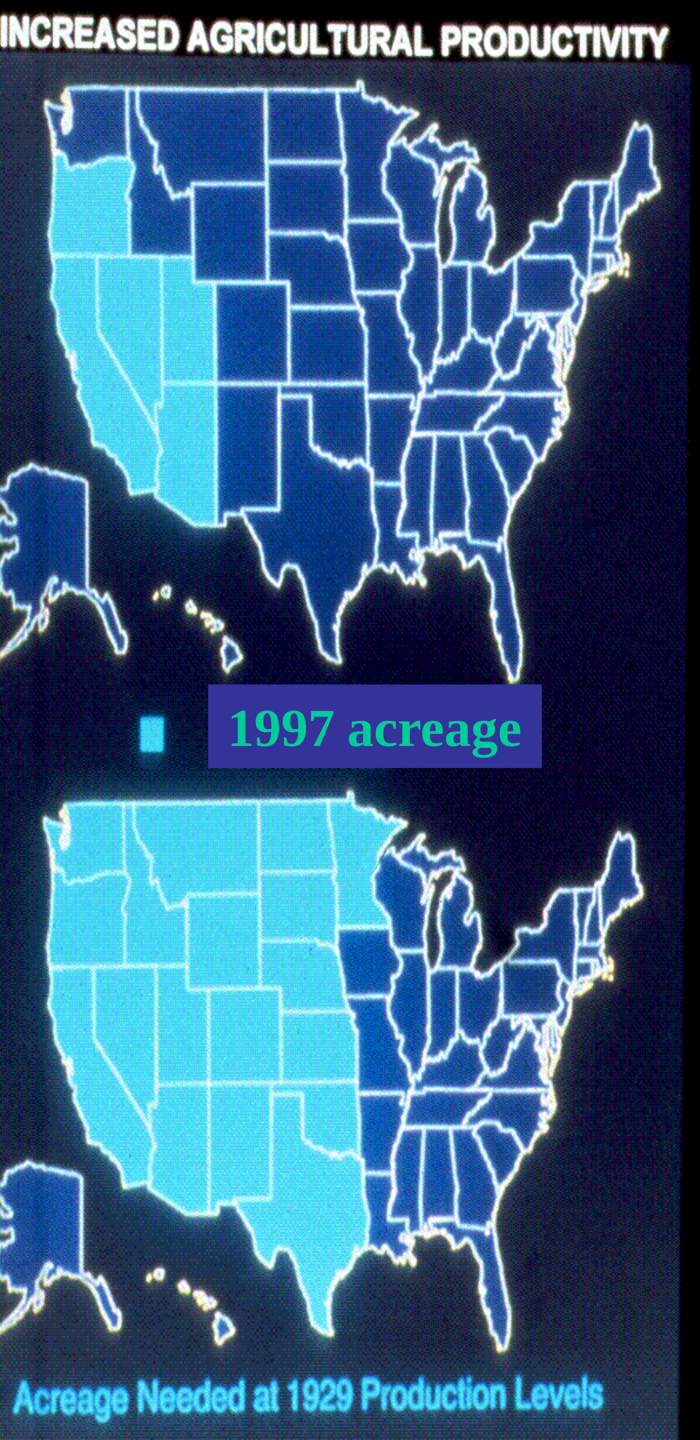
Martina Newell-McGloughlin

Director, International Biotechnology



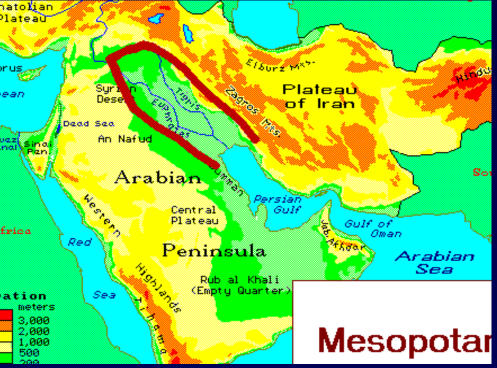


- **9 Billion mouths to feed by 2050**
- **Will need 70% more food**
- **Less water, less fuel, less fertilizer, less pesticides**
- **High yielding, affordable, high quality food, feed, fuel, fibre sustainably produced with minimum inputs**

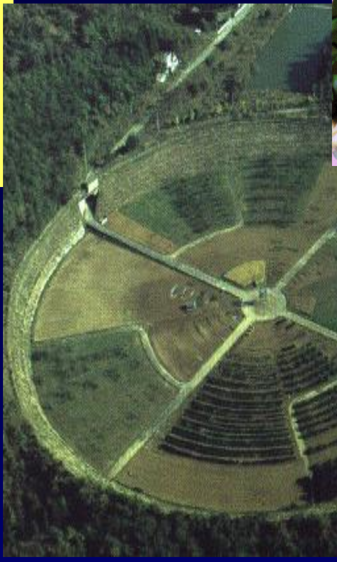


Food Security

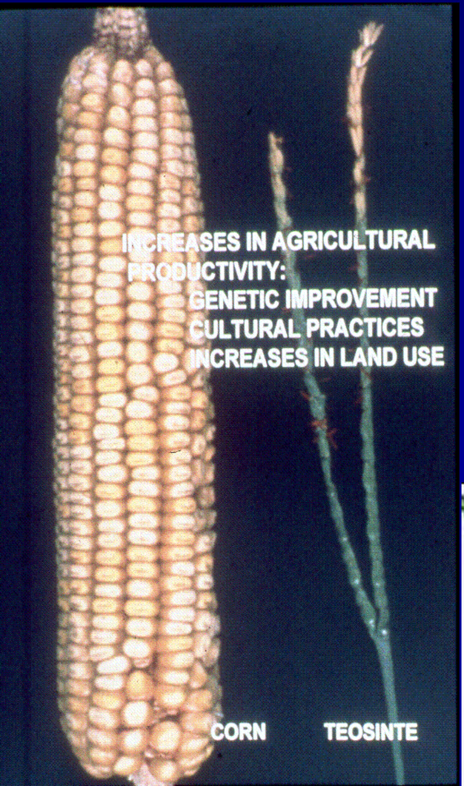
- High yielding, affordable, high quality food, feed, fuel, fibre with minimum inputs – 9 B 2050 – need 70% more food
- 17% of land under cultivation degraded by human activity 1945 to 1990. Ag land shrinks by 20,000 ha yearly. (World Bank)
- Without yield increase land use will 2X by 2050.
- Latin America: greatest yield increase had lower land use (less deforestation)
- High yield "land sparing" better than "wildlife"-friendly inefficient land use farming (Green, Royal Soc. Bird Protection 2005)
- Biotech is contributing by saving 108.7 million hectares from being converted to ag production (James, 2013).



Agriculture: A history of Technology



8,000 BC	Cultivation
19thC	Selective Cross breeding
Ea 20th C	Cell culture
Md 20th C	Somaclonal variation
1930s	Embryo rescue
1940s	Mutagenesis and selection
1950s	Anther culture
1970s	Recombinant DNA
1980	Marker assisted selection
1990s	---omics - Bioinformatics
21st C	TFs/RNAi/genome editing/ ZnF/
2010s	TALENS/CRISPRs/Epigenetics/
	Synthetic biology
	Systems Biology



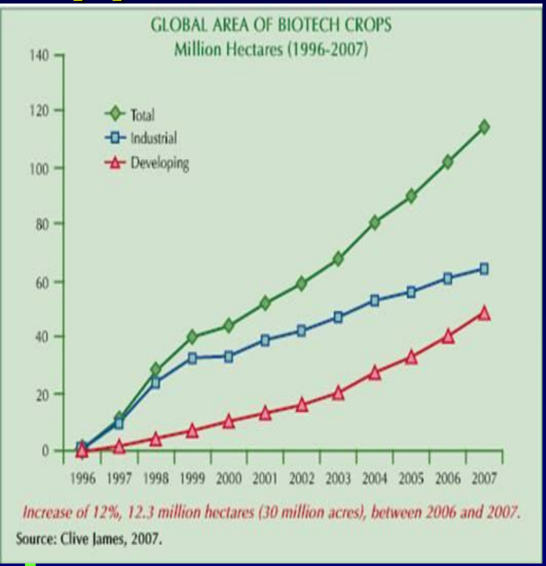
Thoroughly regulated

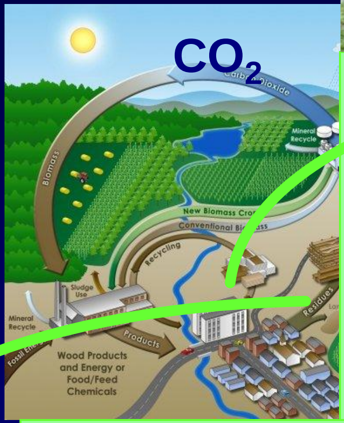
- Commercialization: USDA (APHIS), EPA, FDA - 7 to 10 years -at least 9 review stages
- Biotech crops and foods more thoroughly tested than conventional varieties ("assumed" to be safe)-
  One biotech soybean subjected to 1,800 separate analyses
- >150 feeding studies - dairy, beef, poultry, soy/corn equivalent in composition, digestibility and feeding value to non-GM.
- Substantial equivalence with parent - Molecular characterization (17) Toxicity studies (5) - marker genes (4) - Nutritional content (7+)- Allergenicity potential - Anti-nutritional effects - Protein digestibility
- Environmental aspects (5 items)- Ecological impact (5 items)
- International approval: OECD, CBD, CODEX

<u>Omic studies</u>

Meta-analysis on GM crops using transcriptomic, proteomic and metabolomic profiling techniques show greater variation between conventional bred cultivars and environmental conditions (e.g. drought) than between GM and parental variety (except of course for the intended modification!) Ricroch AE, Bergé JB, & Kuntz M (2011). Wheat (Baker 2006), Potato (Catchpole 2005)

Opportunities/Challenges for Biotech Crops





Renewable Resources

Biomass conversion, feedstocks, biofuels, Phytoremediation

Concerns land/ water use

Plants as Factories

Pharmaceuticals/ Industrial products (Ventria – Rice Lactoferin Lysozyme 30% Diarrhea, recovery 3/6 days,

Concerns gene flow co-mingling

Quality Traits

Improved post harvest characteristics

Shelf life, processing, taste

Improved Nutrition –Improved Functionality

Macro: protein, oils, carbs, fibre

Micro: Vitamins, minerals,

Phytochemicals – Antioxidants

Remove Antinutrients/allergens/ Toxins

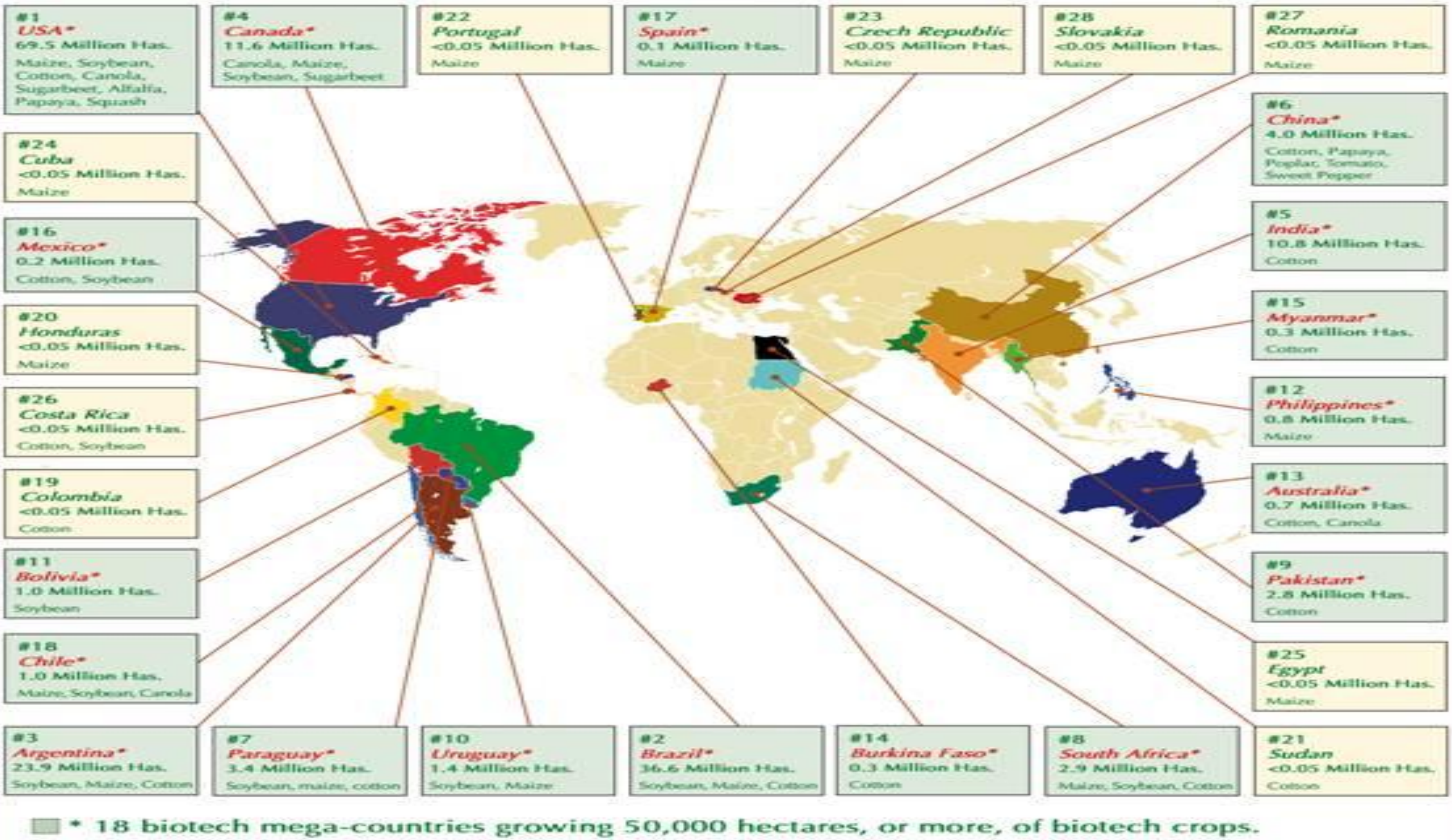
Agronomic Traits

<u>Biotic Stress</u> - pests/disease/weeds/

<u>Abiotic Stress:</u> Drought, heat, salinity, submergence, marginal soils

<u>Yield:</u> nutrient efficiency, fossil genes

Biotech Crop Countries and Mega-Countries*, 2012



- **Biotech Crops 2012: 172 million hectares, up 10.2 million - 6% growth**
- **US 69.5 Mhas (170Mac), (~90% principal biotech crops) -Canada 8.5MHacs (97.5%)**
- **28 countries (20 LDC) 71% 17.3 M farmers 3.5% -90% (15M) resource-poor LDC**
- **Two new Sudan (Bt cotton) and Cuba (Bt maize) – lost Germany Sweden Poland**
- **26% of 420M ac stacked up from 105 M ac or 26% of the 395 M acs in 2011**

Environmental Impact




- Economic gains at the farm level of >$80 B 1996 to 2011
- 1 billion lbs less pesticides
- HT Soybean – Conservation Tillage
- 93% less soil erosion 31% less wind erosion
- Preservation of 1 billion tons of top soil
- 70% reduction in herbicide run-off
- 80% reduction in phosphorus in water
- >50% reduction in fuel use
- 50 billion lbs reduction in CO_2 emissions
- ~10 million cars off the road; saving 270 million acres of land; (Brookes and Barfoot, 2012)

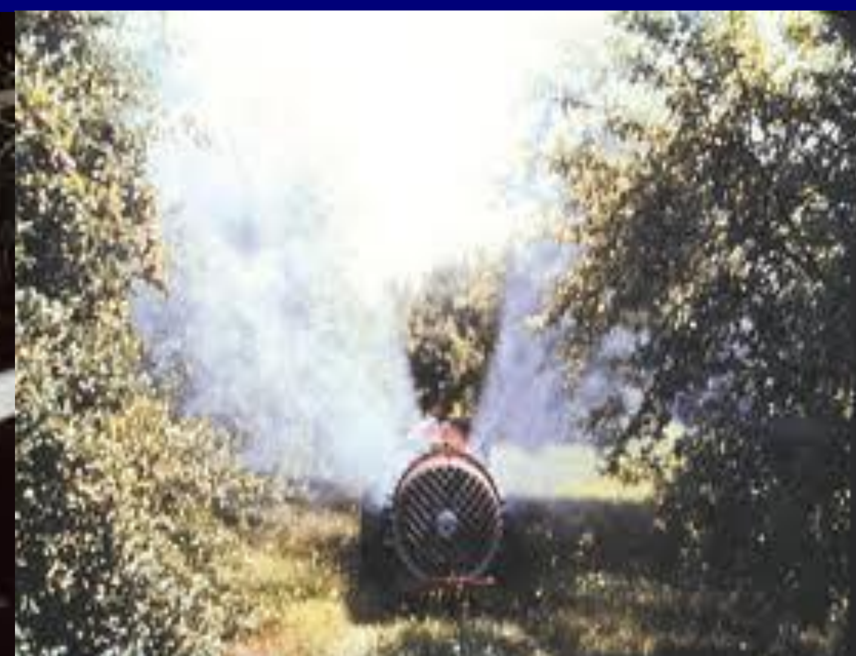




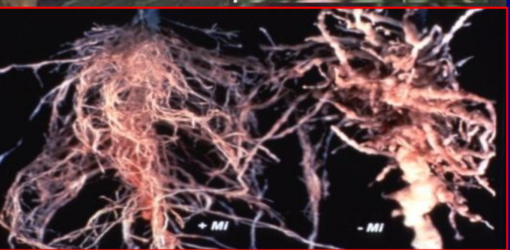

Benefits to Date

- **BT Maize: Cumulative benefits over 14 years $3.2 - $3.6 billion >> $1.9 - $2.4 billion accruing to non-Bt maize growers. Hutchison , 2011**
- **BT corn 90% reduction in mycotoxin fungal fumonisins - total US benefit estimated at $23m annually (Wu, 2006)**
- **Phytase maize – improved bioavailabilty of P and divalent ions increased nutrition – decreased**
- **PRSV CP papaya saved Hawaii papaya industry (and helped organic farmers!)**
- **May be the outcome for plum pox –Plums highly resistant to PPV - System is totally resistant as virus is not harbored unknowingly – Tolerant non biotech trees can harbor virus C5 PTGS insurance against typhoid Mary in nurseries**

Guess the mystery substances ?





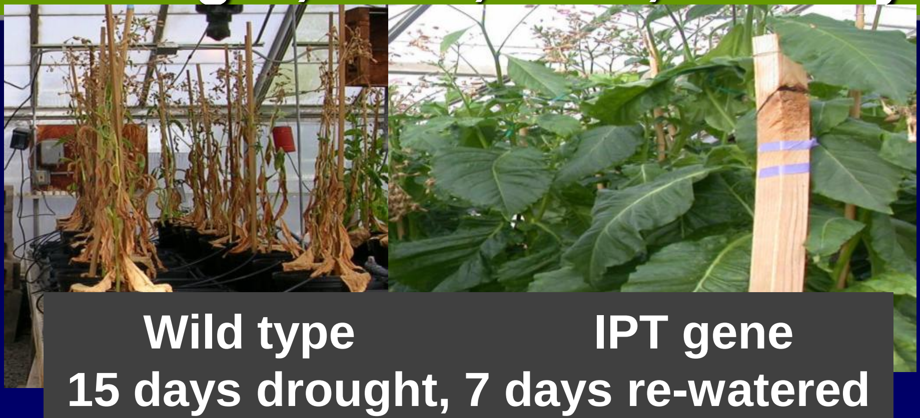
Better Alternatives!

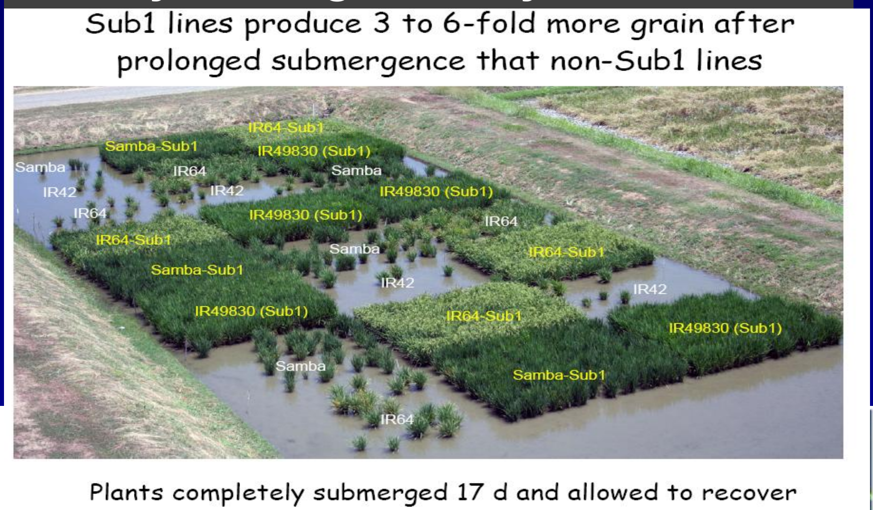
- Potato Late Blight - Up to 75% of crop can be lost – -Fortuna Resistant potato contains two genes from wild Mexican potato - eliminate fungicide spraying -potential saving $4.3 B – Plus Halo effect!
- Grapes- Pierce's disease (X. fastidiosa) - Fusion two genes innate immunity and membrane lysis – preferable to spraying malathion! (Dandekar)
- Citrus Greening (*C.* Liberibacter) – Biotech the only solution 2 spinach genes – showing field R Mirkov 2013
- Apple Fireblight (E. amylovora) – controlled using antibiotic sprays! Cecropin lytic peptide analog (Norelli)
- Apple scab (V. inaequalis) Fungicides 'MacIntosh' trees endo- or exochitinase increased resistance
- Rootknot nematodes R in tomato (*Mi*) and (aphids). Alternate to fumigation (Williamson)

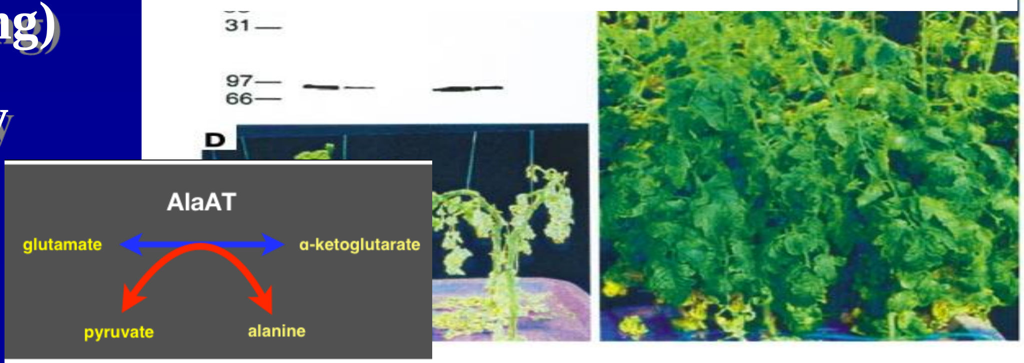
Abiotic stress limiting factor to crops reaching genetic potential

Abiotic Stress: Drought, Cold, Heat, Salinity

- **Drought tolerant maize (30% increase in field trials under H2O stress) Fewer crop losses -Higher yields better water utilization**
- **“Resurrection” gene delay drought-induced leaf loss and stress**
- **Submergence sub -1 gene produces 6X grain - save 3 mil tons rice (save 40 mil people)**
- **Salination: Transport protein. Grow and fruit even in irrigation water that is > 50X saltier than normal. > 1/3 seawater. Blumwald and Zhang)**
- **Arcadia's Nitrogen Use Efficiency (NUE) plants equivalent yields require 30% less Nitrogen fertilizer greater efficiency**







potato (left)
o (right)
g cut.

- **Improved Nutrition**

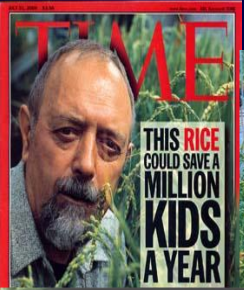
Healthy Potatoes

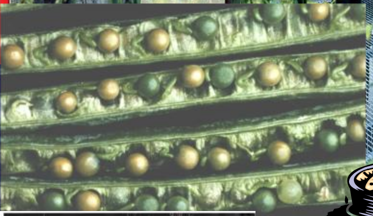
- **Reduced asparagine reduces the potential for the formation of acrylamide by 80%, created when potatoes, wheat, coffee, etc cooked at high temperatures.**
- **Reduced black spot from bruising and Browning RNAi suppression of Polyphenol oxidase (PPO)**
- **Reduced sugars which provide potatoes with a consistent golden color, providing ideal taste texture qualities**

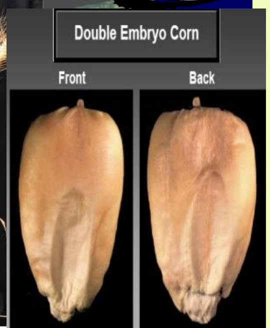
Healthy Oils

- **High Omega 3 fatty acids – right now fatty fish only source – With biotech soybeans etc can provide a land-based source making it more affordable and accessible!**
- **Also high oleic and high stearate/low saturated soybean oil**

Improved Nutritional Content





Many common food crops not perfect for nutritional requirements.

Proteins: Maize, wheat, Sweet potato and cassava

WHO: 800 million people suffer from malnutrition, Protein-energy malnutrition (PEM), the most lethal form, affects 1 in 4 children: 70% live in Asia, 26% Africa, 4% Latin America, Caribbean

Functional Foods: benefits beyond basic nutritional needs.

Macro: Protein (Better ratio, High lys/ meth, Fossil TF partitioning, artificial)

- **Carbohydrates (>complex – resistant starch)**
- **Fats (Higher Oleic (MUFA), Ω-3, Ω- 6 GLA, CLA, MCFA, lower SFA, PUFA**
- **Fibre (low for animals, high for humans (prebiotics, FOS, inulins, lignans)**

Micro: Vitamins (Golden rice II, Golden Cassava, folate, vit C, vit E), co-factors, minerals (Vine-ripe tomatoes GLK2 TF that controls chloroplast controls sugars/soluble solids, lycopene (Powell)

Phytochemicals: anthocyanins carotenoids, flavonoids, isoflavones, isothiocyanates, phenolics (Sirtuins)

Anti-nutrients: Trypsin inhibitors, Phytate; caffeine
Allergens/intolerance: soy P34, peanut; gluten;
Toxins: glycoalkaloids, cyanogenic glucosides, phytohaemagglutinins

- **An estimated 2 trillion meals containing GM ingredients have been eaten around the world over the last 16 years without a single substantiated case of ill-health.**
- **An overwhelming majority of scientists, medical experts, National Academy of Sciences and over 600 peer-reviewed scientific studies have all concluded that genetically engineered food products are safe.**
- **The World Health Organization has said that: 'No effects on human health have been shown as a result of the consumption of such foods by the general population.'**
- **The French Academies of Medicine, Pharmacy & Sciences: "No evidence of health problems exists in the countries where GMOs have been widely eaten for several years"**
- **EU: 150 projects 500 research groups over 25 years "There is no scientific evidence associating GMOs with higher risks for the environment or for food and feed safety than conventional plants and organisms"**

Risk Assessment

Precautionary Principle

Many GE products + Many countries + Slow approvals + Stacked reviews + Zero tolerance (for LLP)

= <u>Trade Wreck</u>

Europe is the loser

EU ag economy runs on cheap animal feed

Imports $15 billion in biotech animal feed each year

Livestock production accounts for 40% of the total value of agricultural production

Impact on EU pig meat sector (deviation from the baseline, %)

PORK	MEDIUM		WORST CASE	
	2009	2010	2009	2010
Net Production	-0.9%	-1.8%	-29.3%	-34.7%
Import	28.6%	74.3%	637.0%	5461.0%
Exports	-0.3%	-1.1%	-86.0%	-85.3%
Consumption	-0.9%	-1.6%	-23.9%	-17.4%

Impact on EU poultry sector (deviation from the baseline, %)

POULTRY	MEDIUM		WORST CASE	
	2009	2010	2009	2010
Net Production	-1.7%	-2.6%	-29.2%	-43.9%
Import	6.6%	10.6%	92.5%	158.3%
Exports	-2.9%	-5.9%	-100.0%	-100.0%
Consumption	-1.0%	-1.5%	-15.7%	-20.9%

Impact on EU beef meat sector (deviation from the baseline, %)

BEEF	MEDIUM		WORST CASE	
	2009	2010	2009	2010
Net Production	0.0%	0.0%	-1.1%	2.1%
Import	12.7%	14.0%	397.4%	295.8%
Exports	-41.2%	-95.1%	-100.0%	-100.0%
Consumption	1.2%	1.5%	30.2%	23.1%

- 2013 Ireland had long harsh winter
- Limited fodder
- Penalized from asynchronous approval of stacked traits

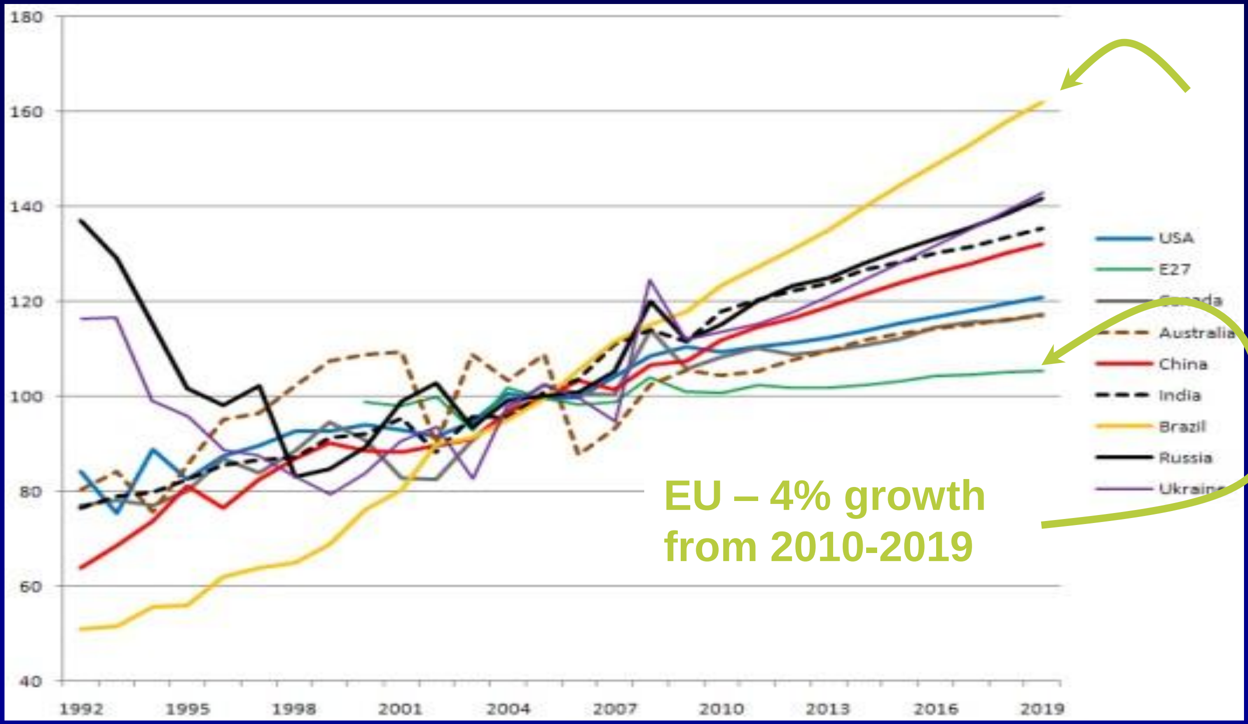
Workarounds

- Regulatory Dichotomy between 'GMO' and 'everything else' is absolute:
  - Cost of compliance for GMO is massive, in terms of $$$, time and potential liability
  - Cost of compliance for non-GM breeding is zero
- Developers are motivated to circumvent onerous regulations, even if it means using less efficient technology
  - Marker Assisted Selection, Cisgenics, Innate genes, transient, non-integrating vectors, etc.

OR

- Non-detectable Technologies coming on board
  - Genome Editing (TALENs, CRISPRs, zinc fingers) non-integrating DNA, etc.

Who has the brighter prospects?



Brazil – 40% growth from 2010-2019

EU – 4% growth from 2010-2019

EU Position Changing

- The existing EU regulatory system is without justification in science, data, or experience. - United Kingdom Advisory Committee on Releases to the Environment (ACRE) August 2013
- Counterproductive to reducing /managing risks discourages investment/innovation needed to address challenges to sustainable agriculture in the EU.
- “There is no substantiated case of any adverse impact on human health, animal health or environmental health, so that’s pretty robust evidence, “GMOs and other scientific advances must be explored in order to head off the increasing scarcity of energy and other resources and competition for land use”

  - Ann Glover EU Chief Science Advisor, 2013
- 'We believe that GM crops can help make agriculture more efficient and also just as importantly more sustainable, by, for example, reducing the use of pesticides and the use of fossil fuels,‘

  - David Willets Minister of Science UK, 2013

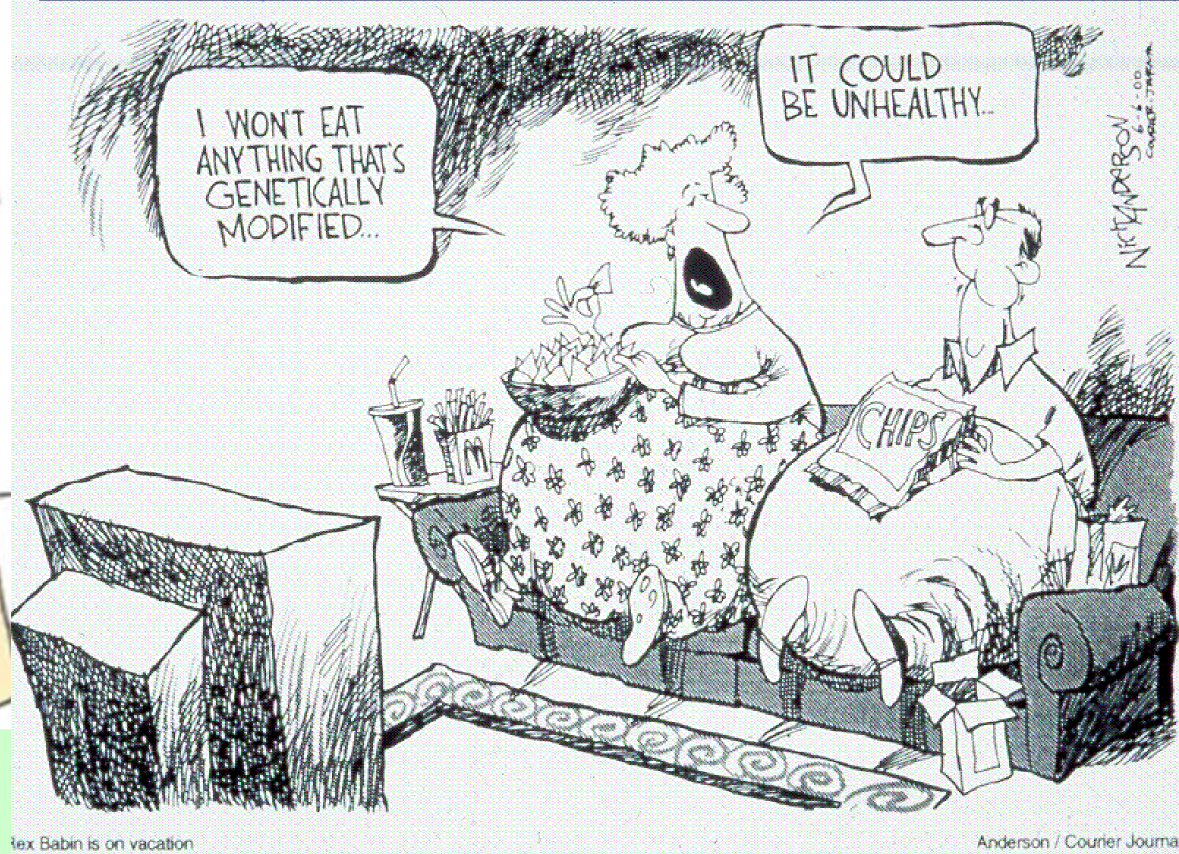
Professional Scientific and/or Medical bodies with an opinion on safety of GMOs

Generally Positive

- ✓ The U.S. National Research Council (NRC)
- ✓ U.S. National Academy of Sciences (NAS)
- ✓ The American Medical Association, (AMA)
- ✓ U.S. Department of Agriculture (USDA)
- ✓ U.S. Environmental Protection Agency (EPA)
- ✓ U.S. Food and Drug Administration (FDA)
- ✓ European Food Safety authority (EFSA)
- ✓ American Society for Plant Biology (ASPB)
- ✓ World Health Organization (WHO)
- ✓ Food and Agriculture Organization (FAO)
- ✓ Royal Society (London)
- ✓ Brazil National Academy of Science,
- ✓ Chinese National Academy of Science
- ✓ Indian National Academy of Science
- ✓ Mexican Academy of Science
- ✓ Third World Academy of Sciences

Generally Negative

I hope that there is nothing genetically modified in this



<u>Greatest Challenges going forward</u>

- Technical
- Intellectual Property: PIPRA - Specialty crops – FTO
- Liability (Coexistence – need reasonable thresholds)
- Regulations: Asynchrony – Lack of uniformity LDCs/ Specialty
- Acceptance: - countering fear and misinformation
  (ethical) - moral imperative real need v. hypothetical risk