Towards a Sustainable Future:

Biotechnology in Harmony with Agriculture and the Environment

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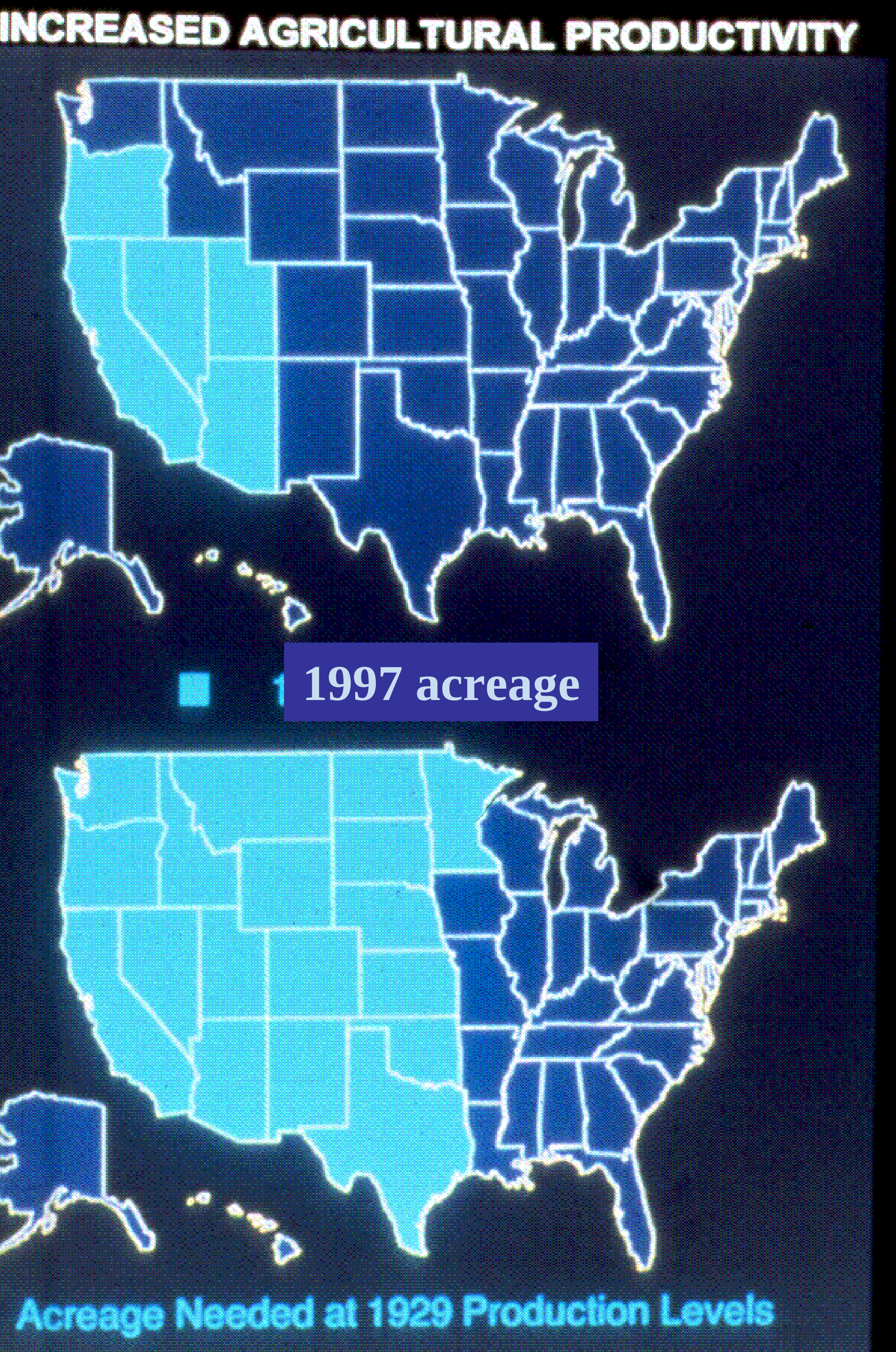
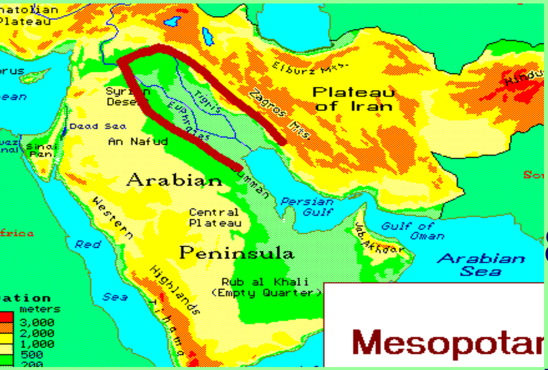
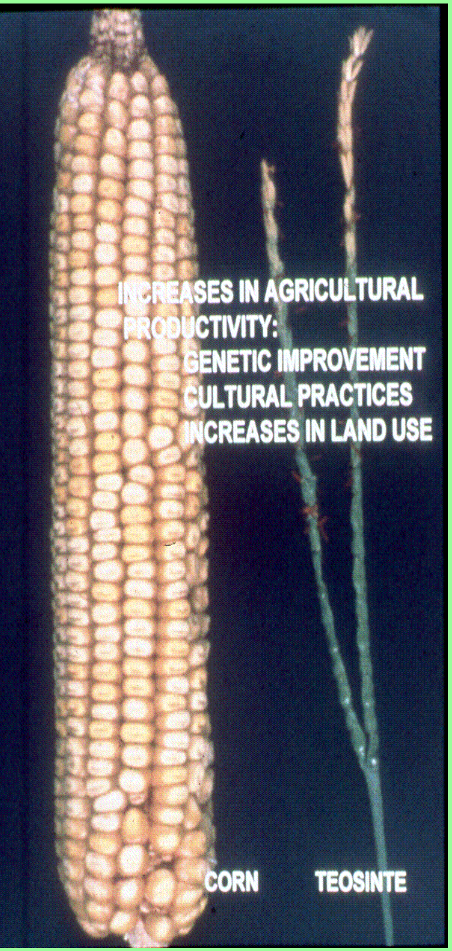


- 90 M pop added each year,
- Greater than 95% born in LDCs.
- Asia's 58 million pa largest; Africa rate 2.9% is steepest.
- FAO: global demand for food 2X: 1990-2030, 2.5 –3X ⇈ in the poorest countries (FAO, Rome).
- Losing about 3,000 square meters of forest and 1,000 tons of topsoil every second; arable land shrinks by 20,000 hectares yearly.
- Erosion made billion hectares of soil unusable for agriculture.
- High yield “land sparing” better than wildlife friendly (Green, Royal Soc. 2005)
- Without yield increase land use will double by 2050

Crop Agriculture Technology Timeline





8,000 BC	Cultivation
19thC	Selective Cross breeding
Ea 20th C	Cell culture
Md 20th C	Somaclonal variation
1930s	Wide crosses/ Embryo rescue
1940s	Polyembryogenesis
1950s	Mutagensis and selection
1970s	Anther culture
1980	Recombinant DNA
1980s	Marker assisted selection
1990s	Genomics
2000	Bioinformatics
2000	---omics
21st C	Systems Biology

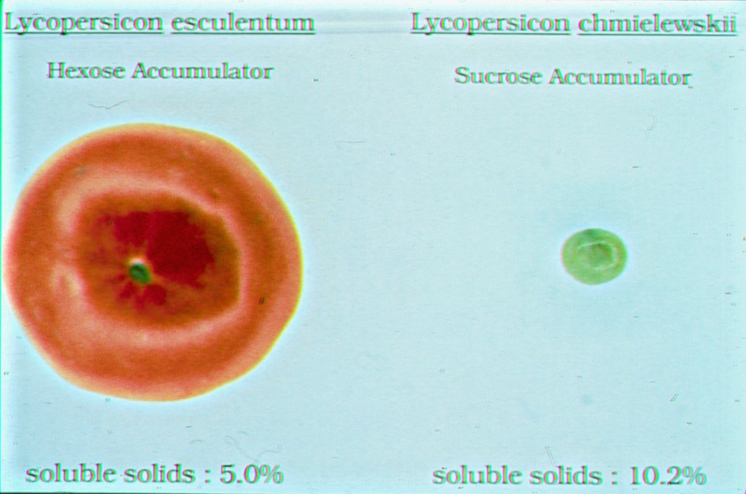
- 90% of the enzymes used in large scale for commercial applications result from the exploitation of rDNA methods in the manufacturing process or for the improvement of the catalysts themselves.
cleaner processes with lower production of wastes and lower energy consumption
food, drink, paper, taning, detergents

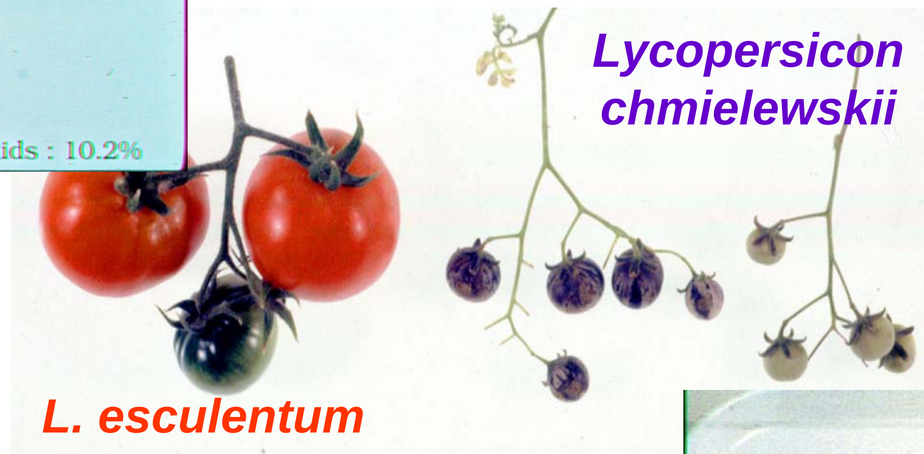
Mutation Breeding

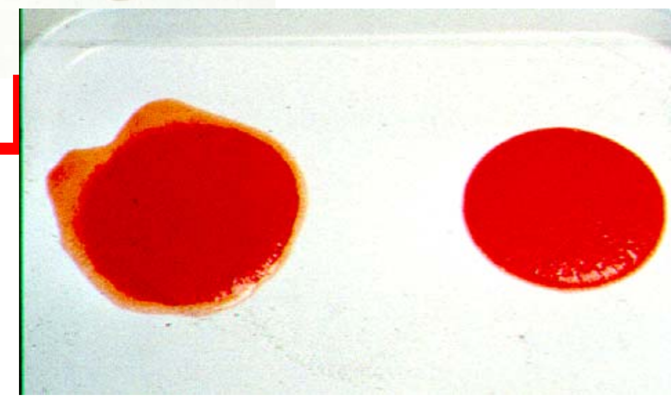
Gamma Greenhouse for chronic irradiation of sub-tropical plants. Cs137 source (4.81TBq, 130 Ci) is used in the octagonal greenhouse with 7m radius at the Institute of Radiation Breeding, NIAR, Ibaragi, Japan – bred for disease resistance and improved quality, yield and adaptability

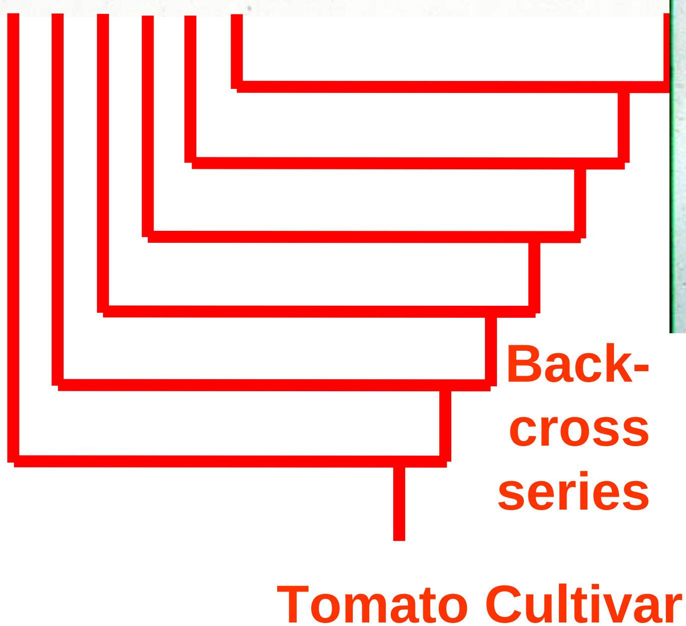
The gamma field is a circular field of 100m radius with 88.8TBq Co-60 source at the center. 2,252 new plant varieties, including Italian durum wheat, "mutations today cover 70 per cent of the area under cultivation. wheat, barley, oats, rice, soybeans, string beans, navy beans, potatoes, onions, cherries, apples, grapes

Two means to one end









Safety Data Requirements for De-regulation of Biotech Crops

Product description (7 items)
Molecular characterization (17 items)
Toxicity studies (as necessary) (5 items)
Antibiotic resistance marker genes (4 items)
Nutritional content (7+ items)
Substantial equivalence with parent variety
Literature review and background
Allergenicity potential
Similarity to natural toxicants
Anti-nutritional effects
Protein digestibility
Environmental aspects (5 items)
Germination, growth, flowering studies (8 items)
Ecological impact (5 items)

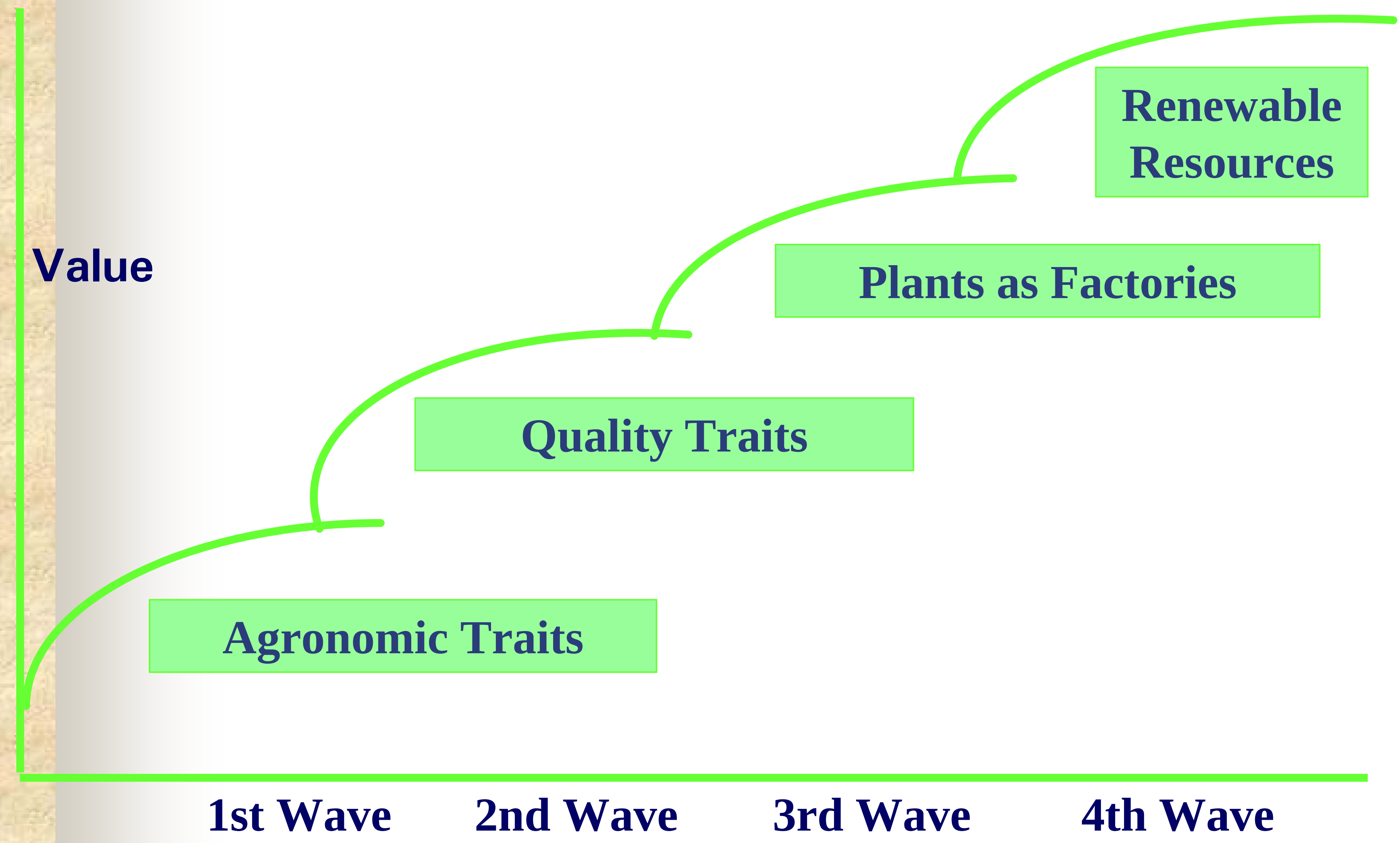
None of this is required for traditionally bred crops.

(Courtesy Alan McHughen)

Regulation of Biotech Crops

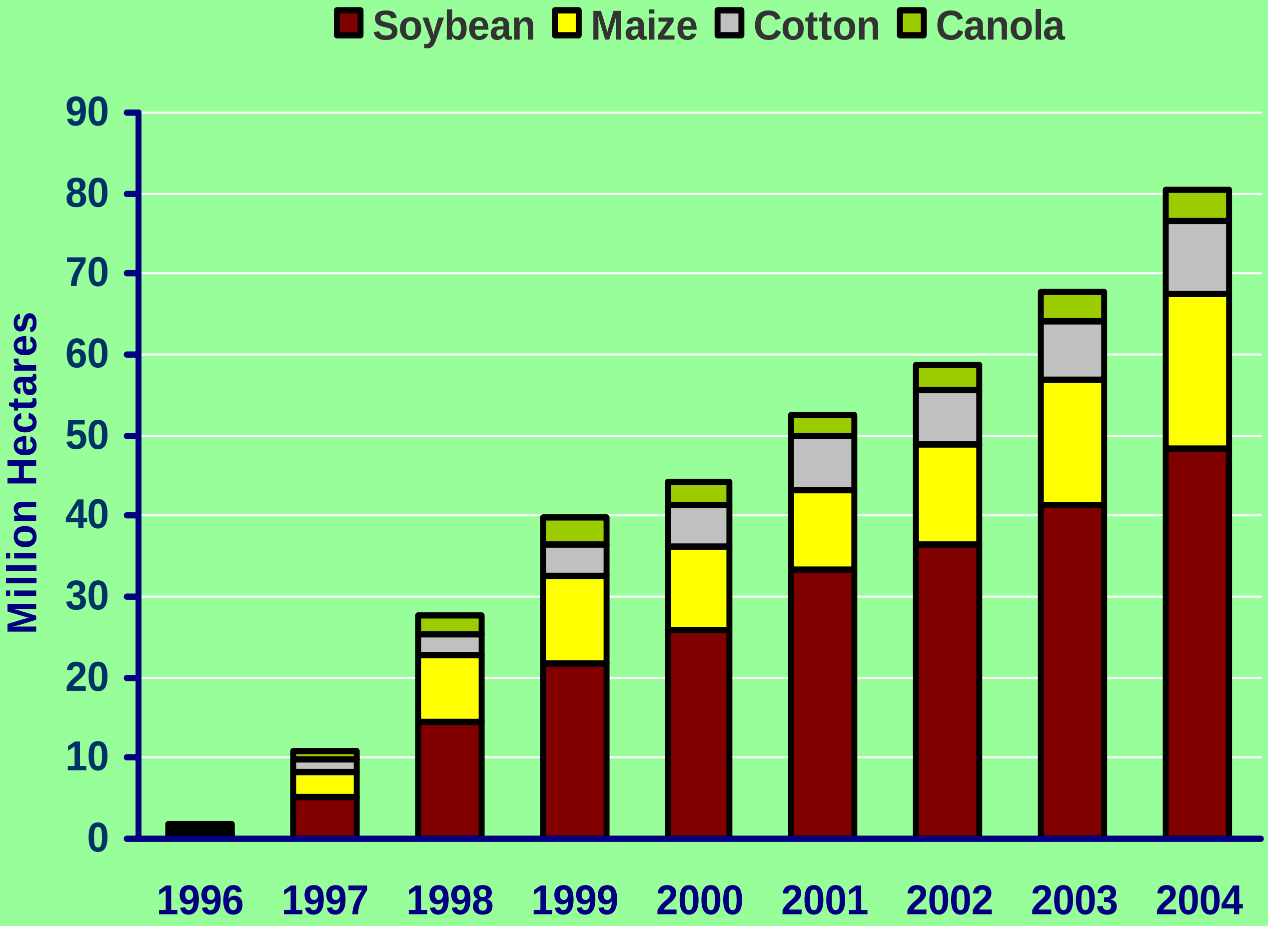
- **Overseen by three federal agencies**
  - **FDA, USDA, EPA**
- **Commercialization takes 7 to 10 years and involves at least nine stages of review**
- **Biotech crops and foods are more thoroughly tested than conventional varieties**
  - **One type of biotech soybean alone was subjected to 1,800 separate analyses**
- **More than 50 different biotech crop products have now completed the regulatory process in several countries**
- **23 feeding studies - dairy, beef, poultry GM soy and corn varieties substantially equivalent in composition, digestibility and feeding value to non-GM equivalents. (J H Clarke et al (2000)**
- **Herb-Tolerant soybeans - easier weed control, less injury to crops, no restrictions on crop rotations increase in no- till, reduction in heavy equipment, soil compaction, fossil fuel usage and less costs.**
- **China, BT cotton eliminated use of 156 M Lbs pesticides**
- **2003 US farmers: 27% increase in net farm income.**

Plant Biotechnology Generations



Global Adoption of Plant Biotechnology Products

Biotech Crops - grown by 8.25 million farmers in 17 countries in 2004 = 20% growth



US 47.6 million hectares (59%) - 11% increase in 2004

- **Tot 81.0 M hc/200 M acs, 67.7M/167 M acs 2003.**
- **5% of the 1.5 B hcs (3.7B acres) of cultivable land**
- **Up from 7 M farmers in 18 countries in 2003.**
- **Notably, 90% resource-poor LDC farmers .**
- **USA, Argentina, Canada, Brazil, China, Paraguay, India, South Africa, Uruguay, Australia, Romania, Mexico, Spain and the Philippines.**
- **1996-2004 accumulated 385 M hcs, 951 M acs**
- **HT soybean -48.4 MHcrs (60%) Bt maize- 11.2 M hcrs (14%) in 9 countries**

Source : C. James, 2005. ISAAA Brief #30

Collateral Effect

Philippines

- Bt corn approved 2002
- 49,400 acres planted
- 5,000 farmers using Bt corn
- Income increased by 34% for farmers planting Bt corn

- Up to 90% reduction in mycotoxin fungi that produce fumonisins
- **Effects on animals: feed refusal, short-term illness, reproductive dysfunction, death.**
- **Human effects: suppression immune system, reproductive dysfunction, cancer, death.**

Mozambique child with liver cancer

Benefits to Smallholder Farmers

CHINA Bt Cotton and Rice

- > 50% of cotton is Bt cotton
- Net revenue increases (>$300/ha vs conventional)
- Insecticide applications reduced by 59-80%
- Reduced sprays can bring social benefits by potentially reducing exposure to insecticides

Source: Ismael et al., 2002

RICE:

- GMO used pesticides < once/season; conventional rice: pesticides 3.7 times per season.
- Pesticides cost applied to the conventional rice was 8 to 10 times as high as GMO.
- 80-percent reduction in pesticide use. Significant decrease in adverse health effects – none for GMOs

Source: Scott Rozelle, Nature 2005

GM crops in Europe

- **Insect resistant (IR) maize in Spain: since 1998**
- **Herbicide tolerant (HT) soy in Romania: since 1999**

2004:

- **58,000 ha Spain (12% of crop),**
- **70,000 ha Romania (58% of crop)**

Thanks to Graham Brookes http://www.pgeconomics.co.uk/ for the EU data here and in following

Farm level of GM crops in Europe

	Average	Range	Value added 2004 €M
Spain: yield impact	+6.3%	+1% to +15%	
Romania: yield impact	+31%	+12% to +50%	
Spain: increase in farm gross margin	+13%	Zero to +29%	€ 5.2M
Romania: increase in gross margin	+156%	+12% to +300%	€ 14.8M

Brookes and Barfoot, 2004

Public debate is often driven by emotion not reason.

- EU Commission Report – Results from 400 teams over 15 years - The use of more precise technology and the greater regulatory scrutiny probably make GMOs even safer than conventional plants and foods.

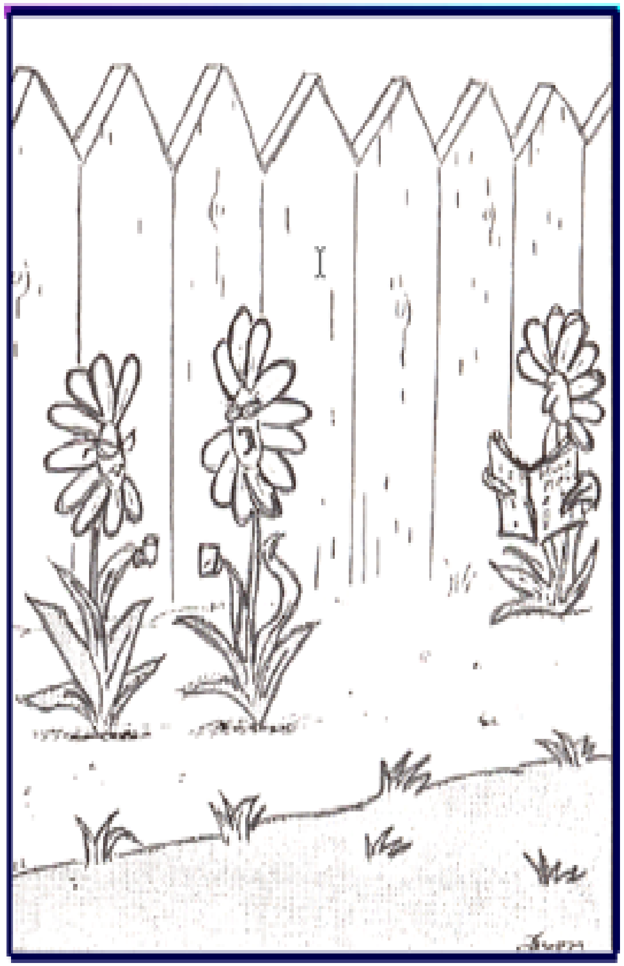
- EU Health and Consumer Protection Commissioner David Byrne: GM corn "is safe for human health and the environment”
- Declaration signed by over 3,700 scientists including 25 Nobel Laureates ,
  - AMA, SocTox, NAS, UK Royal Society, UN, FAO, WHO, OECD

- The NAS, with 6 academies (Royal Society of London, Third World Academy of Sciences, national academies of Brazil, China, India Mexico)
  - be used to increase the production of main food staples,
  - improve the efficiency of production,
  - reduce the environmental impact of agriculture and provide access to food for small-scale farmers.

http://europa.eu.int/comm/research/quality-of-life/gmo/index.html

Concerns

- Antibiotic Resistance
  - Transposon tagging
  - Positive selection – exclusive energy source
- Gene Flow-
  - Space – Time
  - Trap border
  - Male sterility
  - GURT “Terminator” technology
  - Chloroplast transformation
- Effect on non-target species
  - Tissue specific expression
  - Chloroplast transformation
  - Cost/benefit
- Loss of effectiveness – resistance management
  - Refugia
  - Gene Pyramiding
  - Gene shuffling
- Reduced diversity
  - More sources of genetic diversity – rescue heritage varieties and landraces
- Co-existence



“I don't have any hard evidence, Connie--but my intuition tells me that Ed's been cross-pollinating.

Co-Existence

But what of the context in which these crops are grown?
Can all cropping systems co-exist in harmony?

According to European Commission 2003/556/EC (paraphrased!)

- **Co-existence as an issue relates to 'the economic consequences of adventitious presence of material from one crop within another and the principle that farmers should be able to cultivate freely the agricultural crops they choose, be it GM crops, conventional or organic crops'.**
- **"No form of agriculture, be it conventional, organic, or agriculture using GMOs, should be excluded in the European Union".**
- **NOT about product/crop safety, but, about the economic impact of the production and marketing of crops cultivated for different markets.**

Co-Existence

What is adventitious presence?

- **Adventitious presence is simply the unintended incidence of something other than the desired crop such as small quantities of weed seeds, seeds from other crops, dirt, insects, or foreign material (e.g. stones).**

Kershen et al, 2005 The Council for Agricultural Science and Technology (CAST)

Co-Existence

Considerations:

- **Important to determine the relative importance of different crop production systems based on planted area, production and economic value to the region in question.**
- **The heart of the issue is assessing the likelihood of adventitious presence of material from one production system affecting another and the potential impacts.**
- **This requires consistency when dealing with adventitious presence of any unwanted material**
- **It is unrealistic to expect one hundred percent purity for any crops, or products derived there-from, so thresholds that are consistent across all materials should be set and should not discriminate**
- **All measures should be proportionate, non-discriminatory and science-based.**

Co-existence on the farm today: nothing new

- Well-developed crop stewardship programs for all the co-existing systems are important. However, it has become routine for most EU farmers to work under specified crop quality assurance (QA) programs. A significant part of EU agricultural production today is produced under contract and under QA systems.
- There are models from which to work, and a body of experience in the farming community with stewardship programs: for example, the quality management programs imposed by the food distribution companies.
  - Separation of space
  - Separation of time
  - Communication with neighbors
  - Good farm practices

Is co-existence practical?

- EC recommendation 556 has made it clear that: "farmers who introduce the new production type should bear the responsibility of implementing the farm management measures necessary to limit gene flow during the phase of introduction of a new production type in a region".

- However, in addition to the measures (e.g. isolation distances, machinery hygiene) that a GM farmer must adopt to prevent the adventitious presence of their crop amongst a neighbors; the onus is also on the non-gm farmer to bear the burden of costs in regard to genetic testing to prove the purity of their commodity.

Is co-existence an issue?

- Historically, worldwide the market has adequately addressed economic liability issues relating to the adventitious presence of unwanted material in any agricultural crop.
- Certified seed: The onus is on the producers, who require isolation from undesired pollination for the purity of their product, to insure such purity, this is not their neighbor's problem.
- By extension the onus is on growers of any specialty crops to take action to protect the purity of their crops since these are self-imposed standards for and by that market.
- Rewards : Niche Market, Cachet, Higher price

Co-existence in Practice

The measures needed for segregated crop depend on the biology of each and the standard agricultural practices in place.

- Most important biological parameters are
  - flowering biology (mainly the ability of pollen to move over distances)
  - the ability of the crop to make fertile crosses with related wild relatives
  - The survival ability of seed and other storage structures if left in field.
- These biological parameters are influenced by
  - the environment (eg. the windiness of the environment will affect the probable spread of pollen from a wind-pollinated crop like maize).
- Farming systems and traditions vary widely. Field size and crop rotation affect proximity and succession rate
- Also affect the measures needed (e.g. collaboration between neighboring farmers) to achieve crop segregation.
- Standards of purity needed for serving different markets with different types of the same crop strongly affect the possibility of growing them in the close proximity.

Maize and Oilseed Rape Considerations

GM maize:

- Cross pollination between non-GM crops and a neighboring GM maize field through pollen transfer;
- GM impurities in seed lots (cross-pollination during field production or admixture during post-harvest processing).

Oilseed rape

- Out-crossing species with very effective seed dispersal mechanisms.
- Estimated that 3000 seeds need to be tested to determine a 0.1% threshold at around 95% certainty. (technology, costs).
- In oilseed rape, a threshold of 0.3% for certified seed is recommended in order for farmers to achieve below 0.9–1.0% threshold for crops.

Co-existence in Practice

- Existing legislation in North America and the EU is more than adequate to protect all grower and consumer interests
- Methods for assessing and assigning liability for co-existence at the farm level are required that take account of accepted agricultural practices and current law.
- If new regulations are considered to address economic liability the same principle should apply to all farmers regardless of their chosen production methods.
- Equal access to compensation for adventitious presence of material from conventional or organic crops (such as fungal contamination) as conventional and organic producers have from biotech growers.
- No one sector should be able to unfairly prohibit another – access and choice work both ways.
- All co-existence measures should be based on legal, practical and scientific realities and not on commercial or niche marketing objectives.

Biotech crops co-exist successfully

- North America and Spain with conventional and organic crops.
- The market has practical, proportionate, workable coexistence measures without new regulations or government intervention.
- Isolated instances of adventitious presence in conventional or organic crops - usually caused by inadequate implementation of good coexistence practices (e.g., inefficient segregation of crops in storage and transport, non-use of tested, certified seed).
- US: Under civil liability (tort damages) and for intellectual property infringement (except for the unauthorized StarLink), there have been no lawsuits brought by any parties for adventitious presence.
- Every case brought by a seed company for infringement has involved a claim that the farmer charged with infringement was an intentional infringer (i.e. adventitious presence was not the issue).
- To date, each of these cases was upheld by the courts. All except one notable exception (in Canada) conceded to this claim.

Threshold

- The EU made a provision for a *de minimis* threshold for unavoidable presence off GMOs but did not set such a threshold so the default state of the 0.9% on labeling and traceability is the one enforced –
- Organics require 0.1% - pesticide residue is 0.5%
- US organics cannot be (legally) downgraded or growers decertified by unintentional presence but however cannot control market decisions.

Co-existence requirements in Spain

- GM growers receive crop stewardship guidelines on minimising adventitious presence
- Neighbour consultation is required
- Possible use of buffer rows (4) if neighbour non GM crop under 1 ha plot size and within 25 metres
- Protocols for maintenance of planting & harvesting equipment
- Refuge requirements for insect resistance management

Co-existence in Germany

- German GM study complete: Study organizers say the results show that GM corn fields can 'co-exist' with with neighbouring non-GM fields.
- The tests, were performed in 28 GM corn fields surrounded by non-GM fields in seven states,
- Eberhard Weber's study, which measured GM contamination in corn harvested from surrounding non GM fields, shows that non-GM corn planted at least 20 meters from GM corn was not contaminated above the EU-allowed limit of 0.9%
- "There is no doubt that if you keep a certain distance, then co-existence between GM and non GM fields is possible. And that 'certain distance' not less than 20 meters."
- Green Peace insisted that the 0.9% contamination threshold mandated by the European Union is irrelevant, because many German corn processors and millers will not accept corn with GM contamination above 0.2% to 0.4%.

24 November, 2004 - The Scientist

Co-existence in UK

- The Supply Chain Initiative on Modified Agricultural Crops (SCIMAC) stewardship system operated in the UK on the Farm Scale Evaluation program of GM crops was based on procedures for certified seed production and was largely supported by the farmers who used it.

Case Study Spain 2004

Type of production	**Area (ha)**
GM	58,000 (12%)
Conventional	409,000-409,900 (87- 88%)
Organic	100-1,000 (0.02%-0.2%)
Total	**470,000**

Brookes and Barfoot, 2004

Co-existence experience in Spain

No economic or commercial problems have occurred

- Mainstream buyers of non GM (starch) have no problem in sourcing non GM even in main areas where GM is grown (including from co-ops with GM and non GM grower members)
- Isolated instances of GM presence in organic crops cited in 2001 – lack of data to support claims – likely cause use of conventional seed (not tested)
    - Brookes and Barfoot, 2004

Co-existence requires co-operation

- Monitoring
  - Verify the models and predictions about cost, isolation standards, and generally to learn how the farming community copes with the requirements for keeping the product streams separated.
- Dialog
  - Strategy development takes place in a dialog between the scientific and technical community and all relevant stakeholders. (Denmark)
- Stewardship
  - Programs should consider interests of both GM and non-GM farmers. Existing product stewardship programs for non-GM crops in farming should be a starting point for developing stewardship schemes for GM crops. New techniques, genetic ID, agronomic practices (identity preservation, grower districts), grain handling, and market segmentation.
- Research
  - The scientific community should fill the knowledge gaps. Projects to validate models and guidelines, including long-term studies. Building up mechanistic, probabilistic, and predictive models of gene flow etc.
  - Methods for restricting gene flow by eliminating the fertility of pollen or seeds (apomixis, cytoplasmic male sterility, plastid transformation, Genetic Use Restriction Technology (GURT), etc.).

Co-existence requires co-operation

- Co-existence requires ‘give & take’ on all sides
- Emphasis should not all be placed on GM sector – the door swings both ways!

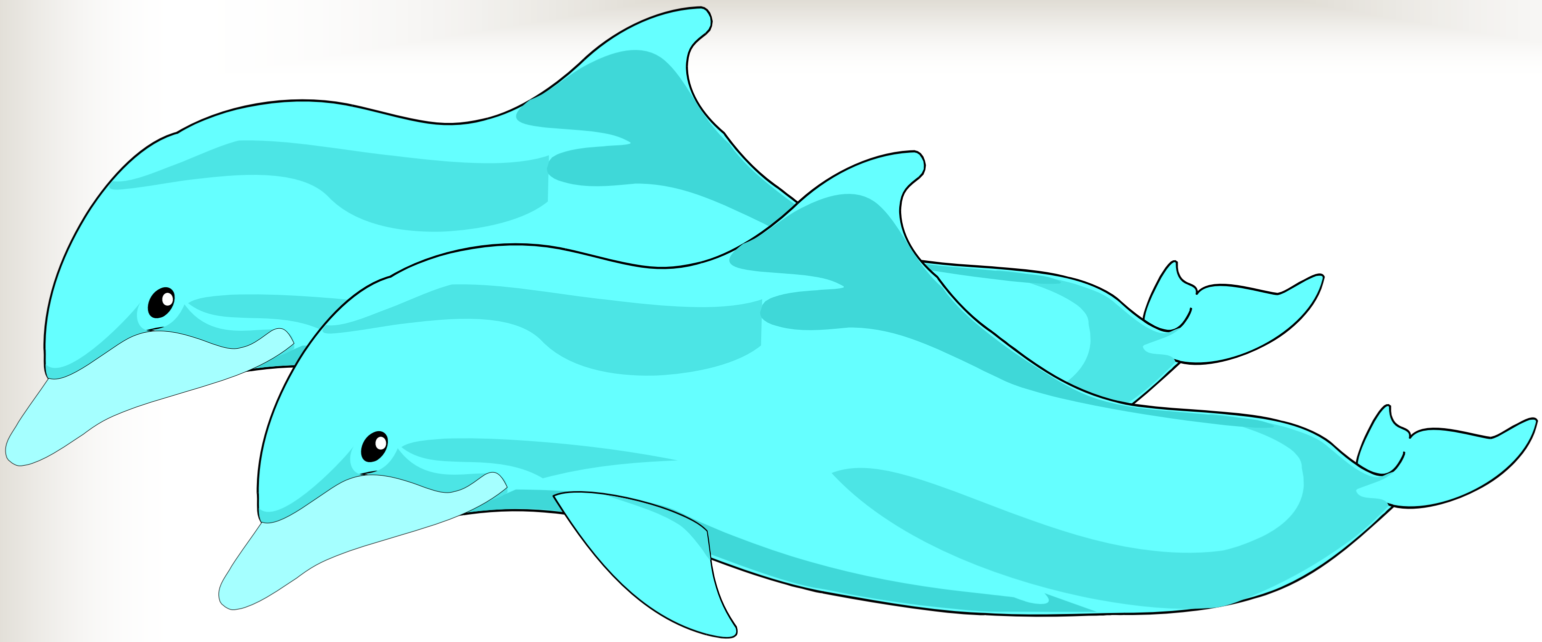
Co-existence guidelines: Implementation

Principle	Issues
Transparency & stakeholder involvement	Has there been any?
Use of science-based decisions	Rules based on robust scientific research and commercial experience
Do measures build on existing methods & practices?	Applying all seed production rules (eg, separation distances) is inappropriate to food & feed crops
Are the measures of an appropriate scale?	Are they practical, reasonable & based on science?
Are the measures proportionate?	Comes from being science-based or from commercial experience – no grounds for applying different rules regarding organic crops
Liability rules	Should be equitable & proportionate: measures like taxes, levies & fines should reflect possible size of economic losses & not be excessive

Brookes 2005

Conclusions

- Biotechnology holds much promise as useful tool to
  - improve qualitative and quantitative aspects of food, feed and fiber production,
  - reduce the dependency of ag on chemicals and fossil fuels
  - diminish over-cultivation and erosion
  - lower the cost of raw materials
  - all in an environmentally sustainable manner.
- Co-existence is nothing new: farmers have been implementing effective measures for many years on specialist crops
- GM & non GM crop co-existence has not been a problem
- Tools exist to implement co-existence – no need for government involvement
- Spain is a model of how co-existence works successfully – other member states should copy



“Although humans make sounds with their mouths and occasionally look at each other, there is no solid evidence that they actually communicate among themselves”