Lecture 5
Agricultural GM applications: Transgenic crops and GM ingredients in foods

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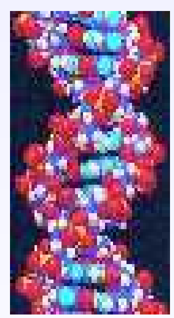
Overview of Presentation

- General introduction
- History of GM foods
- How GM foods are made
- Major debates and concerned stakeholders
- Evaluations from safety and ethics aspects
- Concluding Remarks

Formal Definition:

- “Genetically modified food”: "a food which is, or which is made from, a genetically modified organism and which contains genetic material or protein resulting from this modification".



From: EU Novel Foods Regulation

GM Technology

- **Earlier GM practises: "Selective breeding through hybridisation"**

  Two related organisms (plants or animals) are cross-fertilised and the resulting offspring has the characteristics of both parents. Breeders then select and reproduce the offspring that has the most desired traits.

  Disadvantages: random+long+tedious process, with species barrier

- **Modern practise of "genetic engineering": "Rec-DNA"**

  Direct intervention on the genetic make-up of an organism by introducing foreign DNA into its gene pool by means that would not occur naturally, enabling humans to create artificial organisms that are no longer the result of the natural means of the evolutionary development.

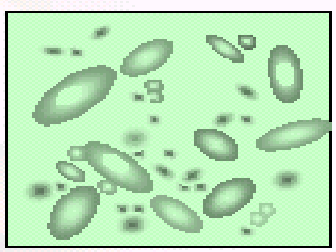
How GM technology is practised: The state of the art

GAO Accountability * Integrity * Reliability

What is Agricultural Biotechnology?

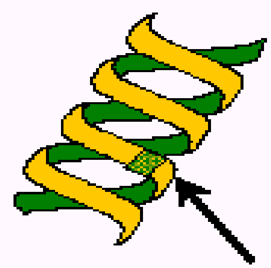
Agricultural biotechnology is a collection of scientific techniques, such as genetic engineering, used to modify plants, animals, or microorganisms by introducing in them desired traits, including characteristics from unrelated species. For example, traits may be introduced to facilitate pest management and improve yield or nutritional value.

Example of Agricultural Biotech Process



The microorganism Bacillus thuringiensis (Bt) produces an insecticidal substance.

→



Bt gene is inserted into corn (maize) DNA.

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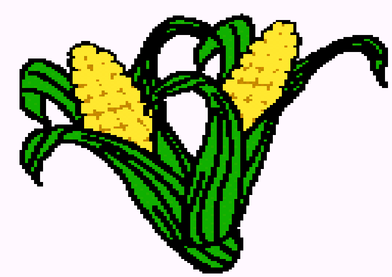
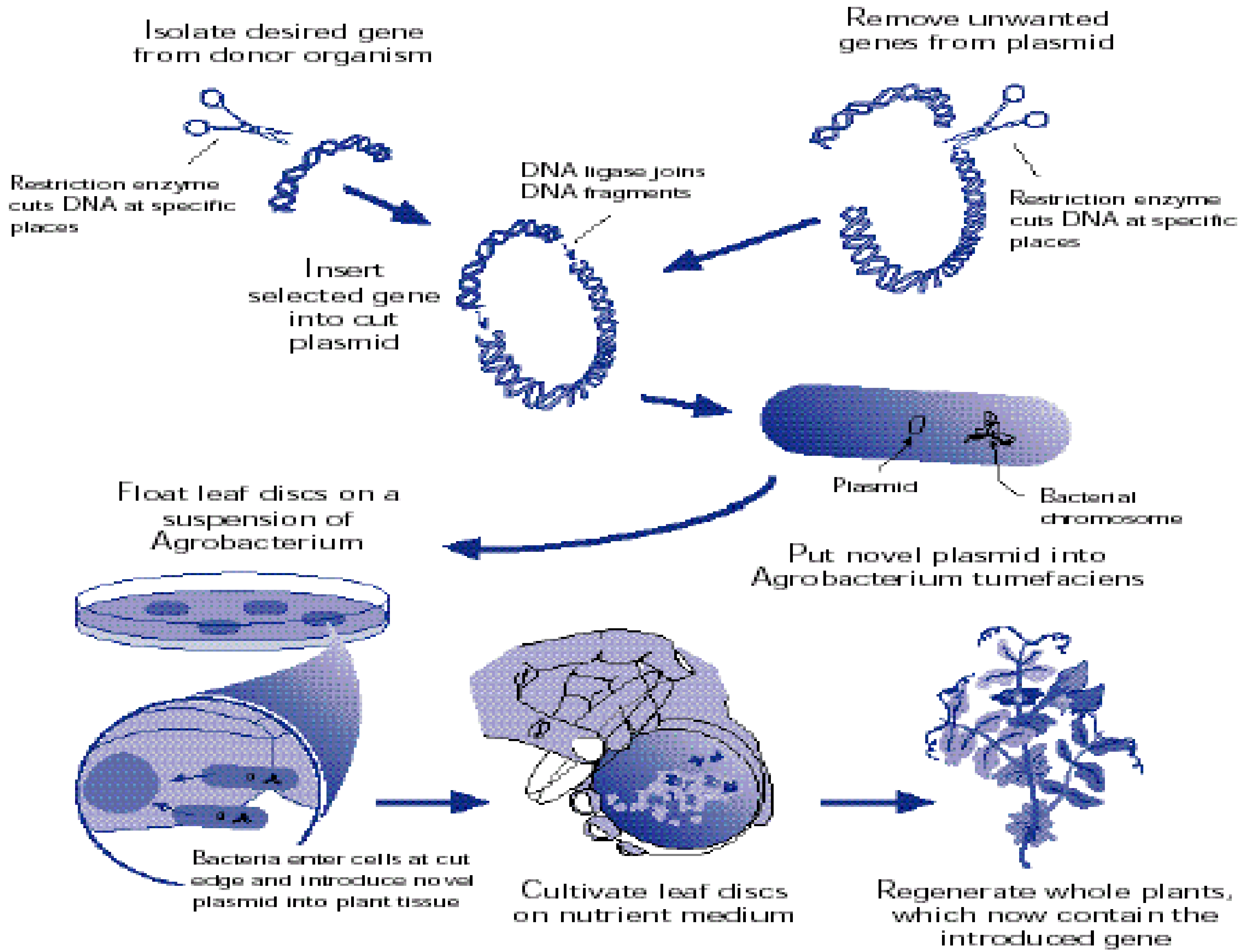
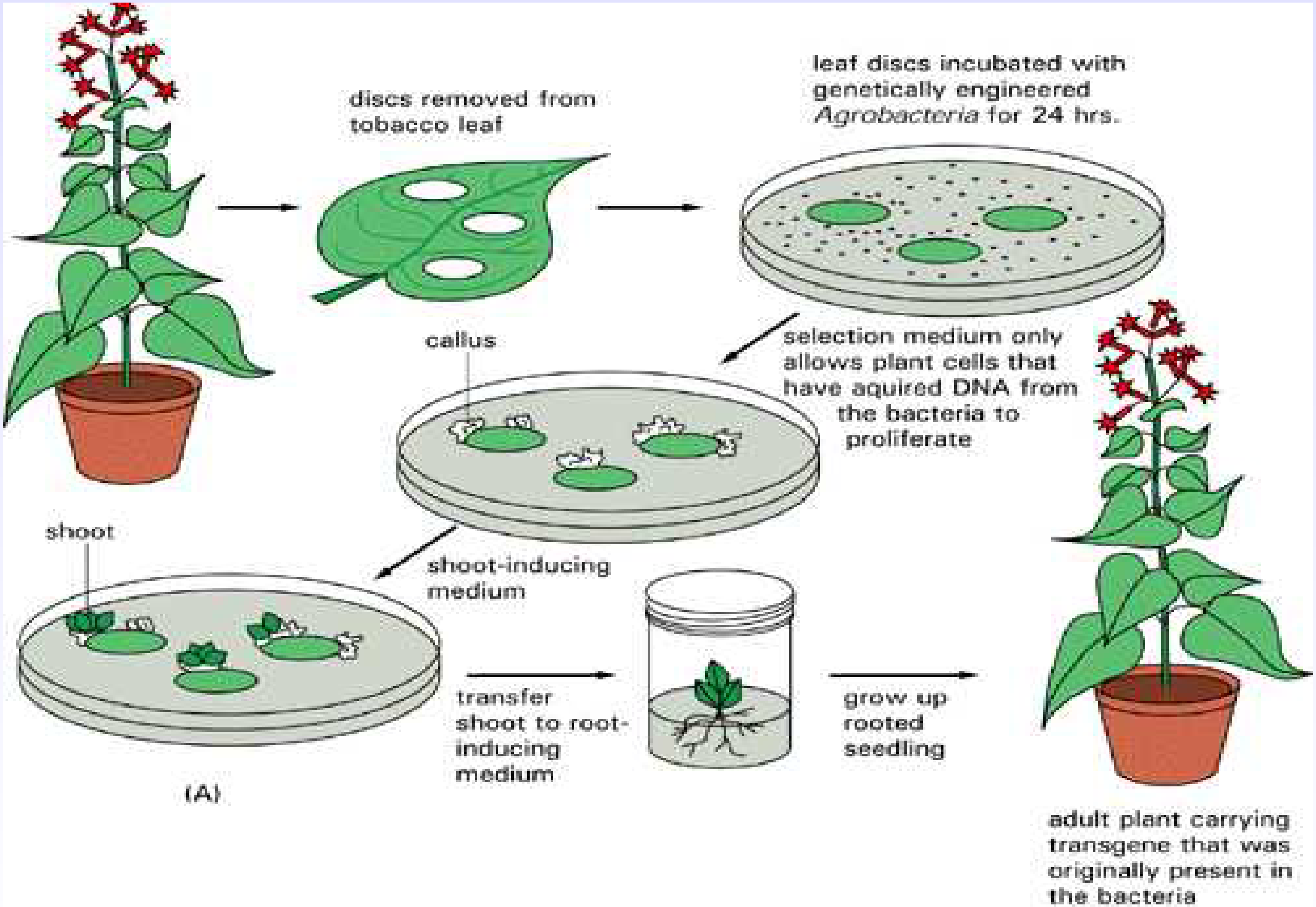


The resulting corn variety (Bt corn) produces its own insecticide, reducing the need for farmers to spray pesticides.


Isolate desired gene from donor organism
Restriction enzyme cuts DNA at specific places
Remove unwanted genes from plasmid
Restriction enzyme cuts DNA at specific places
DNA ligase joins DNA fragments
Insert selected gene into cut plasmid
Plasmid
Bacterial chromosome
Put novel plasmid into Agrobacterium tumefaciens
Float leaf discs on a suspension of Agrobacterium
Bacteria enter cells at cut edge and introduce novel plasmid into plant tissue
Cultivate leaf discs on nutrient medium
Regenerate whole plants, which now contain the introduced gene


discs removed from
tobacco leaf
leaf discs incubated with
genetically engineered
Agrobacteria for 24 hrs.
selection medium only
allows plant cells that
have aquired DNA from
the bacteria to
proliferate
callus
shoot
shoot-inducing
medium
transfer
shoot to root-
inducing
medium
grow up
rooted
seedling
adult plant carrying
transgene that was
originally present in
the bacteria
(A)

The actual procedure of "GM" is a fairly low-technology: today it is possible to realize it even in some high school science laboratories in the USA.

The very precious "know-how", however, is not in how the actual procedure is applied, but in the modern computer databases containing huge amounts of sequence data from the genome projects which make the task of identifying the genes with particular desired characteristics far easier than could ever be imagined in the past.

The "dilemma" here is: this data is not readily available to all nations or all firms, but solely to a few multinational firms who have heavily invested in the field of biotechnology.

Historical Background

- **1970's**: First agricultural GM applications in the laboratories
- **1984**: Introduction of first generation (**producers' benefit oriented**) of field-scale GM products: transgenic plant crops improved for insect protection, herbicide tolerance, virus resistance, delayed or improved ripening i.e. *Bt* crops
- **1990**: GM food ingredients: brewer's and baker's yeasts, rChymosin and similar food enzymes
- **2000's**: Introduction of second generation (**Consumer-benefit oriented**) of GM products: Food raw materials and ingredients with enhanced/altered technological, nutritional and health properties

  i.e. vaccine-fruits, Vitamin-enriched rice, non-staling bread.

TABLE 1

A selection of GMOs that are currently available

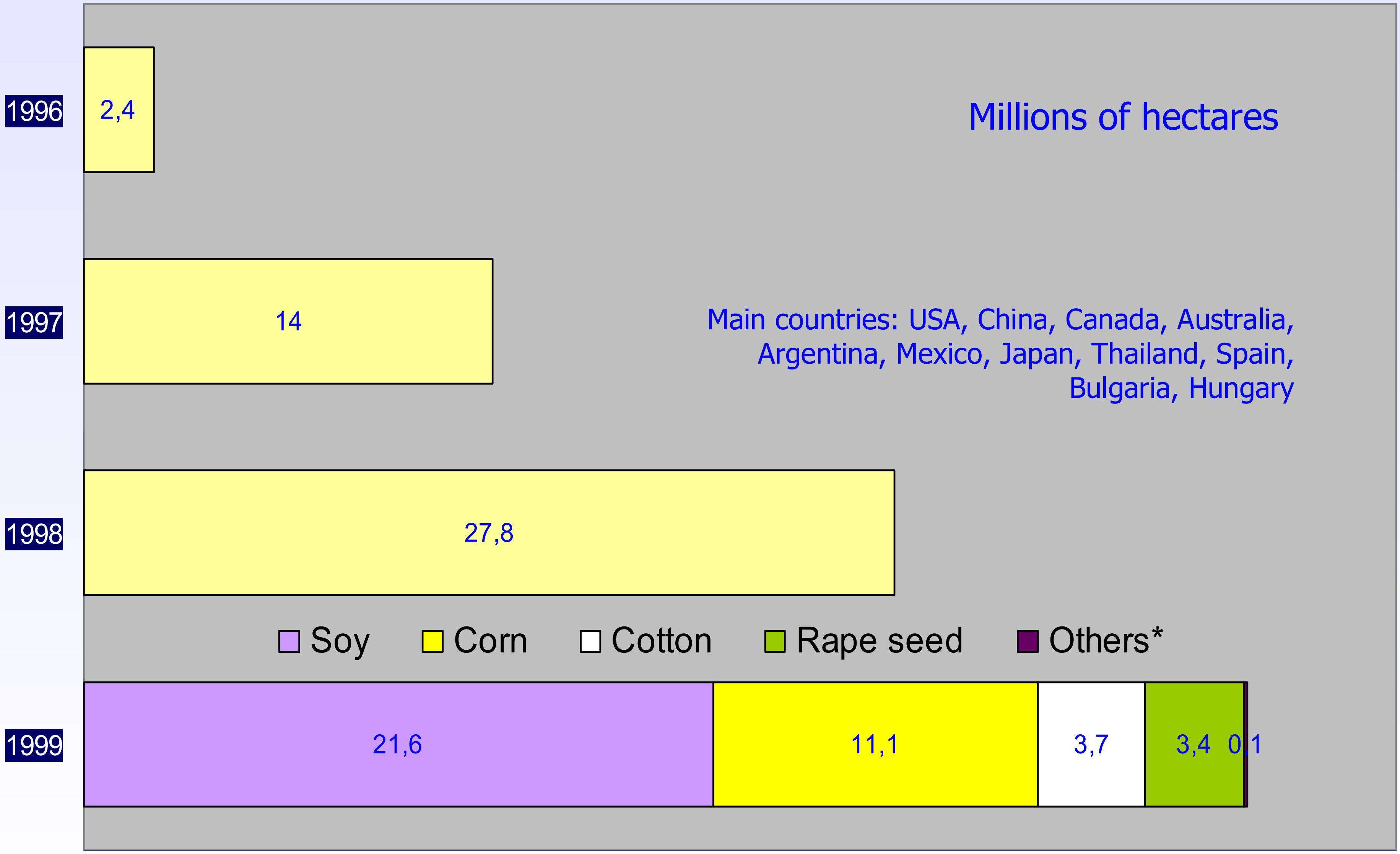
GMO	Genetic modification	Source of gene	Purpose of genetic modification	Primary beneficiaries
Maize	Insect resistance	*Bacillus thuringiensis*	Reduced insect damage	Farmers
Soybean	Herbicide tolerance	*Streptomyces* spp.	Greater weed control	Farmers
Cotton	Insect resistance	*Bacillus thuringiensis*	Reduced insect damage	Farmers
Escherichia coli K 12	Production of chymosin or rennin	Cows	Use in cheese-making	Processors and consumers
Carnations	Alteration of colour	*Freesia*	Production of different flower varieties	Retailers and consumers

TABLE 2

A selection of GMOs currently under development

GMO	Genetic modification	Source of gene	Purpose of genetic modification	Primary beneficiaries
Grapes	Insect resistance	*Bacillus thuringiensis*	Insect control	Farmers
Tilapia fish	Growth hormone	Arctic flounder/ salmon	Increased growth efficiency	Fish farmers
Poplar trees	Herbicide tolerance	*Streptomyces* spp.	Simplified weed control	Forest managers
Salmon	Growth hormone	Arctic flounder/ salmon	Increased growth efficiency	Fish farmers
Eucalyptus	Modified lignin composition	*Pinus* sp.	Pulp and paper processing	Forest managers and paper industry
Rice	Expression of beta-carotene	Daffodil *Erwina*	Added micronutrient	Consumers deficient in Vitamin A
Sheep	Expression of antibody in milk	*H. sapiens*	Fortified milk	Consumers

Land cultivated with transgenic plants -1
Whole world 1996-1999

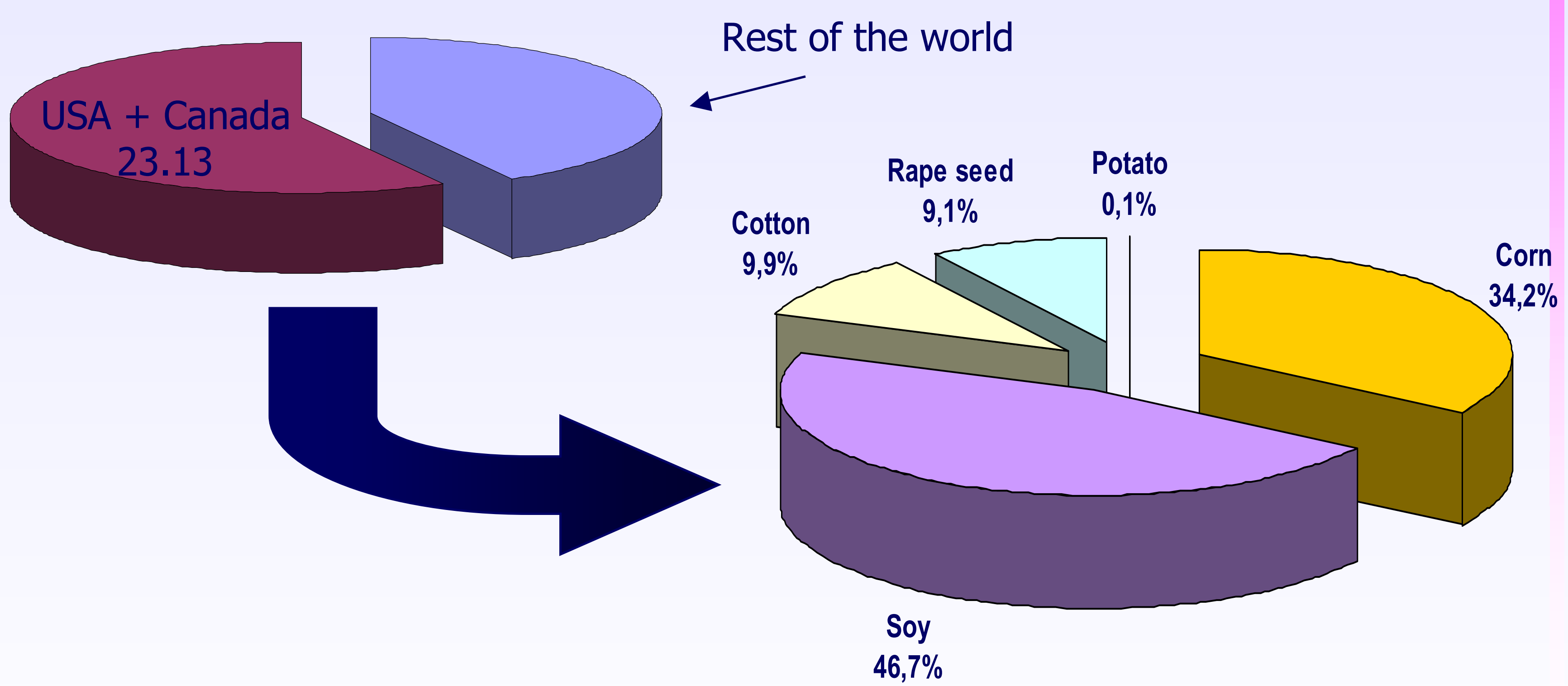


Source: Pogna, 2000 (based on ISAAA data)

* Mainly potato, zucchini, tomato

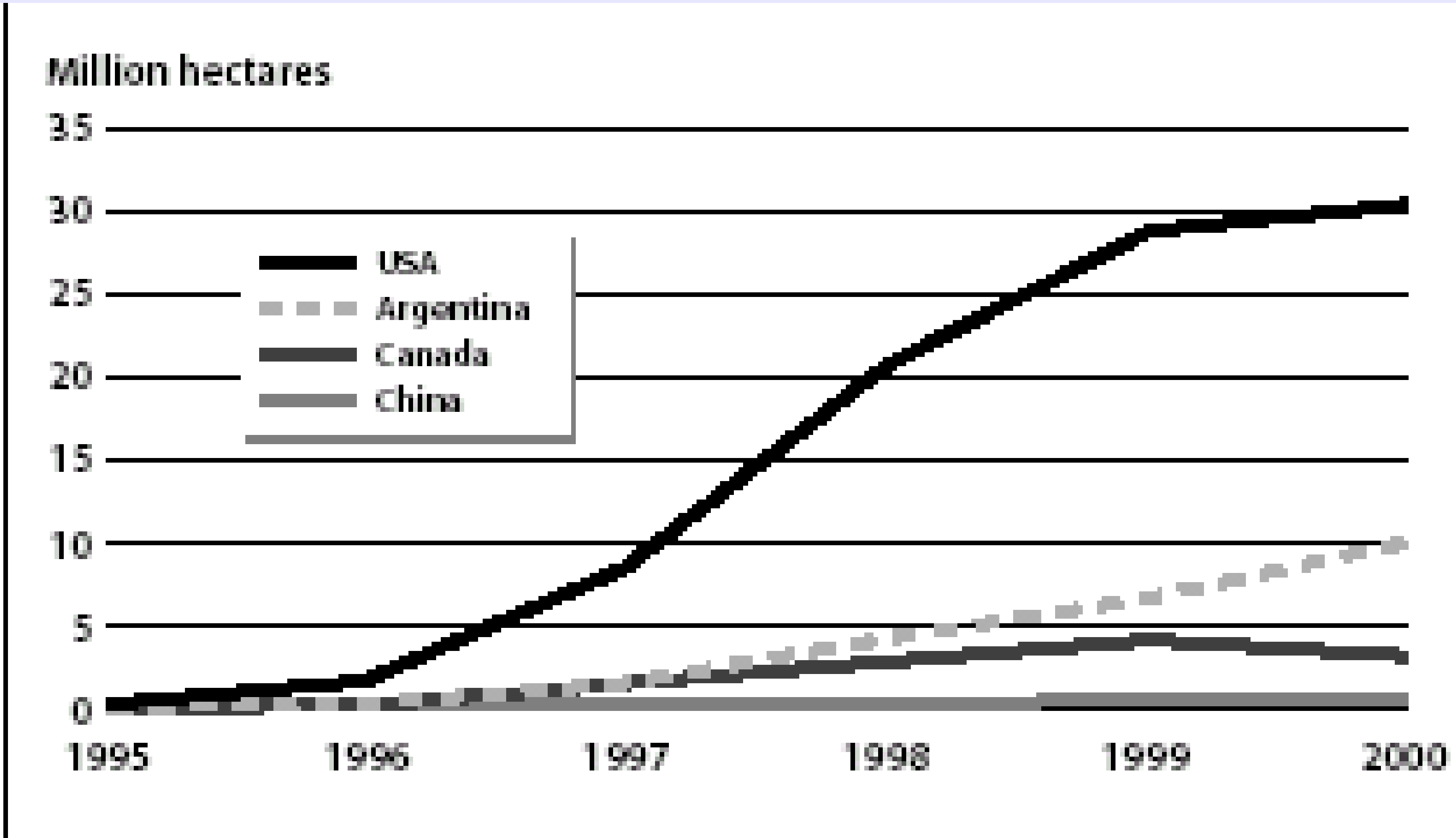
Land cultivated with transgenic plants-2
Whole world 1999

Total = 39.9 Millions of hectares



Source: Pogna, 2000

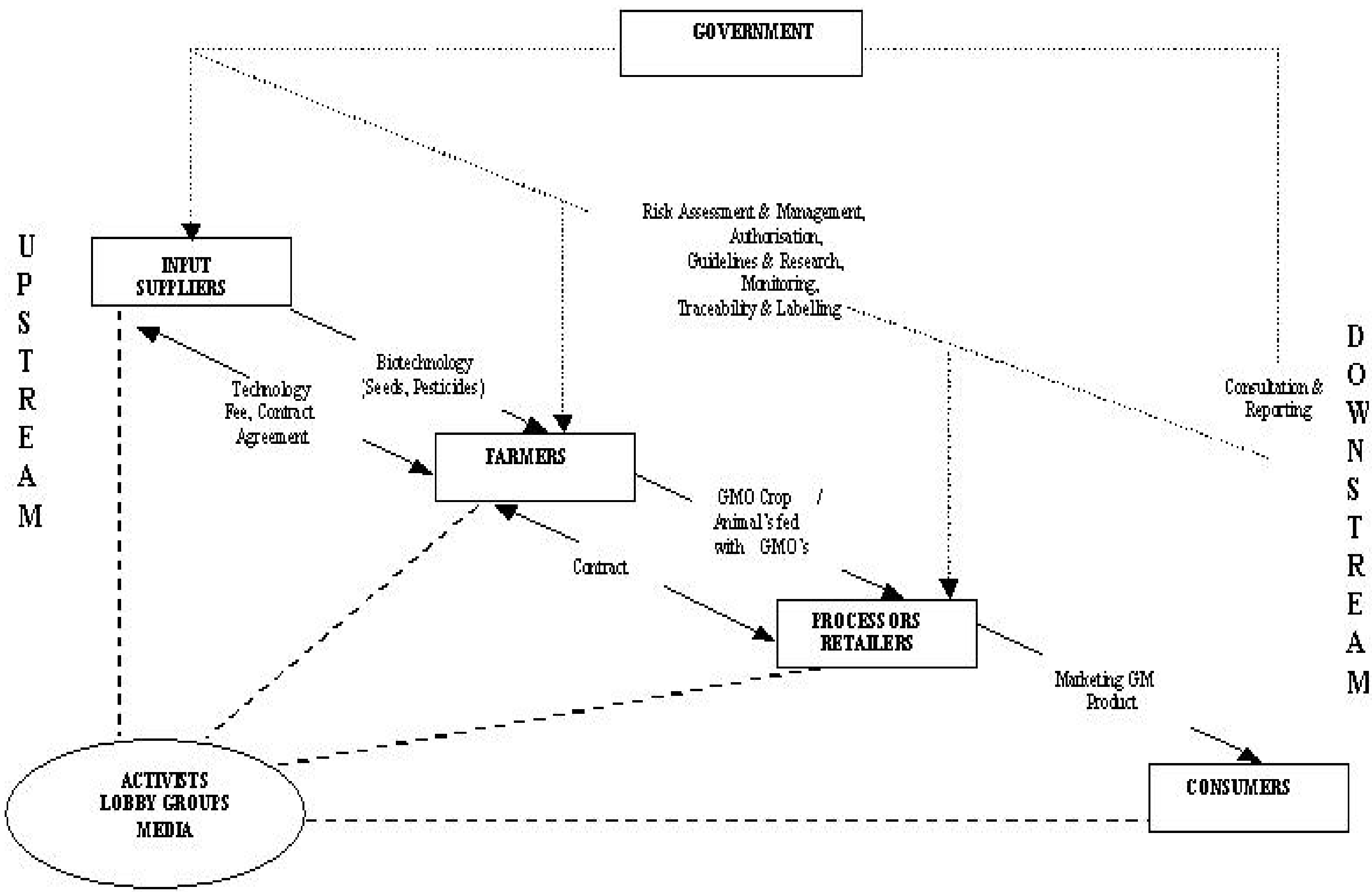
Land cultivated with transgenic plants-3
Whole world in 2000 (2002:>50 M hectares)



In 2000, these four countries accounted for 99 percent of the global transgenic crop area, mostly soybean, cotton, maize and canola.

Debate Issues

- Food safety and health implications;
- Environmental concerns (i.e. threatened bio-diversity and bio-safety over our planet)
- Setting efficient regulations on GMO's release(i.e.labelling issues)
- Patenting issues,intellectual property rights
- Ethical and social concerns


GOVERNMENT
Risk Assessment & Management,
Authorisation,
Guidelines & Research,
Monitoring,
Traceability & Labelling
Consultation &
Reporting
U P S T R E A M
D O W N S T R E A M
INPUT SUPPLIERS
Technology Fee, Contract Agreement
Biotechnology (Seeds, Pesticides)
FARMERS
Contract
GMO Crop / Animal's fed with GMO's
PROCESSORS RETAILERS
Marketing GM Product
CONSUMERS
ACTIVISTS
LOBBY GROUPS
MEDIA

Stakeholders(Actors)in debates

- **GMO suppliers: the "gene-splicing" transnational corporations(TNC) such as Monsanto, Du Pont, Novartis; the farmers who grow GM crops, the food-processors and food-retailers processing and trading GM crops and foods,**
- **Local governments of states who are responsible for regulating the new technology in their countries**
- **The "activist" NGO groups, media, "lobby" groups, ethicists**
- **Consumers**
- **International scientific community: Respective scientists both from industries and from academia and from international organisations (i.e.FAO;WHO;UPOV;WTO; OECD;ILSI)**

On "Food safety" and "health implications"

- **Opponents claim:**

GM may introduce :

-new antinutritional substances (i.e.natural toxicants) to the modified crop,

-decreases in nutritional value(vitamins,minerals)

-altered patterns of food allergies due to new proteins

- antibiotic resistance genes might be transferred from GM organisms to humans

- **Proponents argue:**

There is no current evidence to suggest that the process of genetic modification is inherently harmful. Many of the issues raised for foods produced using genetic modification are equally applicable to foods produced by conventional means. Nothing can be absolutely certain in a field of rapid scientific and technological development. Zero risk is unattainable in modern life.

On "Food safety" and "health implications"

Opponent's Example:

Work was undertaken at the Rowett Institute by Dr Pusztai, in which potatoes were genetically modified to express an insecticidal lectin protein.

Dr Pusztai argued that consumption of these genetically modified potatoes resulted in depression of the immune system.

Proponent's Claims:

- **The Royal Society, after reviewing Pusztai's work, concluded that the work appeared to be flawed in many aspects of the design, execution and analysis and that no scientific conclusions should be drawn from it since there was no convincing evidence of adverse effects due to the GM potatoes studied.**

How safety is assessed

- **Present Approach:**
  ByWHO&US:"Substantial equivalence"

The GM food is compared to its conventional counterpart and consideration is given to both the intentional effects of the modification and also to any possible unintended secondary effects.

This comparison involves the assessment of :

-Aagronomic data derived over a number of generations (such as crop height, yield, flowering pattern, disease resistance and climatic tolerance) ,

-Compositional information on nutrients (proteins, fats, carbohydrates, vitamins and minerals)

- Possible toxicants in both the plant and any derived food product.

- **Recommended Approach**
  By EU: "Precautionary principle"

- **Risk assessments should include detailed description of what the food is and how it is produced; a history of any possible adverse health effects linked to the organism being modified;**
- **a detailed description of the genetic modification process; an evaluation of any possible nutritional effects of the modified food;**
- **an evaluation of any toxicological effects of the modified food; an evaluation of any adverse microbiological effects of the modified food;**
- **an evaluation of any data on people eating the modified foods under controlled conditions; the amounts of the GM food that people are likely to consume, including both average and extreme consumption levels**

Outcome of The EU-US Biotechnology consultative forum: "Precautionary Principle"

"Precautionary decision-making process" requires:

- **Taking action proportionate to the nature of the potential risk, imposing more stringent restrictions on risks that could have irreversible, catastrophic consequences for future generations than against risks with modest repercussions.**
- **Applying more stringent limits on risks that cannot be reversed easily. As the risk of irreversibility rises, mandatory monitoring for specific outcomes should be more easily imposed. Conversely, controls may be relaxed when those concerns prove unfounded.**

- **Consideration of the costs that caution imposes, conserving scarce resources and making the benefits of new technologies available are important societal goals. Therefore the cost that caution imposes on the regulated industry should be a relevant, but never the dominant, consideration. When substantive uncertainties prevent accurate risk assessment, governments should act protectively on the side of safety.**

"Risk-Benefit Equation"

The EU-US Biotechnology consultative forum recommended that it is appropriate to consider,on a case-by-case basis, the potential risks and benefits of each new product, given the health and nutritional status of the people and the ecological and agricultural systems in a particular region of use.

Moreover,when weighing risks and benefits, the effects of introducing genetically modified products should not be compared solely to the status quo (e.g. present pesticide use), but also to other potential alternatives (e.g. bio-intensive pest management systems).

Example of a different "Risk-Benefit" evaluation made by EU:

Contrary to GM foods, pharmaceutical products derived from biotechnology are much more easily approved by the EU.

More than 200 new drugs derived frombiotechnology are currently in phase III of trials (in 1998), having met with almost zero protests.

GM Pharmaceutical Products already in use in EU

Product	Therapeutic use
Triacellueax	Paediatric vaccine against diphteritis, tetanus and pertussis
Mab Thera	Follicular lymphoma treatment
Huma Spect	Colon cancer treatment
Simulect	Renal rejection treatment
Zenepax	Renal rejection treatment
Infergen	Hepatitis C treatment
Forcaltonin	Malignant hypercalcemia treatment
Rescupase	Antithrombosis treatment
Berornum	Soft tissue sarcoma treatment
Refacto	Anti-haemorragic treatment
Regranex	Diabetic ulcers treatment

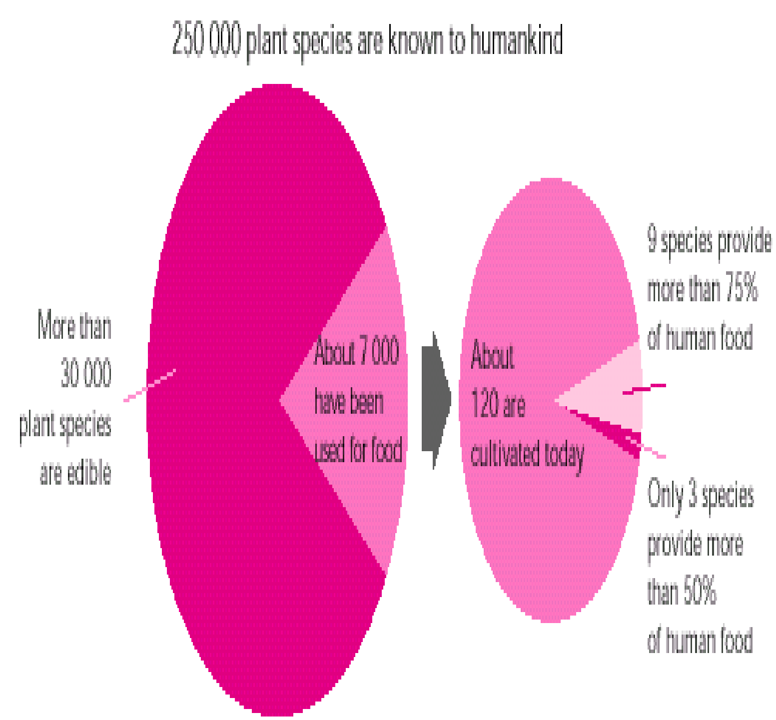
ON "BIODIVERSITY" and "ENVIRONMENTAL ISSUES"

- **Opponents' claim:**

  Man has picked up only about 40 of the tens of thousands of plants that grow on this planet for sustaining human life, and even a smaller number, just 9, accounts for more than 75 % of all the plant foods on the world markets.

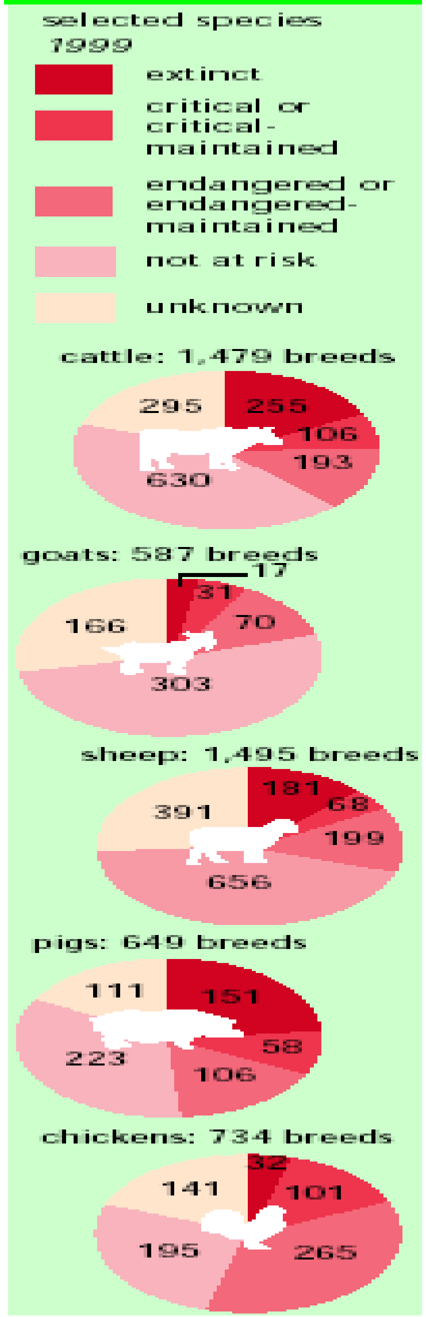
  A larger-scale landscape homogenisation with trans-genic crops only will increase and intensify the ecological problems already associated with monoculture agriculture and the erosion of what remains as bio-diversity will result in total loss of our insurance against any future unfavorable ecosystem changes.

Today's limited use of plant biodiversity for food production



Source: FAO.

Endangered domestic breeds

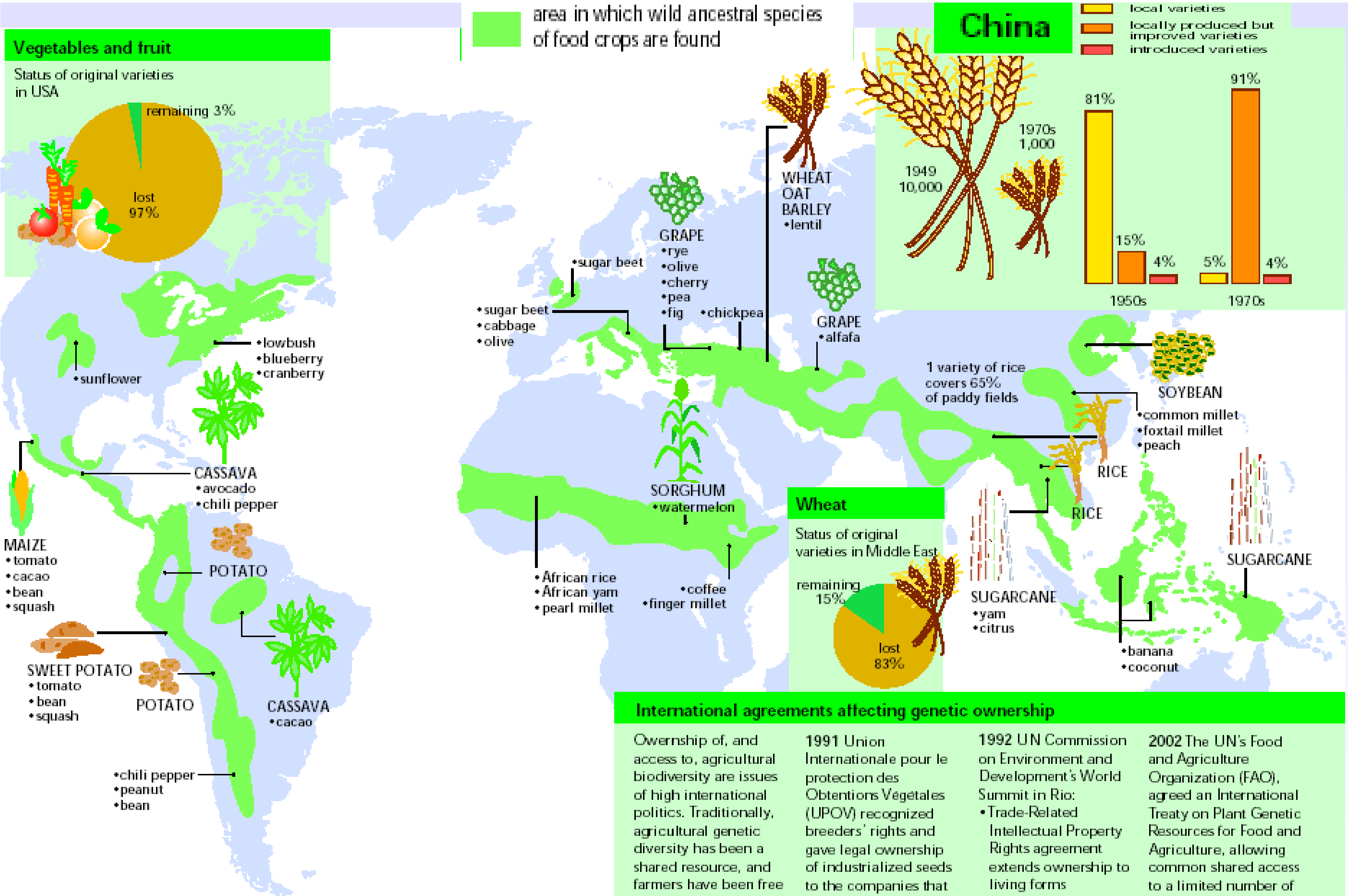


AGRICULTURAL BIODIVERSITY includes not only the animals and plants used for food, but the diversity of species that support food production – micro-organisms in the soil, pest-predators, crop pollinators – and the wider environment within which the agricultural ecosystem is located.

The genetic diversity of our food has arisen from a 10,000-year process in which wild species have been selected and bred to create the domesticated varieties used today. The regions where these developments took place are defined as centers of diversity of specific crops and related wild species. Such diversity is important because it provides a pool of genes that have developed natural resistance to pests and other environmental stress over time, and will help to ensure the future survival of key food crops. Relying on a single variety of crop to provide food makes a population vulnerable to pests and disease.

But the genetic diversification of food crops and animal breeds is diminishing rapidly. At the beginning of the 21st century it is estimated that only 10 percent of the variety of crops that have been developed in the past are still being farmed, with many local varieties being replaced by a small number of improved varieties, often involving non-native plants. Large numbers of animals are known to have become extinct, and nearly a third of domestic breeds are threatened with extinction. A quarter of the world's fish stocks are being fished above sustainable levels.

Privately and publicly owned gene banks – such as those of the Consultative Group of International Agricultural Research centers (CGIAR) – conserve genetic material artificially. In regions relatively untouched by industrial farming practices, however, a huge variety of crops is still in use. Indigenous farmers in Peru, for example, cultivate 3,000 different varieties of potato, while 5,000 varieties of sweet potato are cultivated in Papua New Guinea. But many areas of genetic diversity in the wild are under threat from "contamination" and domination by introduced varieties, including genetically modified crops.



International agreements affecting genetic ownership

Ownership of, and access to, agricultural biodiversity are issues of high international politics. Traditionally, agricultural genetic diversity has been a shared resource, and farmers have been free to save seeds to use in future plantings, but a series of agreements from the 1990s has jeopardized this free access to food crops.

1991 Union Internationale pour le protection des Obtentions Végétales (UPOV) recognized breeders' rights and gave legal ownership of industrialized seeds to the companies that developed them.

1992 UN Commission on Environment and Development's World Summit in Rio:

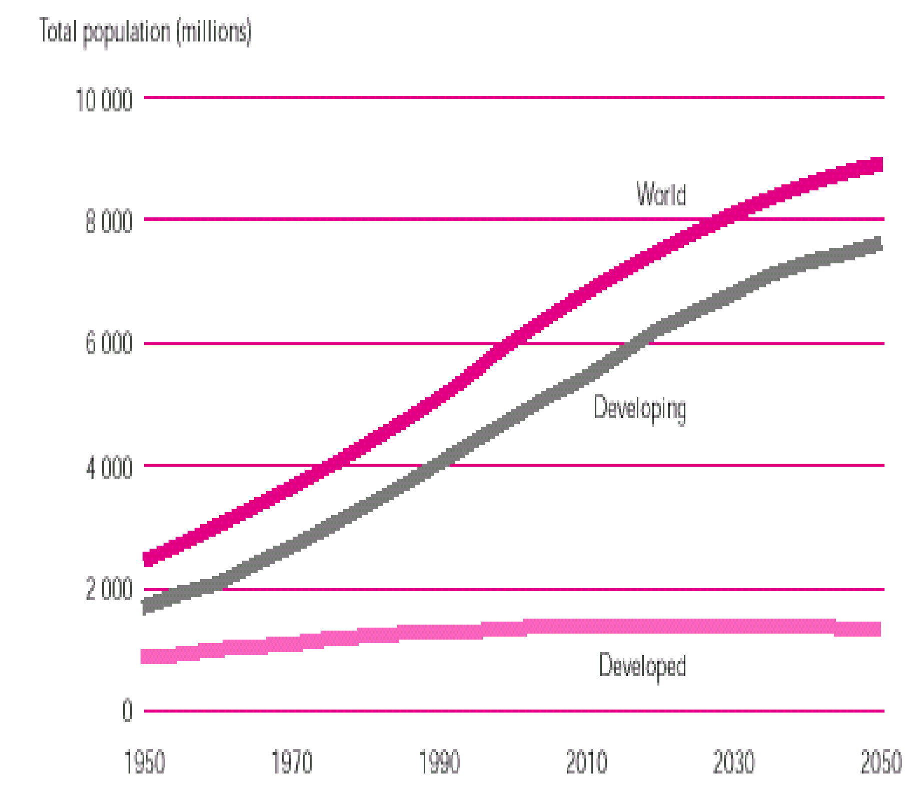
- Trade-Related Intellectual Property Rights agreement extends ownership to living forms
- Convention on Biological Diversity recognized national sovereignty over key genetic resources.

2002 The UN's Food and Agriculture Organization (FAO), agreed an International Treaty on Plant Genetic Resources for Food and Agriculture, allowing common shared access to a limited number of important crop varieties (subject to final approval by the signatories at their respective national levels).

On Food Security

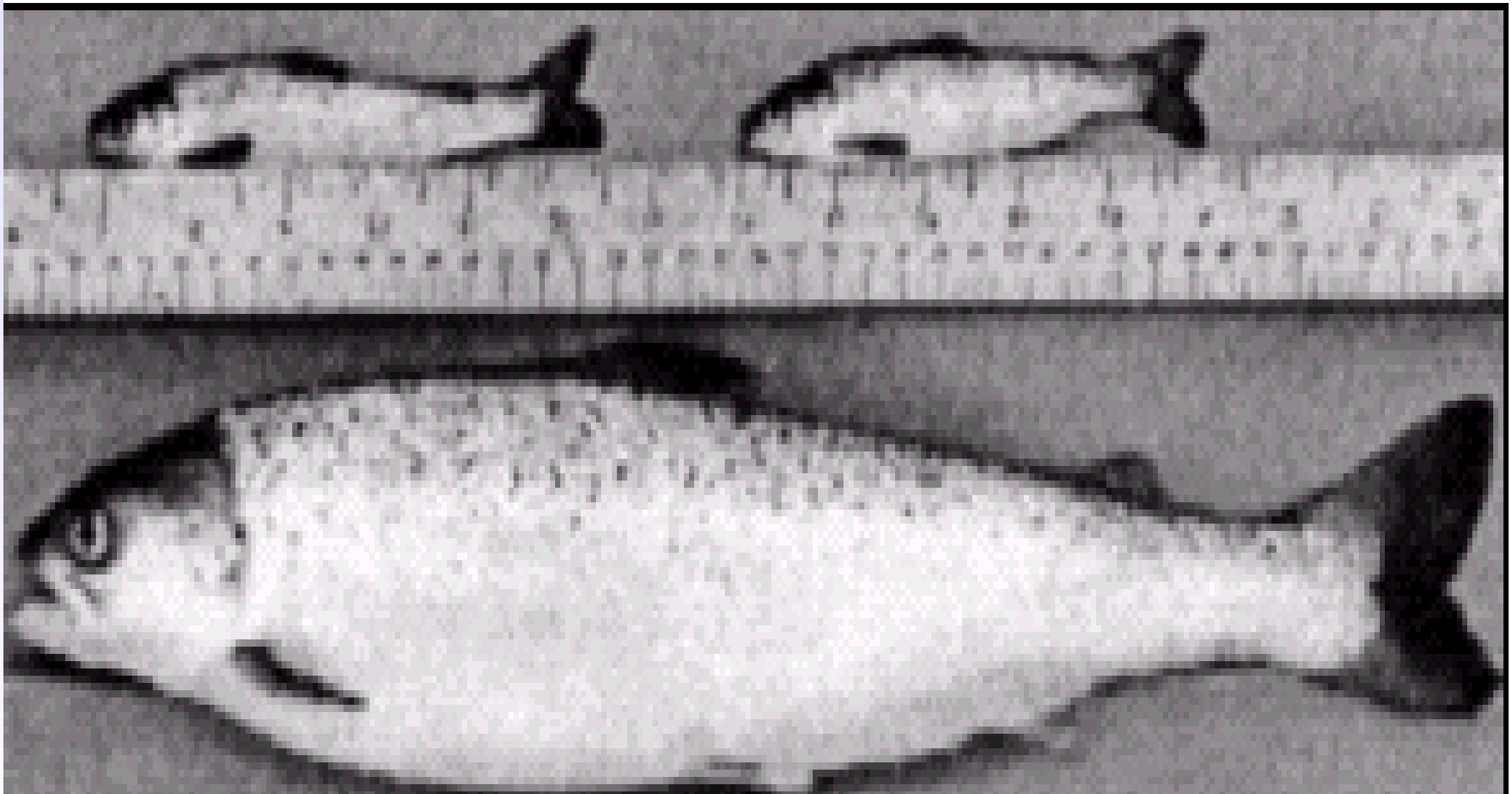
- **Proponents'arguement:** The world's population is continuing to grow and is projected to reach 10 billion by the year 2050, a doubling to be observed mainly in the poorer nations, calling for a parallel doubling of world food production. Given the constant acreage of arable land over our planet, genetically modified plants have the highest potential for increasing the productivity of traditional agricultural crops. The "GMO" era will increase world agricultural productivity, thus enhance food security, and move agriculture away from a dependence on chemical inputs, helping, moreover, to reduce the current environmental pollution problems.

Projected population growth



Source: FAOSTAT, 2000.

Example for Proponents' Claims



This transgenic Atlantic salmon, measured against control siblings, shows biotechnology's potential to increase food supply.

Agroecologists' Claims:

"Social and Ethical Issues"

"The real cause of hunger in lesser developed countries is not 'deficiency of food' but is their poverty, thereby their inequality and lack of access to food and land. Here in those countries, too many people are too poor to buy the food that is already available on earth since wealth is very poorly distributed and/or they lack the land and resources to grow their foods themselves.

Thus GM crops is not a solution. Instead, social processes emphasising local community participation and empowerment should be encouraged through rural development approaches and low-input technologies thus increasing the productivity and profitability of the smallholder farm."

ETHICISTS and GM

The idea of "common morality" should apply:

"Ethics is about respecting others as individuals." KANT

Respect for	WELLBEING (HEALTH & WELFARE)	AUTONOMY (FREEDOM/CHOICE)	JUSTICE (FAIRNESS)
THE BIOTA*	Conservation	Biodiversity	Sustainability
PRODUCERS	Adequate income & working conditions	Freedom to adopt or not to adopt	Fair treatment in trade and law
CONSUMERS	Availability of safe food	Respect for consumer choice (e.g. labelling)	Affordability of food

* Biota are 'the plants and animals of a region' (i.e. wildlife or the 'living environment')

"The Ethical Matrix"

From Report Of "The Food Ethics Council"

On “Labelling Regulations”:

Technical Problems:

- **Lack of global harmonization in respective regulations among trading countries:**

  1. Whether “to label”(EU) or “not to label”(US)

  2. “What ” to label: In defining the basis of the "tolerance" limits, should it be the % of transgenic DNA in final product, or the % of transgenic protein, or the % by weight of GMO ingredients in the final products?

- **Unavailability of standardised and easily applicable analytical methods for detecting and quantifying GM foods (absolute absence of rec-DNA camnnot be proved.)**

Differences in attitudes:

EU:

- **Novel Foods and Novel Food Ingredients (258/97), 15 May 1997.**
- **The EC regulation, 49/2000, setting the *de minimis* threshold for labelling requirements for food commodities containing more than 1% of any individual GM-derived ingredient that possesses any genetically modified DNA and protein.**

US:

- **No General Requirement to Label (If safe, why stigmatize the product?)**

  >70 Percent of Foods Contain GMOs

  (To Eat in America is to Eat GMOs)

- **U.S. Eats What It Exports: Jan., 2001: GM Food developer should notify FDA 120 days before putting on the market, and voluntary labelling for improved quality traits.**

On Patenting Issues (IPR's)

In GM foods area, two TRIPS (trade-related intellectual property) systems have been developed: those which enable the technology, and application patents which cover specific traits for improving plants but which are dependent on the enabling patents for their implementation.

- **Proponents claim:**
- **TRIPS (Trade-related intellectual property system) schemes are intended to provide a system that ensures a fair return on investments made in research and novel inventions.**

Withholding IP protection for GM innovations with the potential to improve agriculture will risk putting the related industry at a competitive disadvantage with firms which did not invest in GM research and slow their pace of further research .

- **Opponents argue:**
- **IPR's have potential for to foster monopolies on plant genetic material or germplasms. In developing countries, controversies include the implications of patents for food security and meeting the basic food needs of the poor.**
- **The divergences in opinion over whether the "World's plants and animals" should be patented at all also carry some ethical as well as practical implications, since access to any patented materials and processes is being severely restricted to the rest of the World by agro-chemical GM TNC's through their licensing agreements.**

"Privatisation of world's genetic resources"

Conclusion

- **Genetically-modified foods might have the potential to contribute to the solution of world's hunger and malnutrition problems, and to help protect and preserve the environment by increasing yield and reducing reliance upon chemical pesticides and herbicides.**
- **Yet there are many challenges ahead for governments, especially in the areas of safety testing, regulation, international policy setting and food labeling.**
- **"Genetic engineering" seems to be the inevitable wave of the future and we can not afford to ignore a technology that promises such potential benefits. However, we must proceed with caution to avoid causing unintended harm to human health and the environment as a result of using this powerful technology.**