



THE UNIVERSITY OF
WESTERN AUSTRALIA
Achieving International Excellence

GM Agriculture

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Outline

- Food from GE agriculture-should we worry?
- EU legislation
- Genome editing - CRISPR

Maarten J. Chrispeels

Food from genetically engineered crops.
Should we worry?



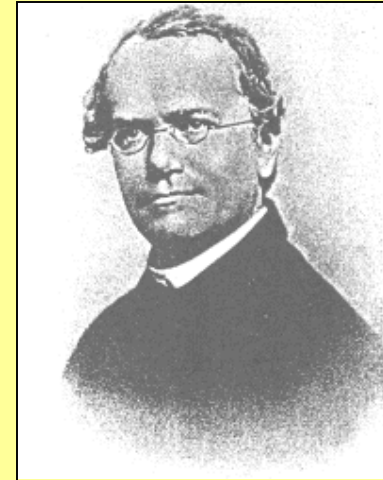
**Genetic change resulting from crop domestication
took 10,000 years.**

Teosinte (top) and corn or maize (bottom)

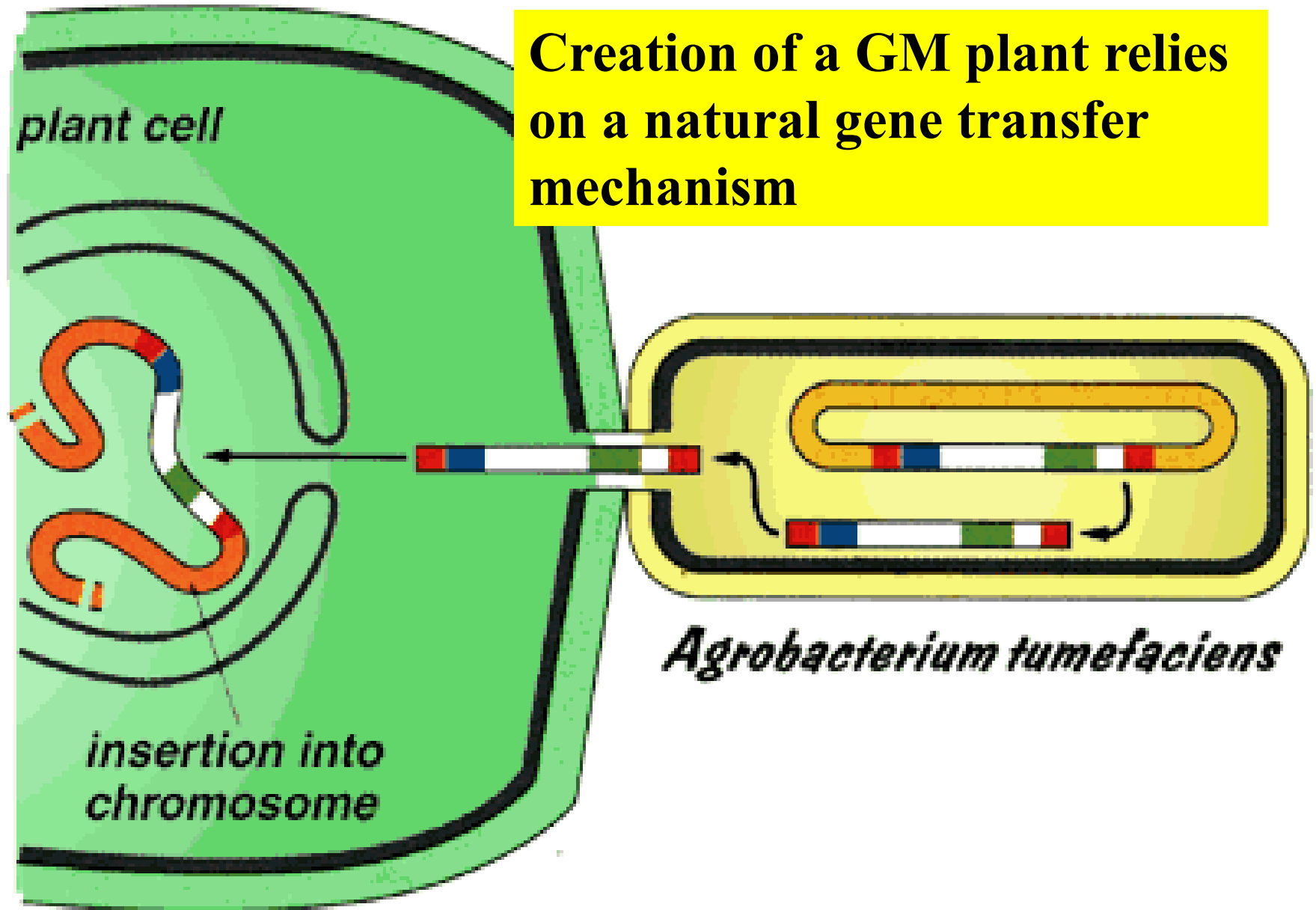


The March of Genetic Technology

- 1860 Mendel: making crosses, introducing genes**
- 1920 Discovery of hybrid vigor**
- 1950 Inducing mutations**
- 1960 Tissue culture and embryo rescue**
- 1980 Plant transformation and GMOs**
- 2000 Genomics**



Creation of a GM plant relies on a natural gene transfer mechanism



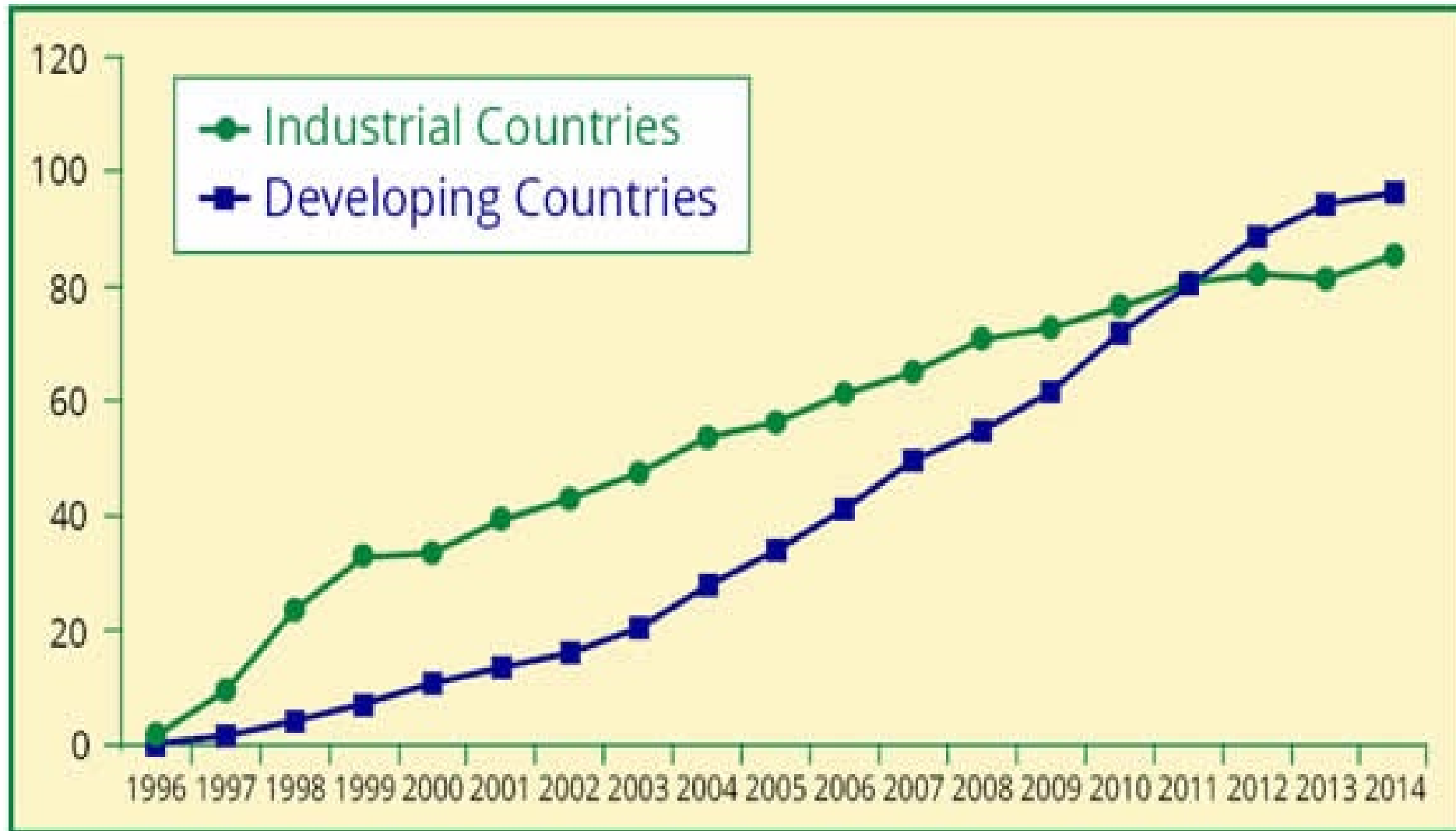
The scientific basis of all crop improvement is the identification of the genes that encode certain phenotypic characteristics.

Those genes can now be transferred more easily (via marker assisted breeding - no GM) or directly (through genetic engineering - GM)

Genetically-Modified Foods

- GM Crops grown commercially by 18 million of the world's 513 million small farmers on over 444 million acres spread over 28 countries (2015)
 - Up from 4.3 million acres in 1996
 - 175 million acres in U.S. (1/2 total land used for crops)

Figure 2. Global Area of Biotech Crops, 1996 to 2014: Industrial and Developing Countries (Million Hectares)



Source: Clive James, 2014.

Genetically-Modified Foods

- Top producers: United States, Brazil, Argentina, India (until 2012 moratorium), Canada, and China



Genetically-Modified Foods

- 85% of processed foods available in the U.S. today come from GM crops
 - Processed foods comprise 75% of world food sales
- Global value of GE seeds sold annually = \$15 billion
 - U.S. farmers pay average \$100 more per acre for GM seeds

Agricultural/Biotech Companies

- Monsanto
 - \$8.2 billion profit on \$15 billion revenues in 2015
 - 90% of GM seeds sold by Monsanto or by competitors that license Monsanto genes in their own seeds

Genetic Modification of Conventional Crops (US/Worldwide)

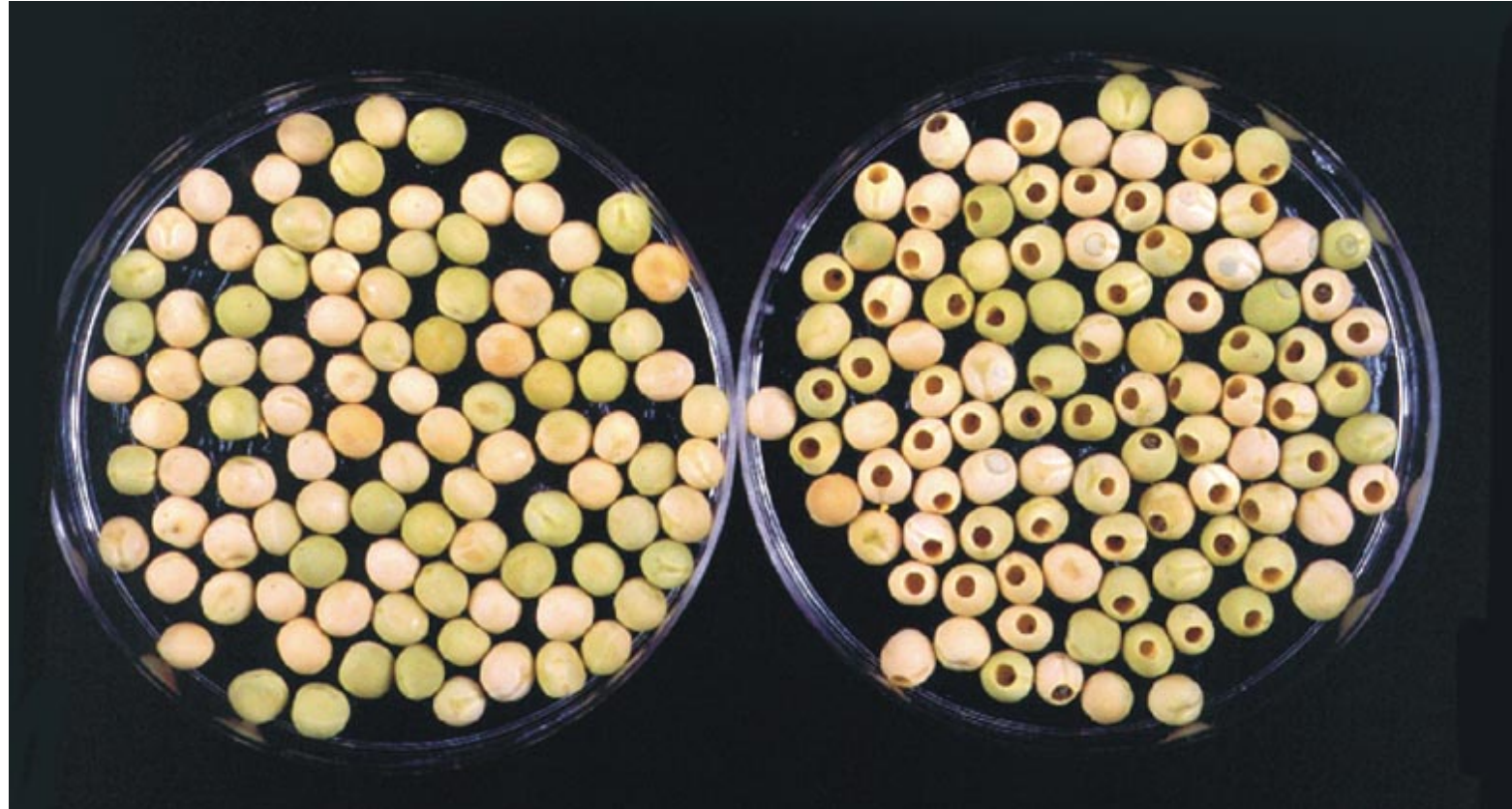
- 95% of sugar beets
 - Just over ½ of sugar comes from sugar beets (the rest comes from sugar cane)
- 94%/81% of soybeans
- 93%/26% of canola
- 90%/81% of cotton (oilseed rape)
- 88%/35% of corn
- Corn and soy cover over half of US cropland

Genetic Modification of Conventional Crops (US/Worldwide)

- Other crops
 - Rice
 - Tomatoes
 - Potatoes
 - Hawaiian papaya (resistant to ringspot virus)
 - “Arctic Apples” (slow-browning – genes from one plant virus and 2 bacteria, Inxtron)
 - USDA approved
 - Arctic avocados, pears, and lettuce planned

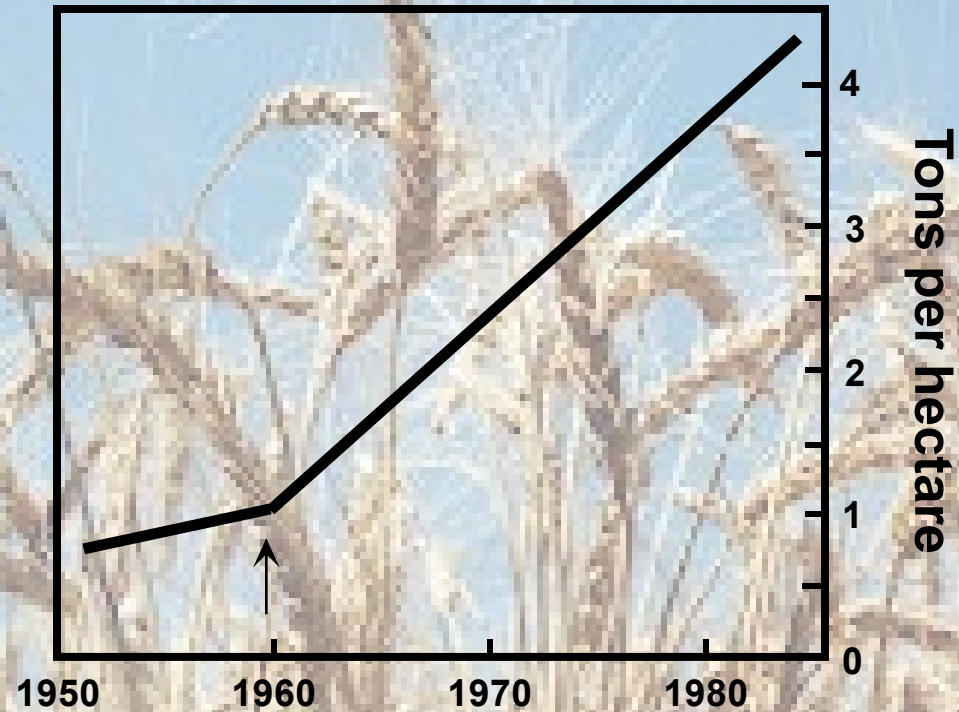
GM Agriculture - Advantages

Molecular agriculture makes new gene combinations possible



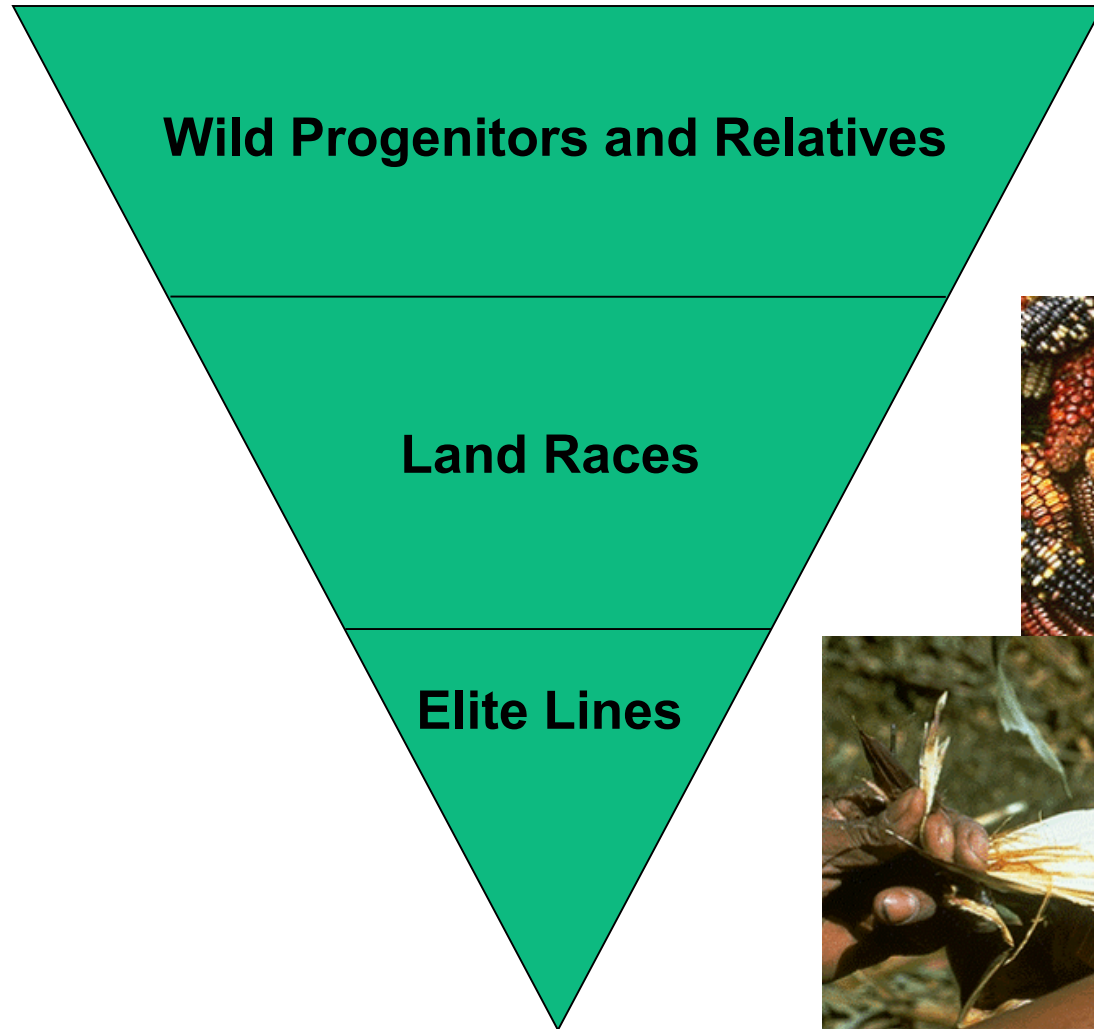
Peas (on the left) that make a genetically engineered bean protein are insect-resistant and do not need to be sprayed with pesticides.

Plant Breeding and Crop Yield



Wheat in Mexico

Agriculture has narrowed the gene pool and caused a loss of biodiversity



Some GM crops have the potential to mitigate the environmental impact of agriculture: less pesticide, less dust, more biodegradable herbicides

“Roundup” tolerant soybeans can be Planted with no-till procedures, which eliminate plowing (dust), Save water and use a biodegradable herbicide





What about their nutritional value and safety?



What are the main food issues in the US?
The # 1 safety issue is bacteria (6000 deaths per yr.)
The # 1 health issues are fat, sugar and salt

Golden



- Rice is a major staple food in Asia
- The outer oil-rich, nutritious aleurone layer is usually milled because it turns rancid upon storage in tropical areas
- The remaining endosperm lacks provitamin A (β carotene)

Vitamin A Deficiency in China

- The deaths of over 20,000 children each year from increased susceptibility to infection.

Cause: vitamin A deficiency

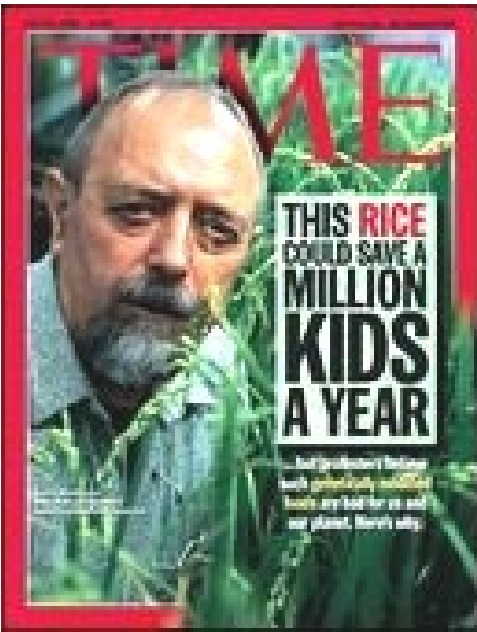
- Approximately 12% of China's children growing up with lowered immunity, leading to frequent ill health and poor growth.

Cause: vitamin A deficiency (the prevalence of vitamin A deficiency in children under 6 is estimated at 12%).

Vitamin & Mineral Deficiency: A damage assessment report for China. Micronutrient Initiative and UNICEF 2004

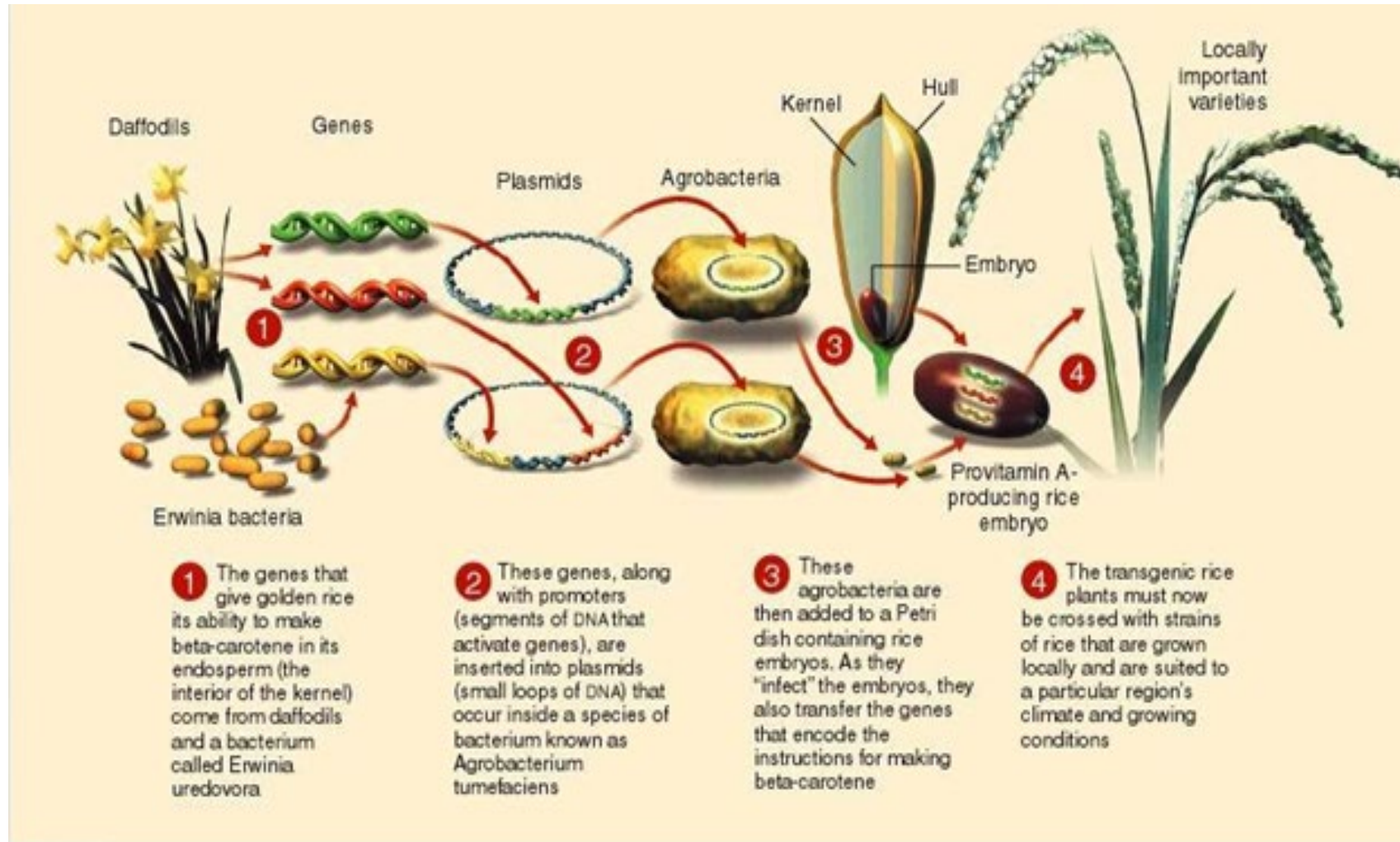
Golden Rice Project

- Started in 1982 by Ingo Potrykus-Professor emeritus of the Institute for Plant Sciences
- Peter Beyer-Professor of Centre for Applied Biosciences, Uni. Of Freiburg, Germany
- Funded by the Rockefeller Foundation, the Swiss Federal Institute of Technology, and Syngenta, a crop protection company.



- *Golden Rice* Humanitarian Board-responsible for the global development, introduction and free distribution of Golden Rice to target countries.

Golden Rice



“Not-So Golden” Rice

- Crop not yet adapted to local climates in developing countries
 - Types 1 and 2 utilize poorly-growing japonica rice, instead of indica rice
- Amounts produced minute: 3 servings of $\frac{1}{2}$ cup/day of original version provides 10% of Vitamin A requirement (6% for nursing mothers) – current version promises 1 bowl = 60% of daily requirement

“Not-So Golden” Rice

- B-carotene is a pro-oxidant, which may be carcinogenic
- Chinese children with vitamin A deficiency used for feeding trials of Golden Rice by Tufts University investigators (backed by USDA)
 - Done without preceding animal studies
 - Parents not informed re use of GM rice
 - Violates Nuremberg Code

“Not-So Golden” Rice

- Chinese Golden Rice Feeding Trial
 - Published in Am J Clin Nutr (2011)
 - Criticized in Nature (2012)
 - Am J Clin Nutr to retract article (2014)
- GM banana (Vitamin A) feeding trial planned for Iowa State students cancelled (2015)(unethical, would be illegal in Europe)
 - HarvestPlus’ traditionally bred sweet potato contains much more carotene

GM Agriculture - Concerns

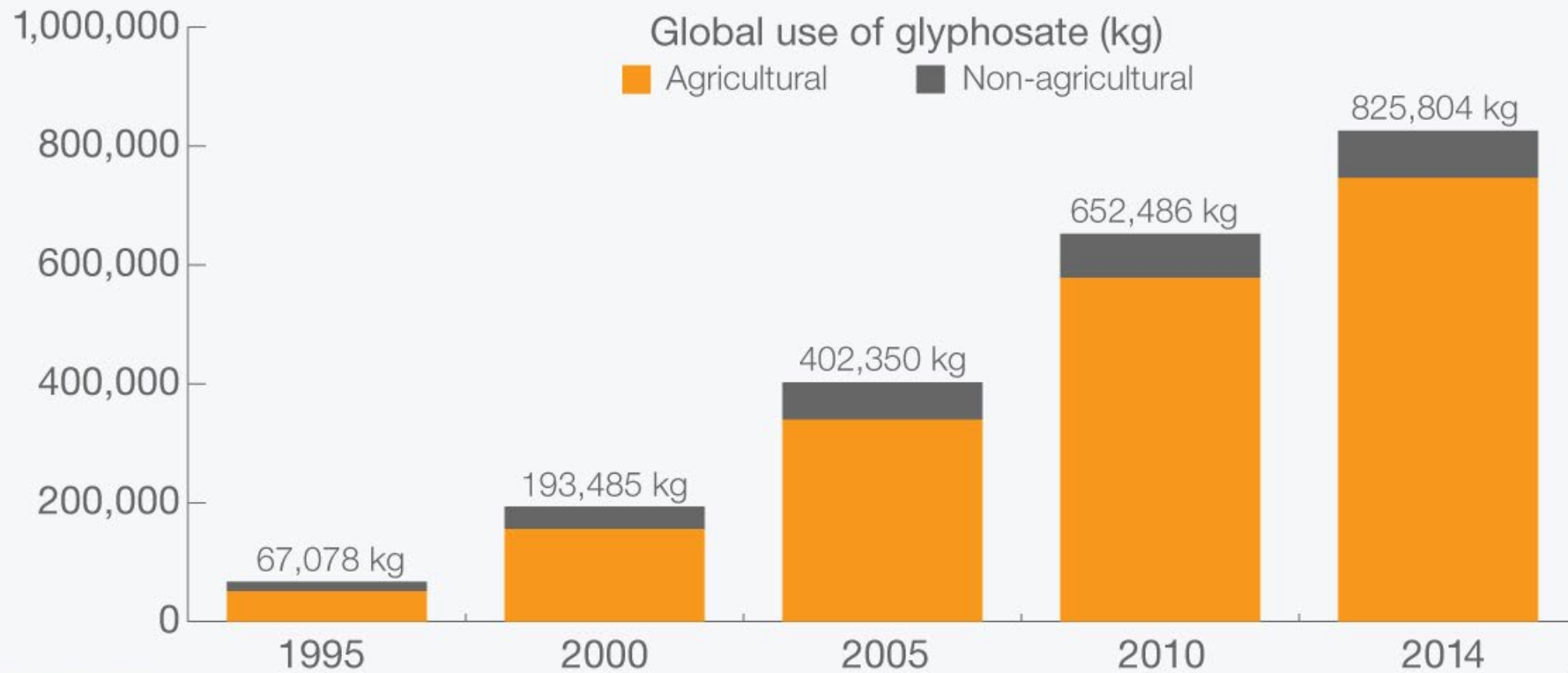
Health and Environmental Risks of GE Foods

- Increased pesticide use when pests inevitably develop resistance to GE food toxins
 - Reproductive and neurotoxic effects

Global use of glyphosate

Glyphosate is the main ingredient for Roundup, one of the world's most used herbicides.

Its use has increased significantly over the last decades.



Source: Environmental Sciences Europe (28:3)



ALJAZEERA

Herbicide Resistance

- International Survey of Herbicide Resistant Weeds (2016):
- 464 unique cases of herbicide-resistant weeds globally among 249 species
- Weeds have developed resistance to 22 herbicide sites of action and to 159 different herbicides
- Herbicide-resistant weeds found in 86 crops in 66 countries.

Herbicide Resistance

- At least 14 weed species in the US have developed glyphosate resistance, affecting over 60 million acres of farmland
 - (32 species worldwide)
- 2015: EPA announces management plan

Health and Environmental Risks of GE Foods

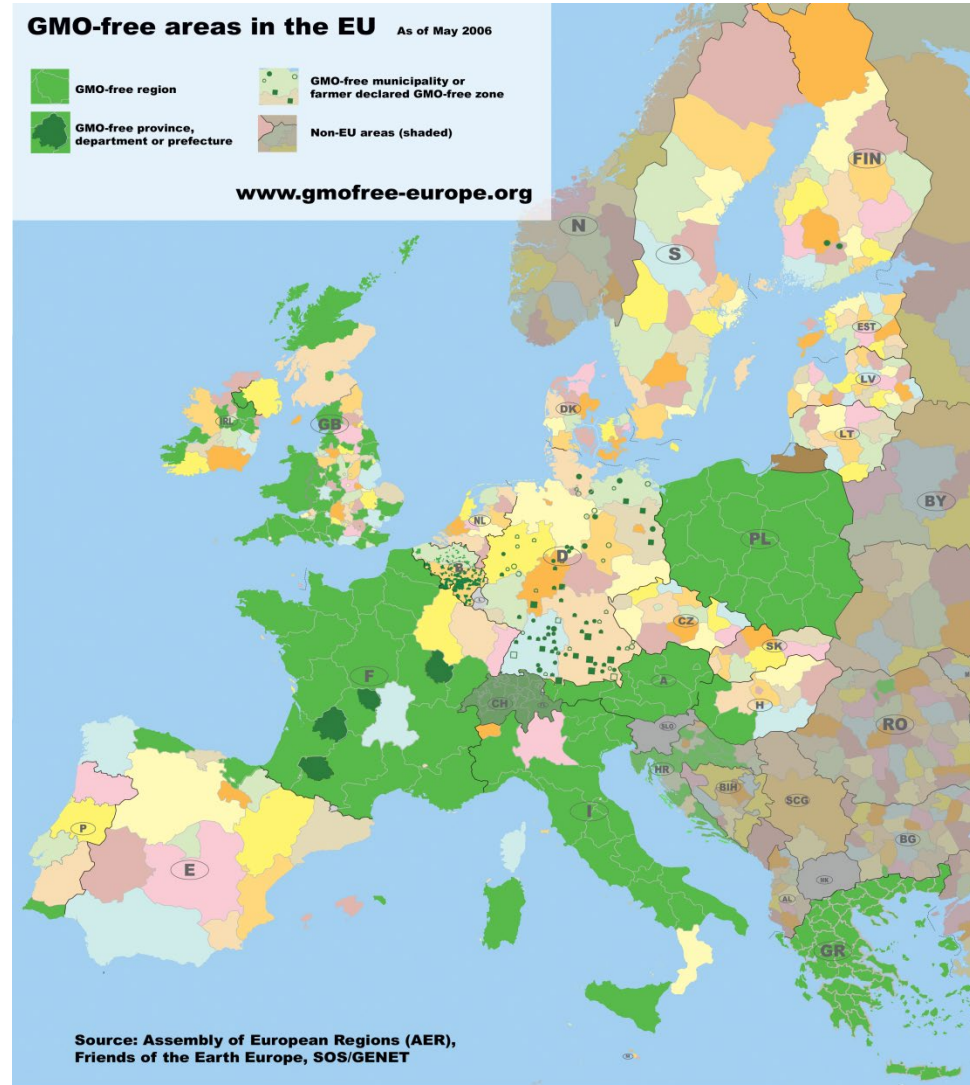
- Greater herbicide use
 - Glyphosate-tolerant plants require 14-20% more water
 - Glyphosate adversely affects root growth by altering local biota; reduces micronutrients necessary for human and animal health (e.g., dairy cows); enhances growth of aflatoxin-producing fungi
 - Aflatoxin causes liver cancer

GM free regions

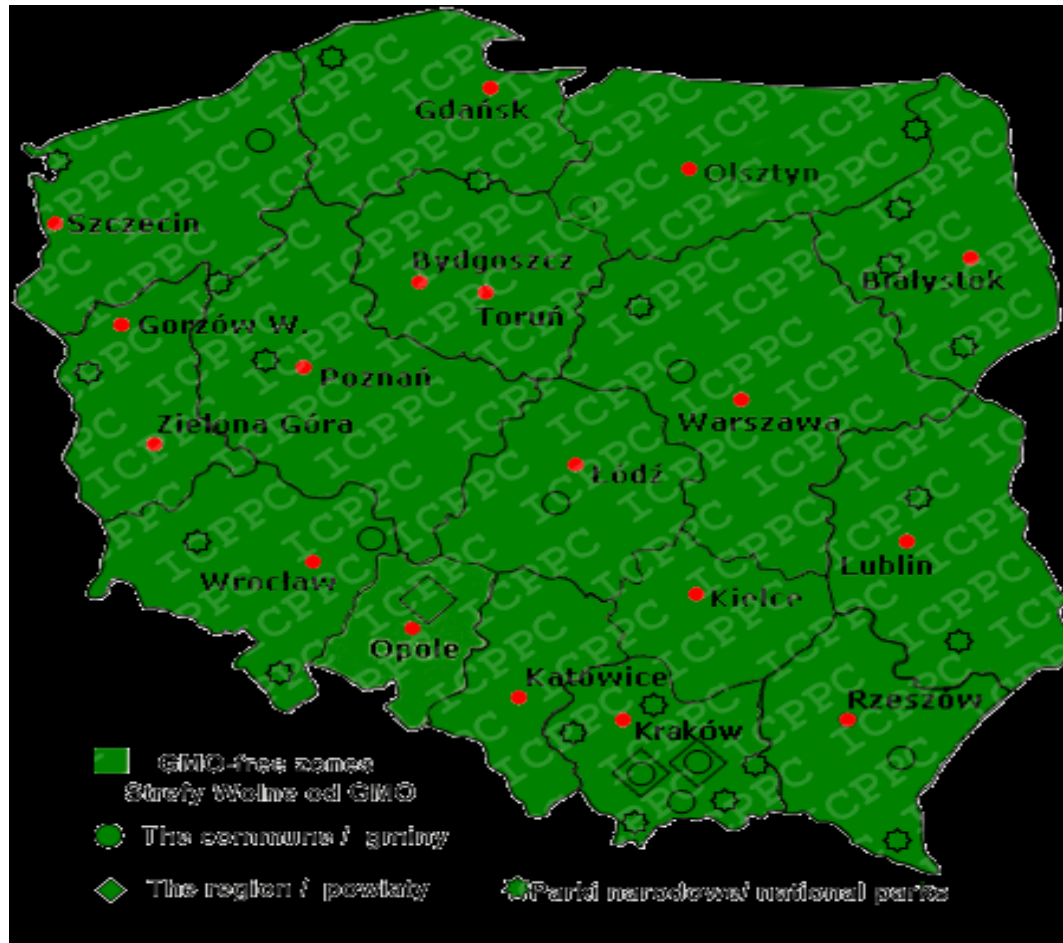
Opposition to GM crops in Europe

Clare Oxborrow
Friends of the Earth

www.gmofree-europe.org



Poland

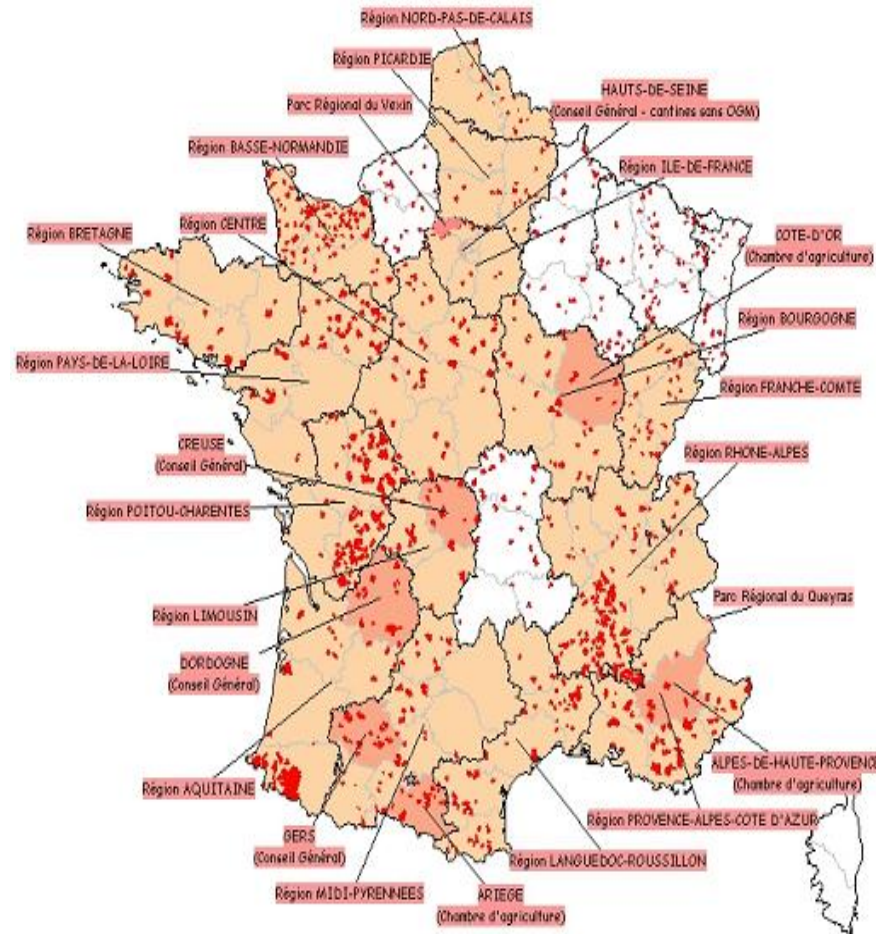


- **February 2006 – all regions declared GM-free**
- **Joins Austria and Greece: 100% GM-free**
- **Over 300 GM-free farms**
- **May 2006 – Parliament bans all GM seeds**

Austria – striving to be GM-free

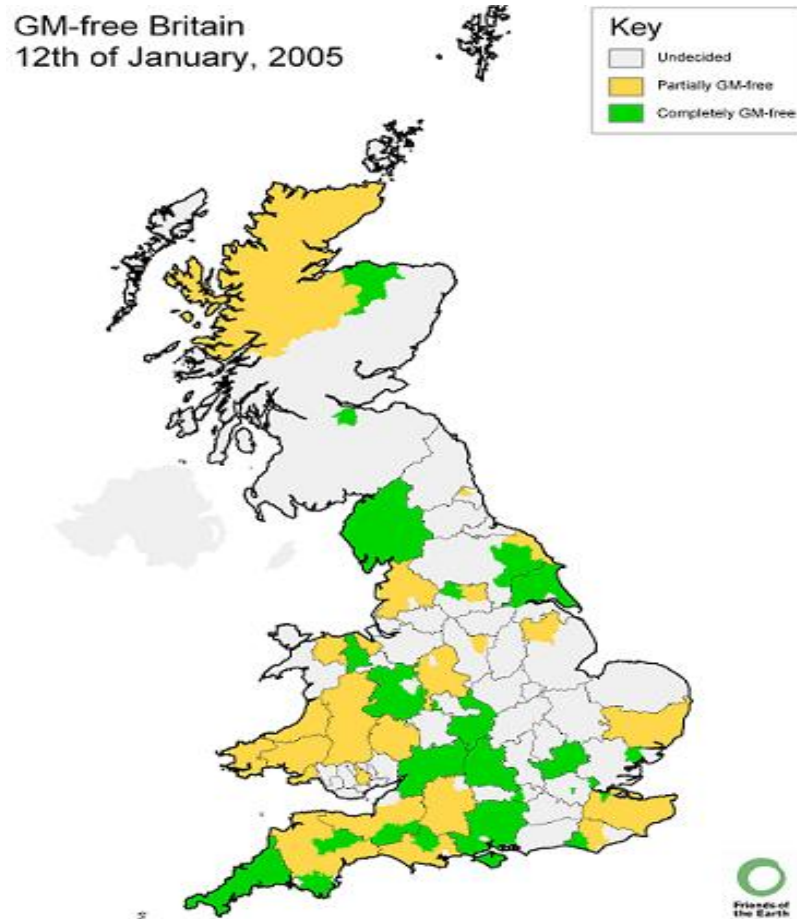
- 4 national bans (MON810 maize, GT73 oilseed rape, T25 maize & Bt176 maize)
- National law allows coexistence laws to be set at regional level (9 regions)
- 7 regions - government can forbid the release of GMOs if there is a danger of contamination of the neighbouring fields
- Styria – GM contamination must be prevented to 0.1%
- Upper Austria – precautionary law wanted to ban GMOs in agriculture for 3 years

France “No GMO in my municipality” campaign



- supported by 12 organisations
- 1250 majors issued declarations
- 15 regions and 6 departments

GM-Free Britain campaign



- Ban GM crops on council-controlled land
- GM-free policies for council services eg school meals
- Apply to prevent GM crops being grown (Art. 19 2001/18/EC)
- 60 local authorities, over 18 million people



Jurors give \$289 million to a man they say got cancer from Monsanto's Roundup weedkiller



By [Holly Yan](#), CNN

🕒 Updated 0128 GMT (0928 HKT) August 12, 2018



The Monsanto Papers: Roundup (Glyphosate) Cancer Case Key Documents & Analysis



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Multi District Litigation: More than 515 lawsuits are [pending against Monsanto Co.](#) in U.S. District Court in San Francisco, filed by people alleging that exposure to Roundup herbicide caused them or their loved ones to develop non-Hodgkin lymphoma, and that Monsanto covered up the risks. The cases have been combined for handling as multidistrict litigation (MDL) under Judge Vince Chhabria. The lead case is 3:16-md-02741-VC.

Monsanto sought to have its internal records and communications sealed from public view but the judge has allowed many to be made part of the public record, and these “Monsanto Papers” are contained within the records below.

EU Legislation

- DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 March 2001 on the deliberate release into the environment of genetically modified organisms

Article 2 Definitions

For the purposes of this Directive:

- (1) .organism. means any biological entity capable of replication or of transferring genetic material;
- (2) .genetically modified organism (GMO). means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

Article 4 General Obligations

1. Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively.

2. Any person shall, before submitting a notification under part B or part C, carry out an environmental risk assessment.

The information which may be necessary to carry out the environmental risk assessment is laid down in Annex III.

ANNEX IA TECHNIQUES REFERRED TO IN ARTICLE 2(2)

Techniques of genetic modification referred to in Article 2(2)(a) are inter alia:

(1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

ANNEX I B TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed

Article 2(5) 'genetically modified organism' or 'GMO' means a genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC;

Article 4,2

2. No person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

Article 4.3

No GMO for food use or food referred to in Article 3(1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article.

Article 4.1

1. Food referred to in Article 3(1) must not:

(a) have adverse effects on human health, animal health or the environment;

(b) mislead the consumer;

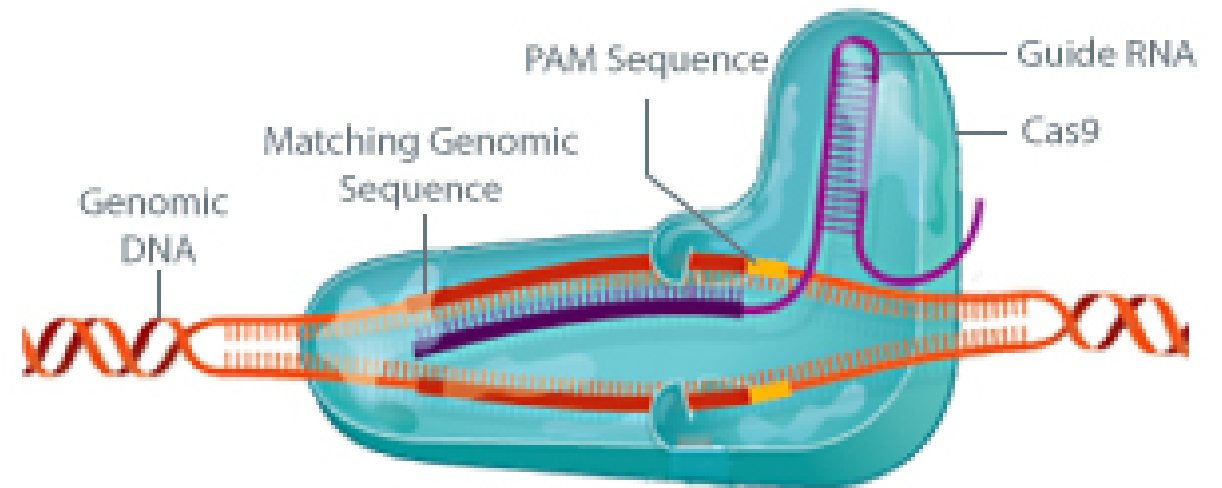
(c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

Genome editing - CRISPR

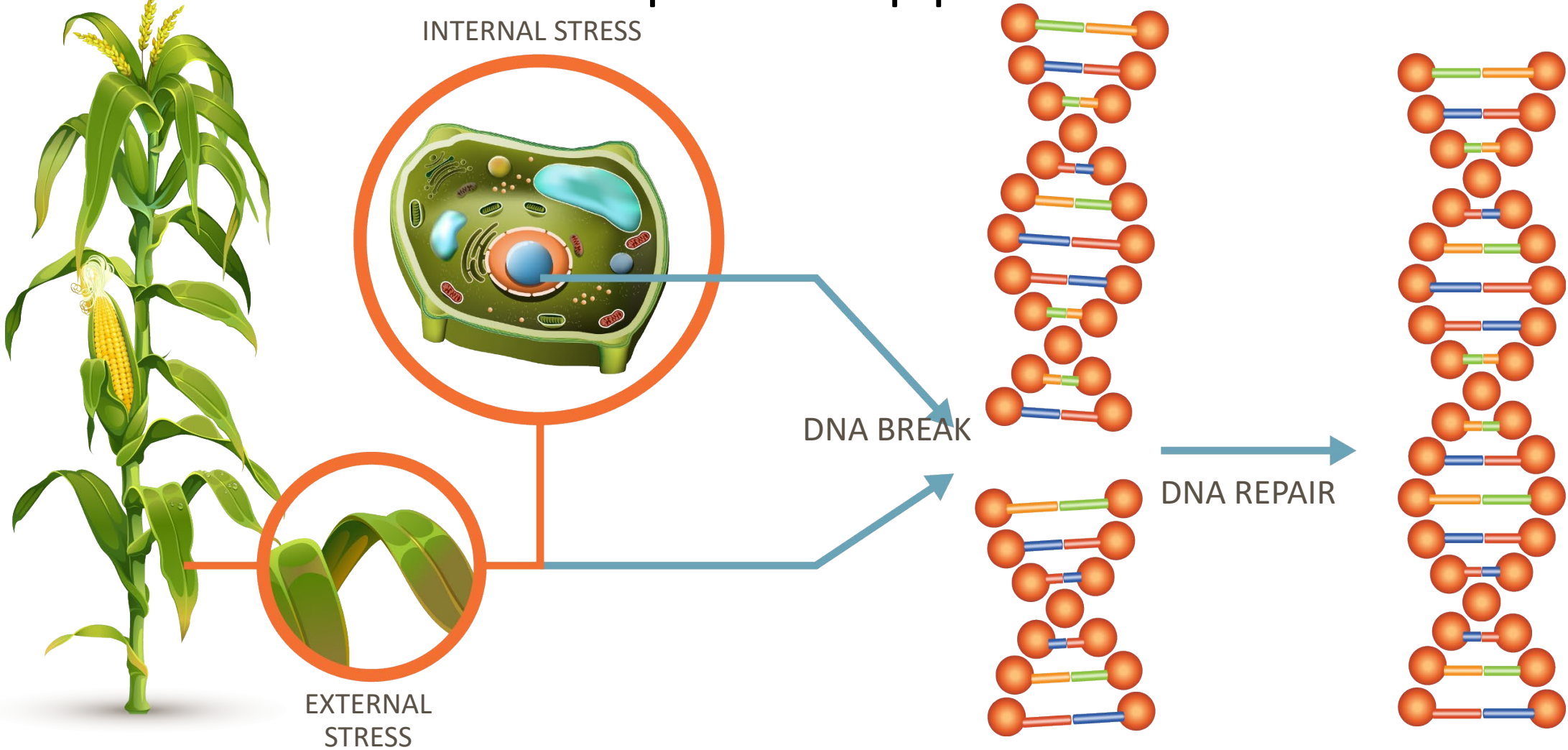
A genetic engineering approach in which DNA is inserted, removed or replaced at a precise location within the genome.

CRISPR (Clustered regularly interspaced short palindromic repeats)

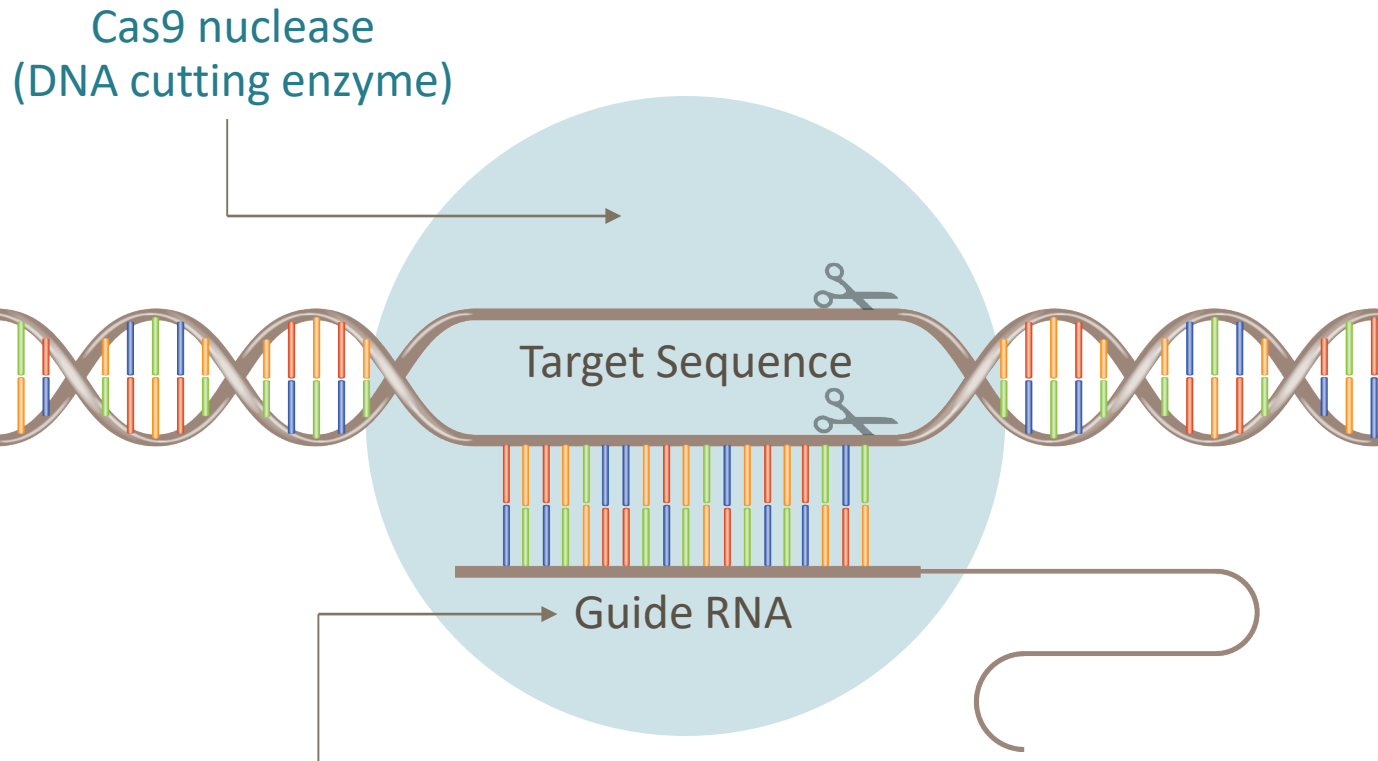
- ❖ derived from a natural process found in bacteria to protect themselves from pathogens
- ❖ targets genes for editing and regulating
- ❖ comparable to Photoshop



DNA Breaks and Repair Happen in Nature



CRISPR-Cas Enables Targeted DNA Breaks



Guide RNA matches the target DNA sequence

Guide RNA is designed to direct Cas9 enzyme to the DNA sequence of interest

Cas9 enzyme binds to the targeted DNA and makes double strand break

DNA double strand break is repaired through a plant's own cellular process

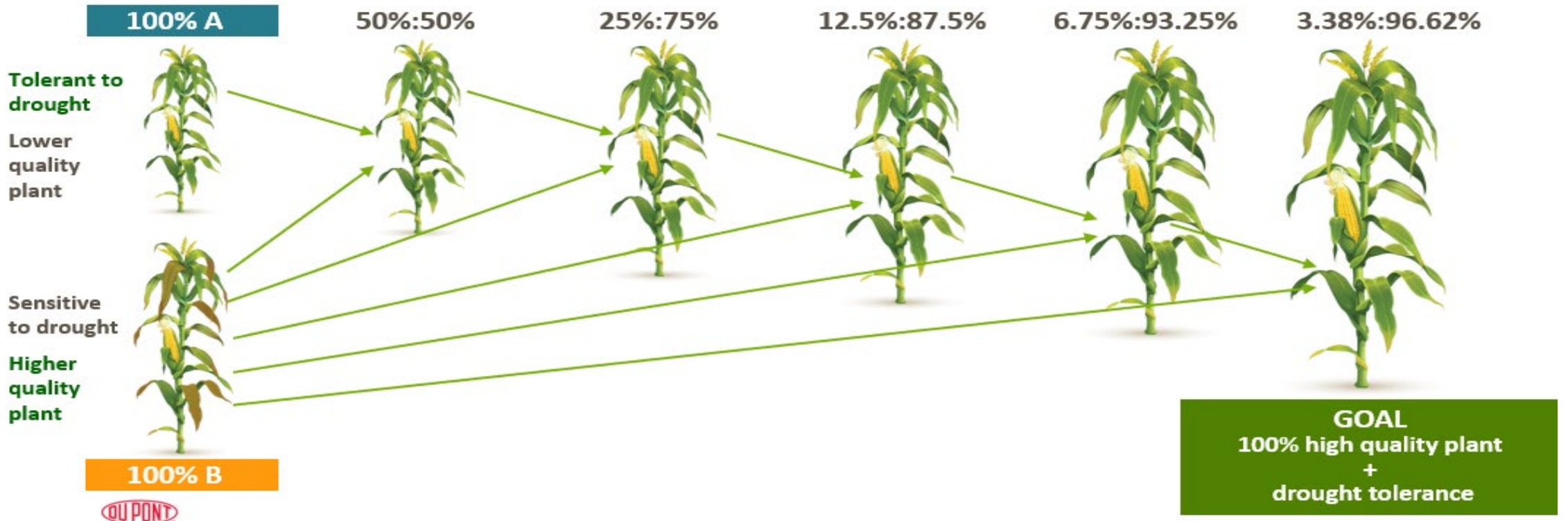


CRISPR-Cas Applications

CRISPR – Agricultural applications

Conventional Breeding Practices Involve Many Generations of Crossing

Drought tolerance example:

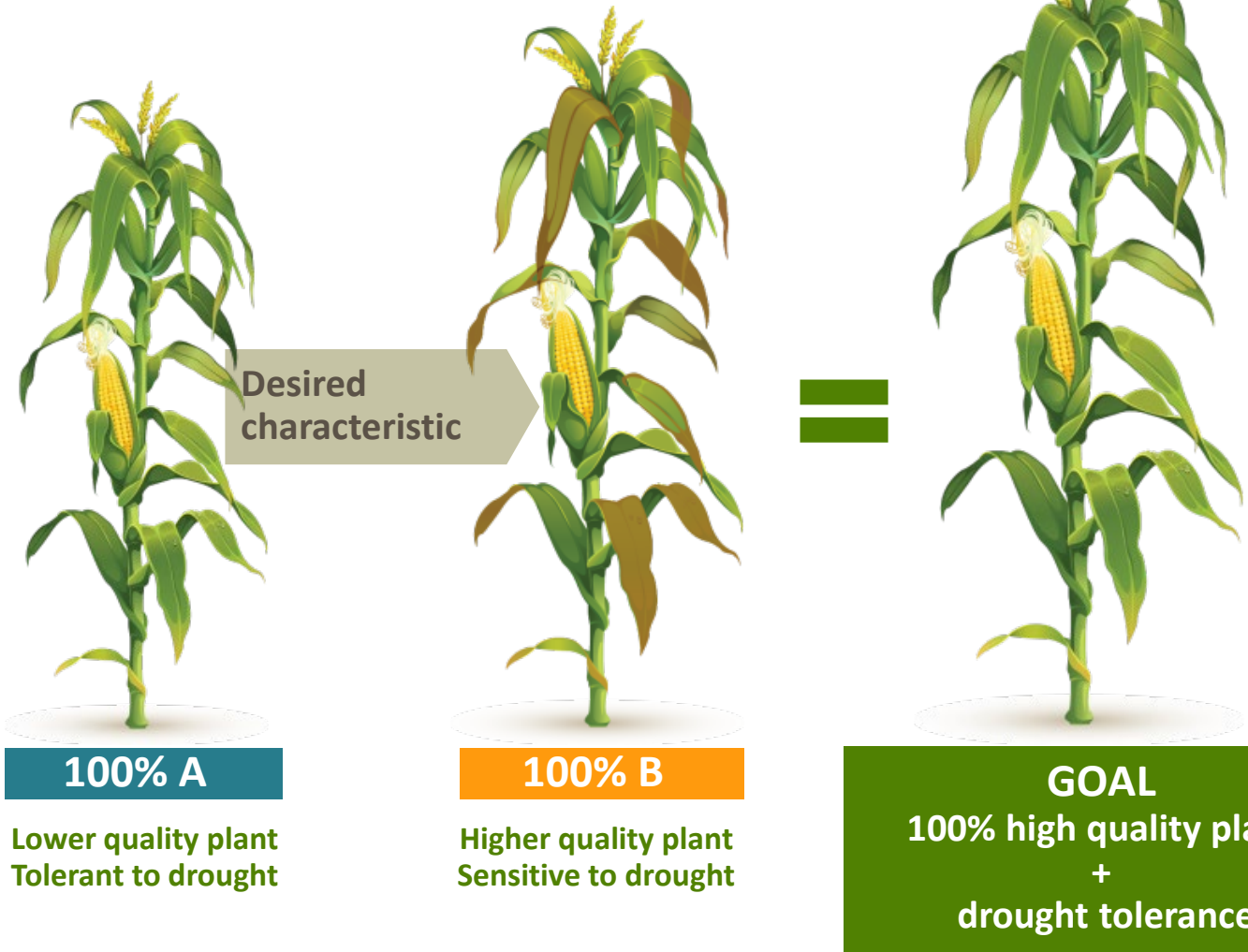


CRISPR-Cas Enables Efficient Introduction of Desired Characteristics

Drought tolerance example:

FROM: Incorporating desired characteristics in multiple cycles of common breeding practices

TO: Incorporating desired characteristics in as little as 1 to 2 cycles via CRISPR-Cas advanced breeding



NEAR-TERM PRODUCTS TO MARKET WAXY CORN HYBRIDS

- Foundational for future product development
- First commercial agricultural product
- To market by end of current decade

NORTHERN CORN LEAF BLIGHT

- Devastating global disease with potential to cause \$1.6B* annual losses in North America alone
- Leveraging germplasm base
- Utilizing native genes, genomic selection, and genome editing
- Providing sustainable grower solutions

BROAD AGRICULTURAL APPLICATIONS OF CRISPR-CAS

	DISEASE RESISTANCE	YIELD & YIELD STABILITY	DROUGHT TOLERANCE	OUTPUT TRAITS	MATURITY
CORN	●	●	●		●
SOY	●			●	●
CANOLA	●	●		●	
RICE	●	●	●		●
WHEAT	●	●			
SUNFLOWER	●			●	



NORTHERN LEAF BLIGHT READINESS:
First half of next decade

Products, benefits and concepts described herein will not be offered for sale or distribution until completion of field testing and applicable regulatory reviews.

** Source: Internal analysis and USDA*

Commercial applications

■ R&D tool

- » CRISPR tools *per se* can be protected and monetized
- » CRISPR can produce cells/organisms useful for drug discovery

■ Cell therapy

- » Cancer, HIV treatment (6/21: NIH approved clinical trial for CRISPR-modified cells for cancer)
- » Gene therapy

■ Genetic modification of any species

- » Improved industrial fermentation
- » Crops
- » Non-browning mushrooms
- » Germline gene modification (e.g., designer babies)

Public Investments

■ CRISPR Therapeutics

- » Early VC from Versant
- » Vertex \$105M deal
- » Bayer €325M investment in JV

■ Editas

- » \$210M from several investors (Flagship, Polaris, Third Rock, Partners Innovation)
- » \$94M IPO
- » collaboration with Juno

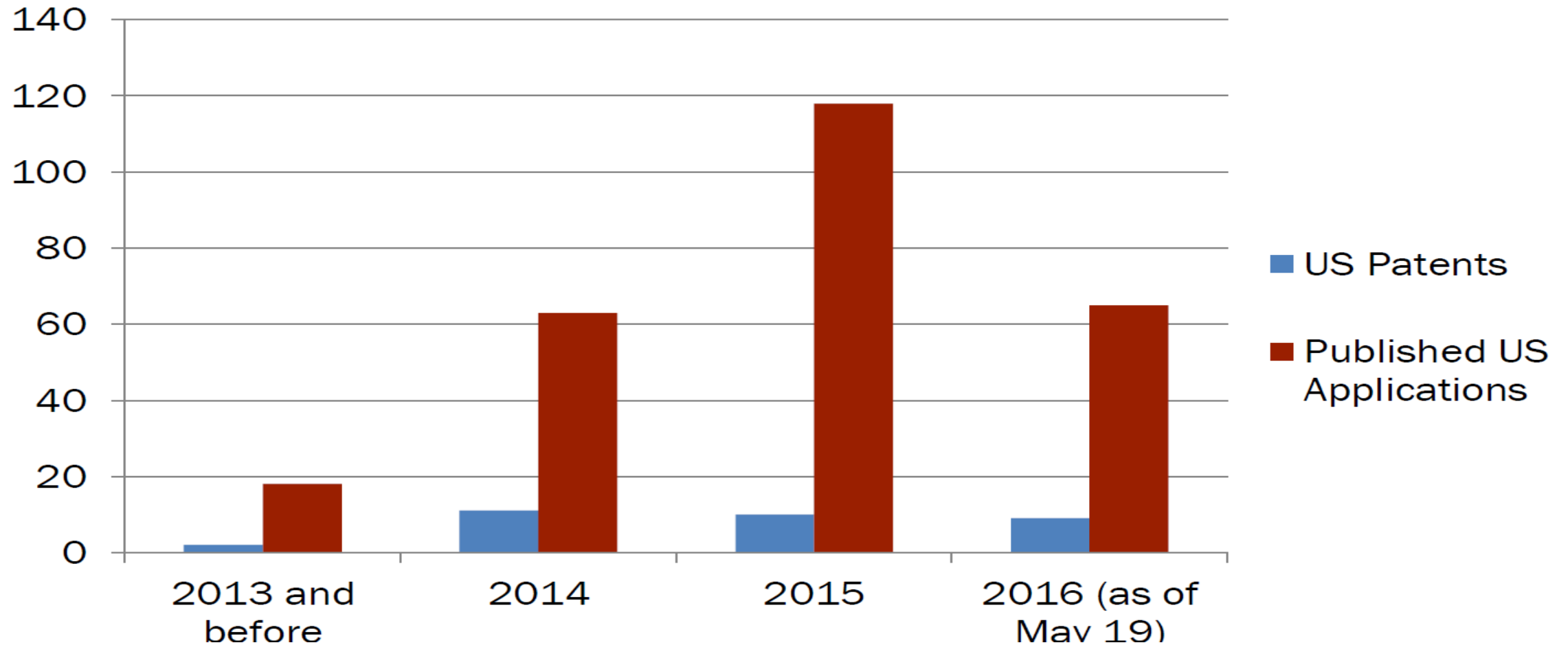
■ Intellia

- » VC's include Atlas Ventures, Orbimed, Novartis
- » \$108M IPO

CRISPR/Cas9 Patents



Growing Numbers of US Cas9 Patents/Patent Publications



US Patents (Universities)

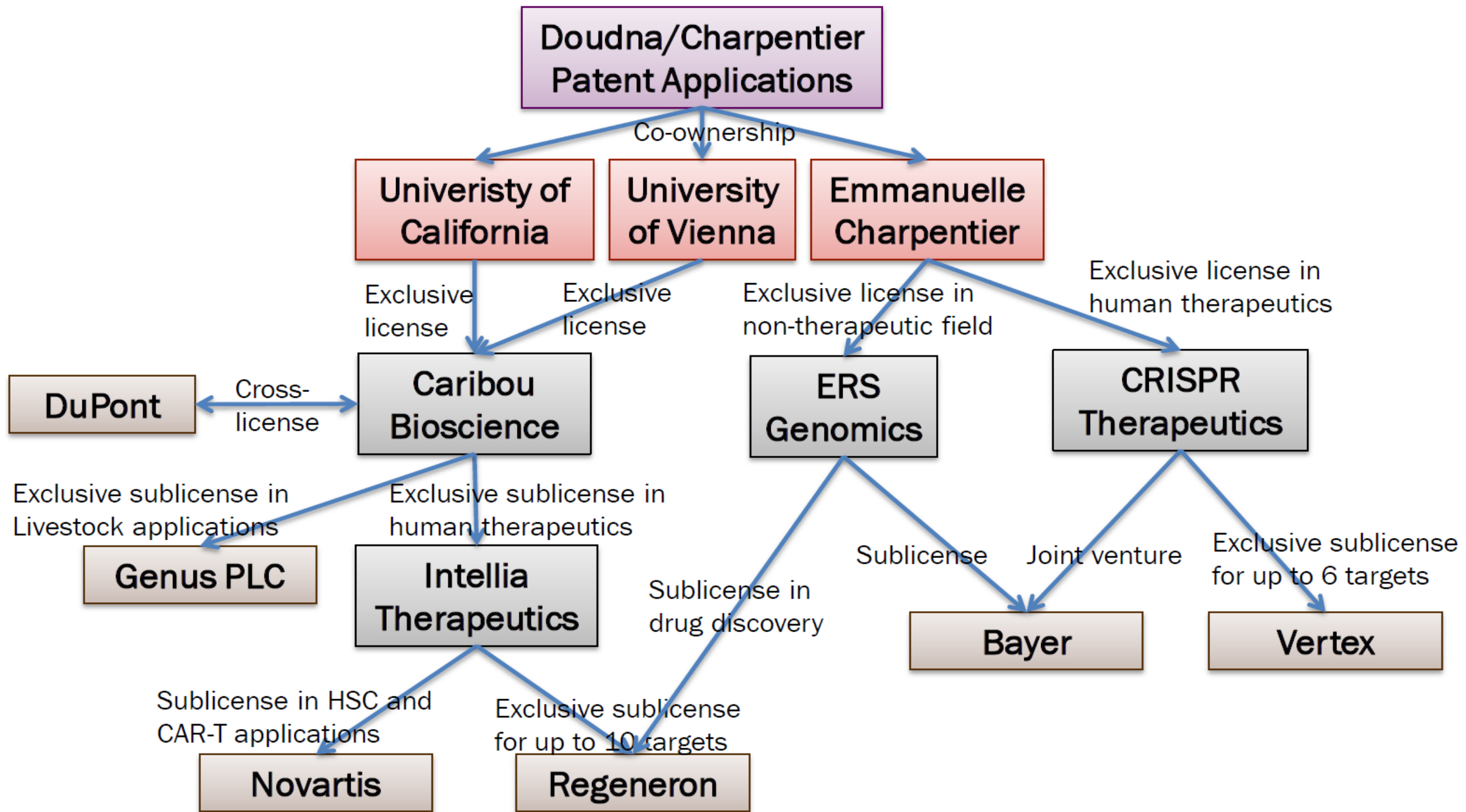
	US Patents	Published US Applications
Harvard	15	44
Broad Institute & MIT	13	35
U. Cal. & U. Vienna		8
Mass. General Hospital		7
Rockefeller U.		5
Vilnius		4
Stanford		4
U. Washington		4
U. Minnesota		3
U. Georgia	1	3

US Patents - Corporate

	US Patents	Published US Applications
Caribou	1	11
Regeneron	1	10
Agilent	1	9
Sangamo		15
Dow		12
DuPont	3	4
Recombinetics		6
Cellectis		4
Sigma Aldrich		4
Toolgen		4
Danisco		3

US Patents - Inventors

	US Patents	Published US Appl.
Feng Zhang (Broad/MIT)	13	35
David Liu (Harvard)	6	18
George Church (Harvard)	4	14
Jennifer Doudna (Berkeley)		17
Emmanuelle Charpentier (Max Planck)		8
Luciano Marraffini (Rockefeller)		7



Patent fights

		Comments
Broad Institute/Feng Zhang Patents	US Pat. Nos. 8697359, 8771945, 8795965, 8865406, 8871445, etc.	*Patent interference declared against Doudna/Charpentier patent applications
Doudna/Charpentier Patent Applications	US Pat. Appl. No. 13/842,859, etc.	*Patent interference declared against Broad's patents
Toolgen Patent Applications	US Pat. Appl. Nos. 14/438098, 14/685568 and 14/685510.	*Toolgen suggested for interference against Broad's patents in US 14/485568 and 14/685510 on April 13, 2015
Vilnius Univ. Patent Applications	US Pat. Appl. Nos. 14/385241, 14/385857, 14/683443 and 14/743764.	*Currently directed to CRISPR system assembled in vitro *The USPTO forwarded US 14/385241 to the BPAI for a potential interference on June 9, 2016

The European patent fight

The patent in question, EP 2771468 derives from a PCT application on 12 December 2013, **claiming priority from 12 US provisional applications**, the earliest of which was filed on 12 December 2012. The patent was granted on 11 February 2015 to three co-proprietors, The Broad Institute, MIT and Harvard College, with the following claim 1:

1. A non-naturally occurring or engineered composition comprising:

a Clustered Regularly Interspersed Short Palindromic Repeats (CRISPR)-CRISPR associated (Cas) (CRISPRCas) system chimeric RNA (chiRNA) polynucleotide sequence, wherein the polynucleotide sequence comprises

(a) a guide sequence of between 10 - 30 nucleotides in length, capable of hybridizing to a target sequence in a eukaryotic cell,

(b) a tracr mate sequence, an

(c) a tracrRNA sequence

wherein (a), (b) and (c) are arranged in a 5' to 3' orientation,

wherein when transcribed, the tracr mate sequence hybridizes to the tracrRNA sequence and the guide sequence directs sequence-specific binding of a CRISPR complex to the target sequence,

wherein the CRISPR complex comprises a Type II Cas9 protein complexed with (1) the guide sequence that is hybridized to the target sequence, and (2) the tracr mate sequence that is hybridized to the tracrRNA sequence, wherein the tracrRNA sequence is 50 or more nucleotides in length.

ANNEX I B TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be **excluded from the Directive**, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) **mutagenesis**,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.

Mutagenesis

- **Mutagenesis** is a process by which the genetic information of an organism is changed, resulting in a mutation.
- It may occur spontaneously in nature, or as a result of exposure to mutagens. It can also be achieved experimentally using laboratory procedures
- Mutagens are chemical compounds or forms of radiation (such as ultraviolet (UV) light or X-rays) that cause irreversible and heritable changes (mutations) in the cellular genetic material, deoxyribonucleic acid (DNA).

Confédération paysanne and Others v Premier ministre and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt Case C-528/16, judgement 25 July 2018.

- The case concerned the refusal by the French Minister for Agriculture, the Food Processing Industry and Forestry to revoke the national legislation according to which organisms obtained by mutagenesis are not, in principle, considered to result in genetic modification, and the refusal to ban the cultivation and marketing of herbicide-tolerant rape varieties obtained by mutagenesis.

French law

15 Article L. 531-1 of the Code de l'environnement (Environmental Code) defines a genetically modified organism as an 'organism whose genetic material has been modified other than by natural mating or recombination'.

16 Article L. 531-2 of that code provides:

'The provisions of this Title and of Articles L. 125-3 and L. 515-13 shall not apply to genetically modified organisms obtained by the use of techniques which, **by reason of being natural**, are not considered to involve genetic modification or by those which have been traditionally used without proven harm for public health or the environment.

18 Article D. 531-2 of the code provides:

‘The techniques referred to in Article L. 531-2, which are not considered to give rise to genetic modification, are the following:

...

2 On condition that they do not involve the use of genetically modified organisms as recipient or parental organisms:

(a) mutagenesis;

Questions referred to the CJEU

(1) may new directed mutagenesis techniques implementing genetic engineering processes, be regarded as techniques listed in Annex I A, to which Article 2 refers?

(2) Do varieties obtained by mutagenesis constitute genetically modified varieties within the meaning of Article 4 of Directive [2002/53] which would not be exempt from the obligations laid down in that directive?

CJEU on mutagenesis

27 Article 2(2) of Directive 2001/18 defines a GMO as an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

29 since, as is apparent from the order for reference, certain of those techniques/methods involve the use of chemical or physical mutagenic agents, and others involve the use of genetic engineering, those techniques/methods alter the genetic material of an organism in a way that does not occur naturally, within the meaning of that provision.

30 It follows that organisms obtained by means of techniques/methods of mutagenesis must be considered to be GMOs within the meaning of Article 2(2) of Directive 2001/18.

48 As the referring court states in essence, the risks linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those which result from the production and release of a GMO through transgenesis.

It thus follows from the material before the Court, first, that the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into that organism and, secondly, that the development of those new techniques/methods makes it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis.

49 Moreover, as stated in recital 4 of Directive 2001/18, living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers, thereby affecting other Member States.

The effects of such releases on the environment may be irreversible. In the same vein, recital 5 of that directive states that the protection of human health and the environment requires that due attention be given to controlling risks from such releases.

Industry shocked by EU Court decision to put gene editing technique under GM law

By [Sarantis Michalopoulos](#) | [EURACTIV.com](#)

📅 25 Jul 2018 (updated: 📅 9 Aug 2018)

- The European Court of Justice ruled on Wednesday (25 July) that organisms obtained by mutagenesis plant breeding technique are GMOs and should, in principle, fall under the GMO Directive, in a surprising move that went contrary to the Advocate-General's non-binding opinion.
- The decision shocked the industry, which described it as a severe blow to innovation in EU agriculture and warned about economic and environmental consequences.
- József Máté, Corporate Communications Leader at Corteva Agriscience, described the Court decision as a “bad day” for the EU agri-food sector.

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CJEU gene-editing decision 'could stifle' innovation in Europe

ECJ ruling on gene editing products: Victory for consumers, farmers, environment



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Exposing the power of corporate lobbying in the EU

26 Jul 2018 | News

Ruling on gene editing crops a threat to innovation and future food security, scientists say

Plants traits introduced by Crispr gene editing will be subject to the same lengthy regulatory process as 1980s-style genetically modified organisms containing genes from other species, Europe's highest court rules

By Éanna Kelly



expert reaction to Court of Justice of the European Union ruling that GMO rules should cover plant genome editing techniques

- **Prof Cathie Martin, Group Leader, John Innes Centre, said:**

“This is going to impact plant breeding in Europe hugely and negatively.”

- **Dr Nicola Patron, Head of Synthetic Biology, Earlham Institute, said:**

Mutagenesis is a natural phenomenon responsible for the genetic diversity that can be seen in all living organisms. This decision may negatively impact our ability to respond to the challenge of securing sufficient food for our growing population in a changing climate. It may also hinder the competitiveness of the EU’s biotechnology sector.”