“Biotech 101: Scientific Facts About Genetic Engineering”

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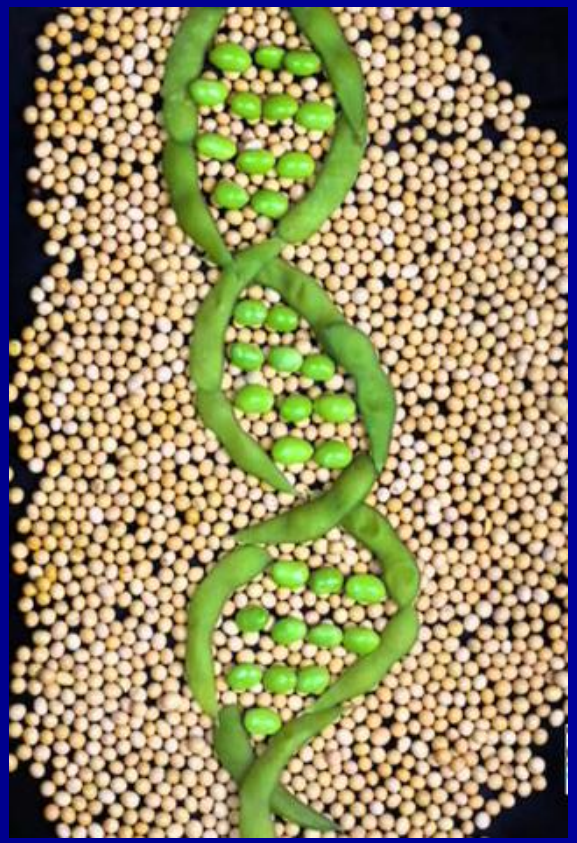


http://animalscience.ucdavis.edu/animalbiotech

I do not like the term GMO (genetically modified organisms) – because it is ambiguous as to what "modified" means



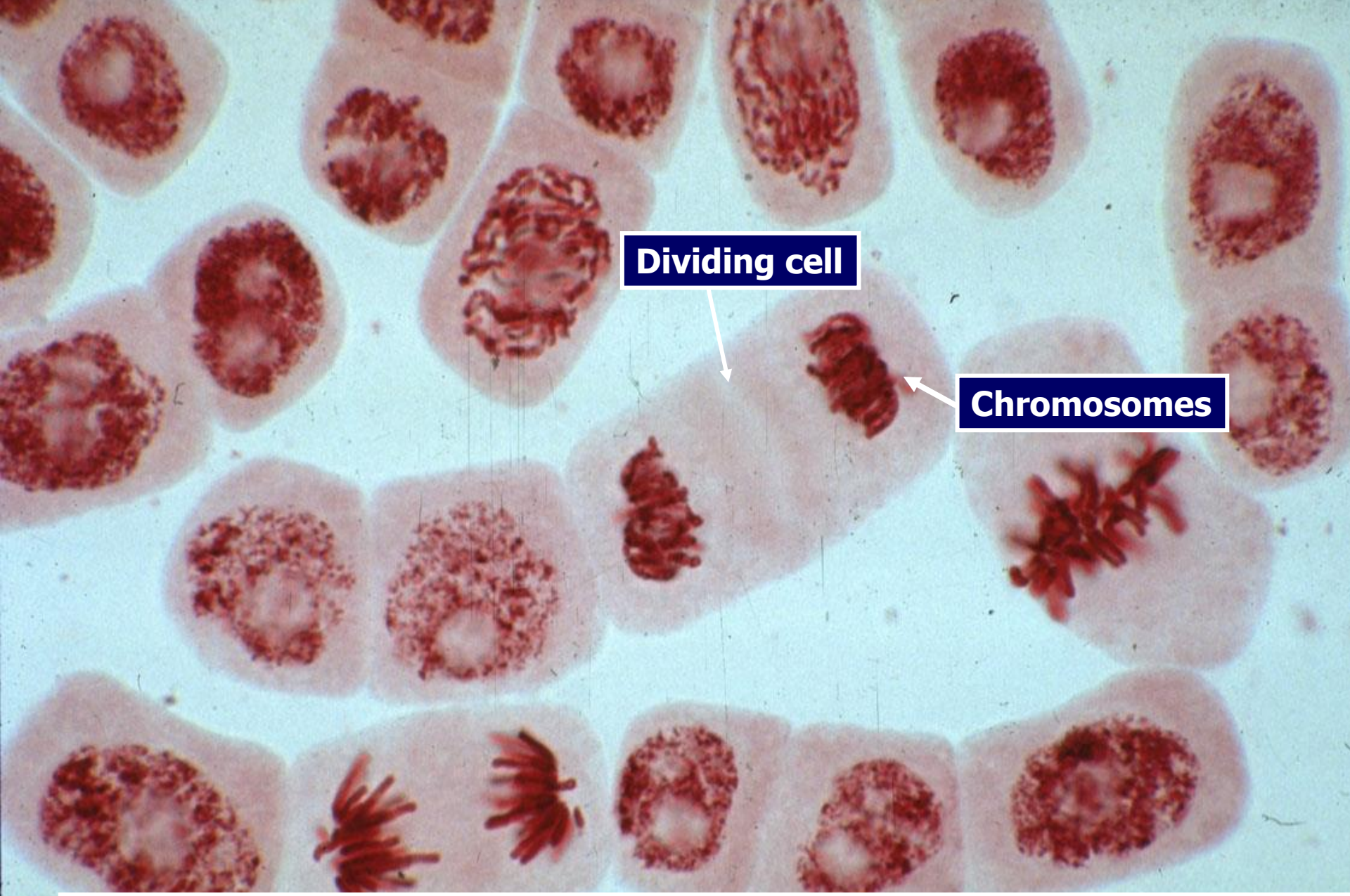



I prefer the term genetic engineering (GE) as it means something specific

- The **USDA's** current definition of genetic engineering is "manipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA (rDNA) techniques."

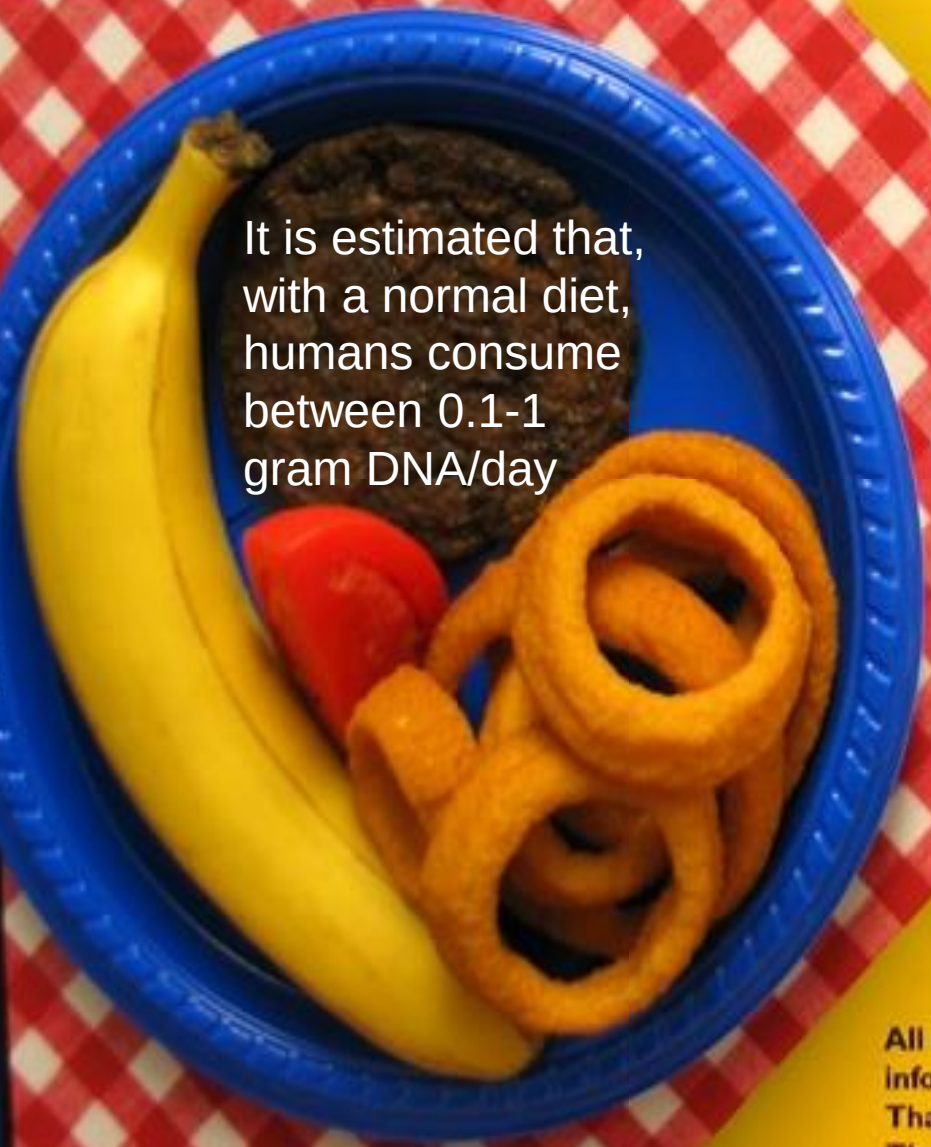
- Also known as genetically modified, GM, GMO, transgenic, bioengineered, biotech, made with modern biotechnology, frankenfood

Since this is BIOTECH 101 University!
Let us review Genetics 101



Stretched out, the DNA in each cell would be ~ 5 feet lon

HOW MUCH DNA DO YOU EAT?*



It is estimated that, with a normal diet, humans consume between 0.1-1 gram DNA/day

HAMBURGER
(60mg)

ONION RINGS
(10mg)

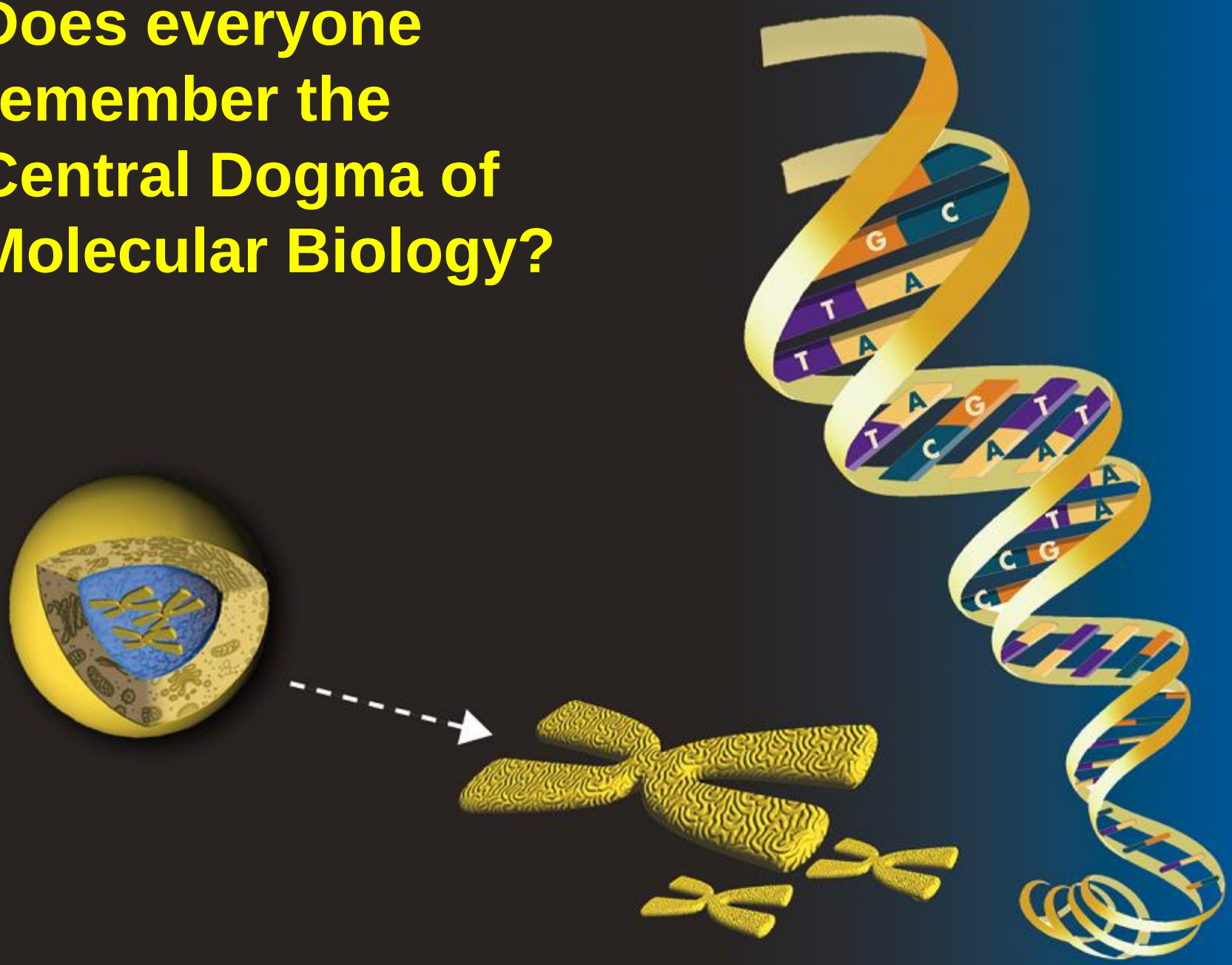
WHOLE TOMATO
(7mg)

WHOLE BANANA
(50mg)

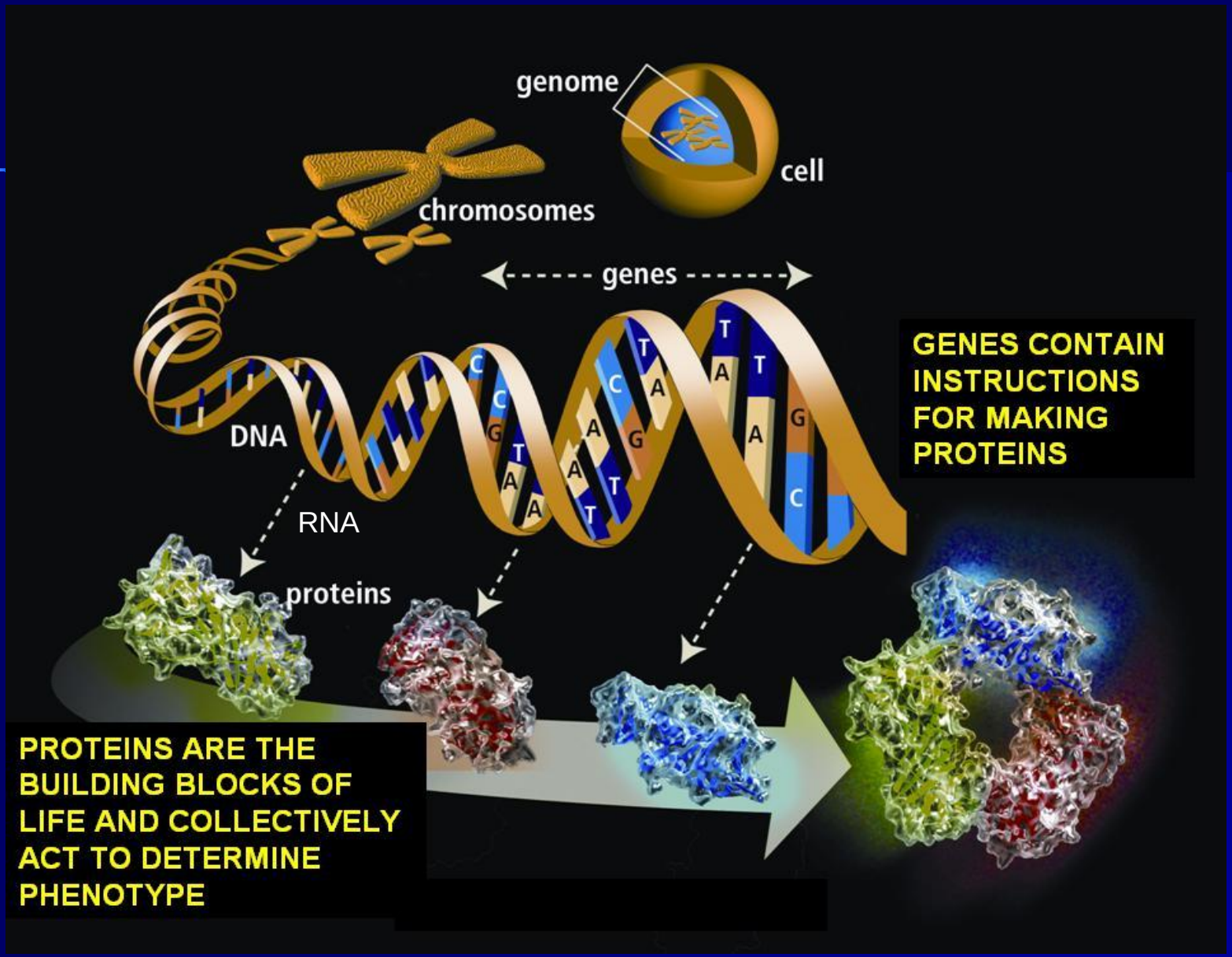
REAL DNA

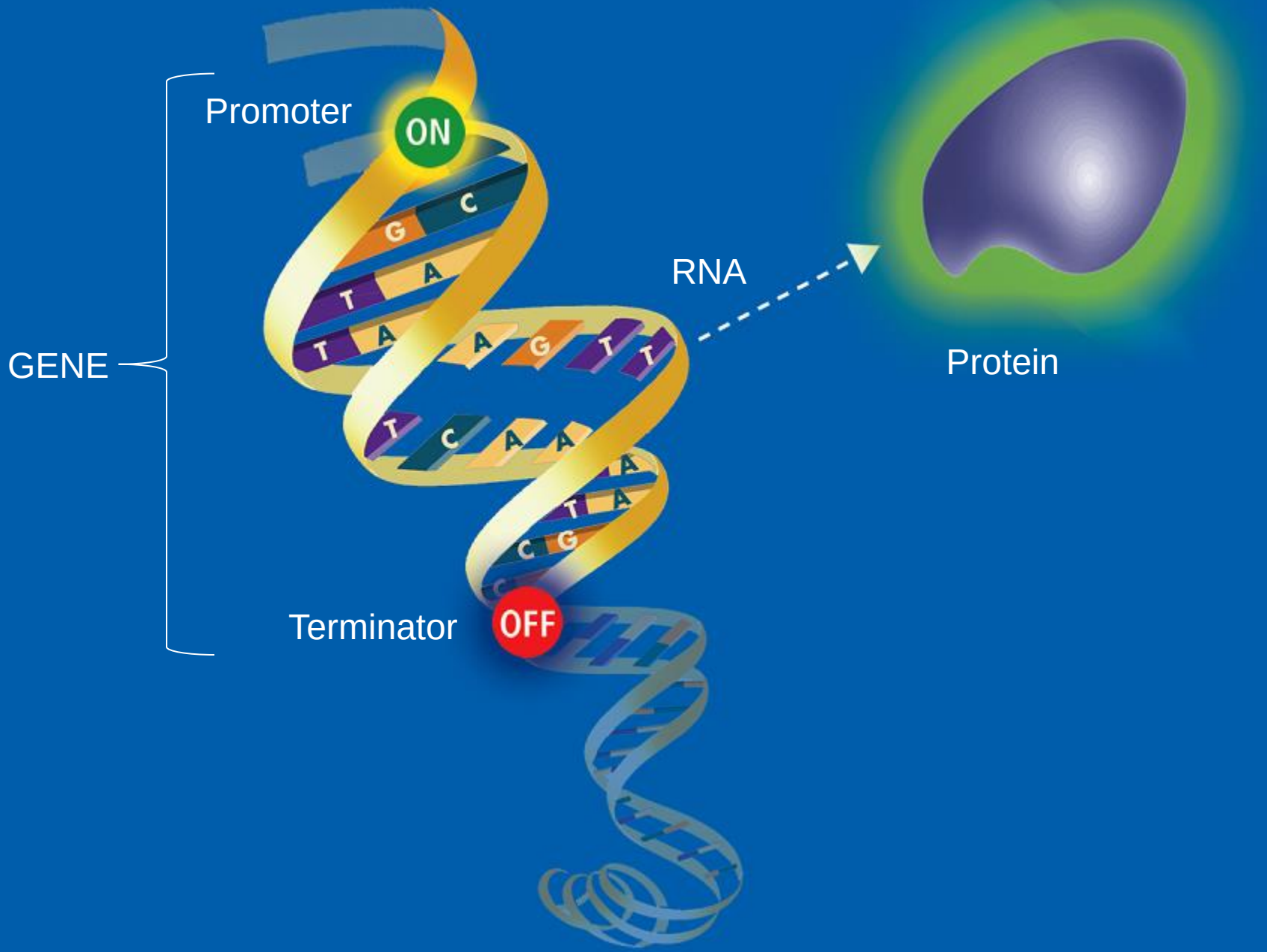
All living things have DNA, the chemical that contains all information responsible for the way it looks and how it works. That chemical, a string approximately 5 feet long, can be isolated. The isolated DNA in each food is seen in the tube on the right.

Does everyone remember the Central Dogma of Molecular Biology?



The central dogma



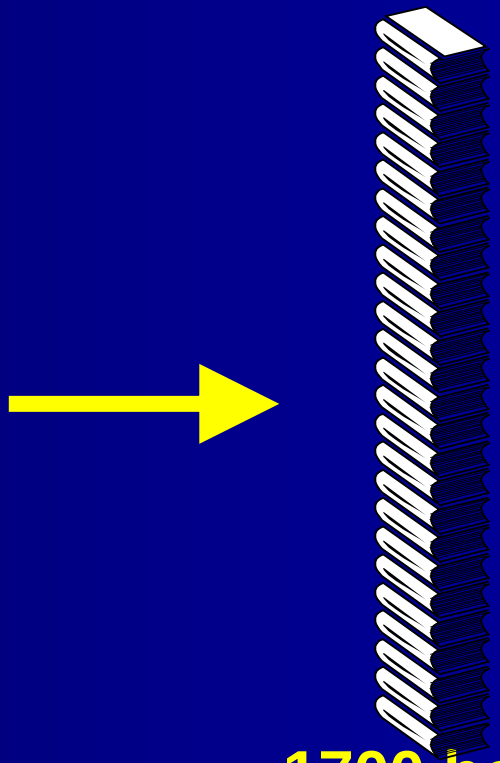

Promoter
ON
GENE
RNA
Protein
Terminator
OFF

The genome is like an encyclopedia of protein recipes for a given species

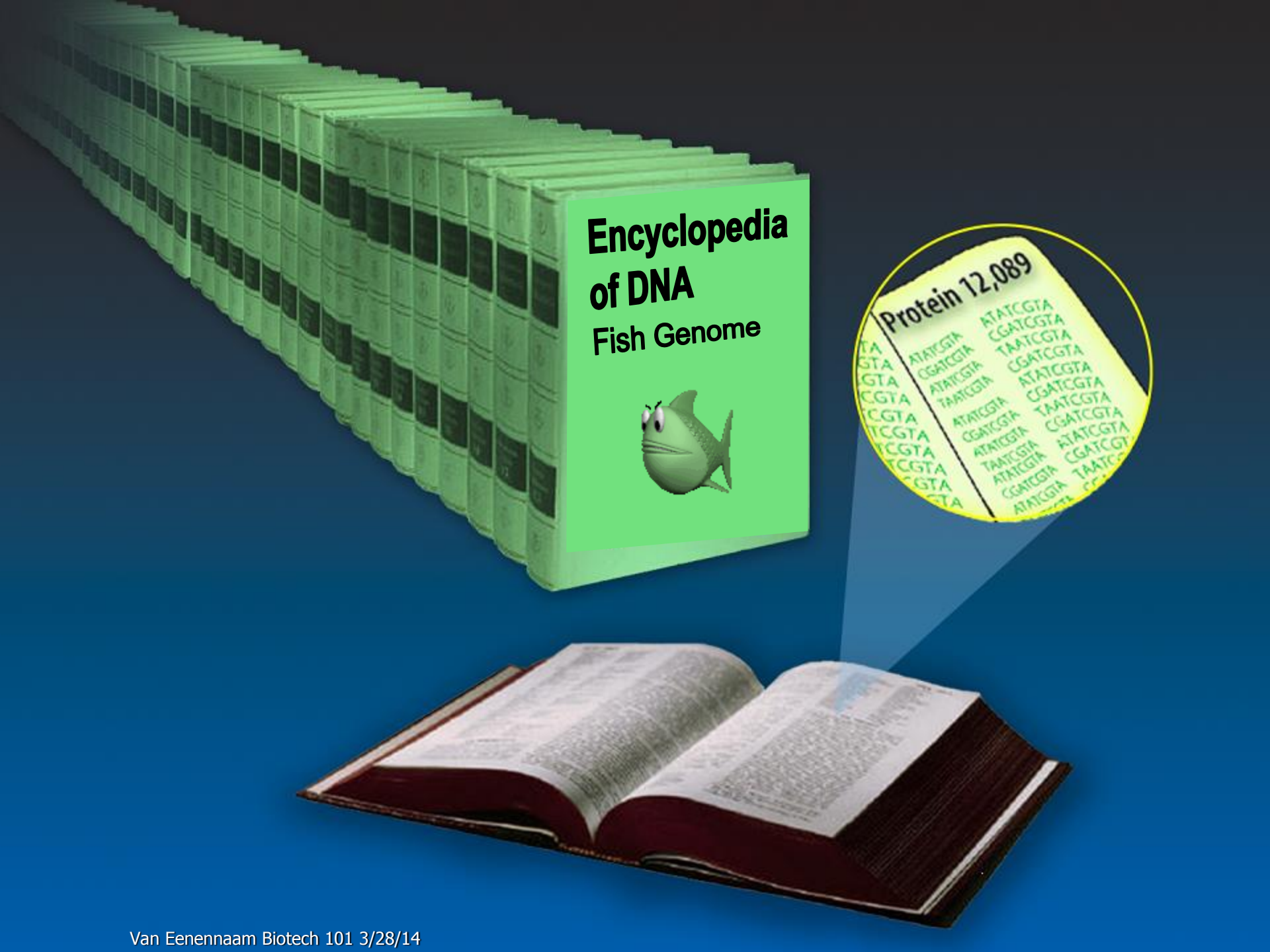
Proteins are encoded by base pairs of DNA

CTGACCTAATGCCGTA...

1700 books
1000 pages each



1700 books
(or 1.7 million pages)


Encyclopedia
of DNA
Fish Genome
Protein 12,089

How do traditional plant breeders create a new wheat – with better nutritional qualities – using an ancient variety?

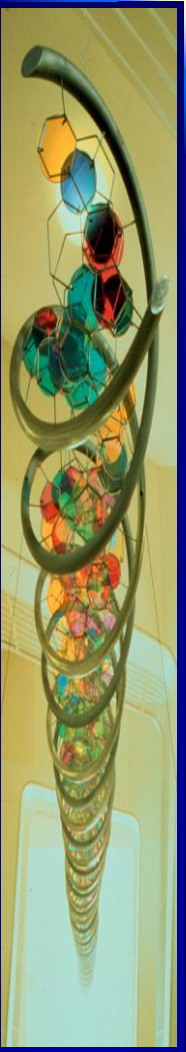
Triticum monococcum

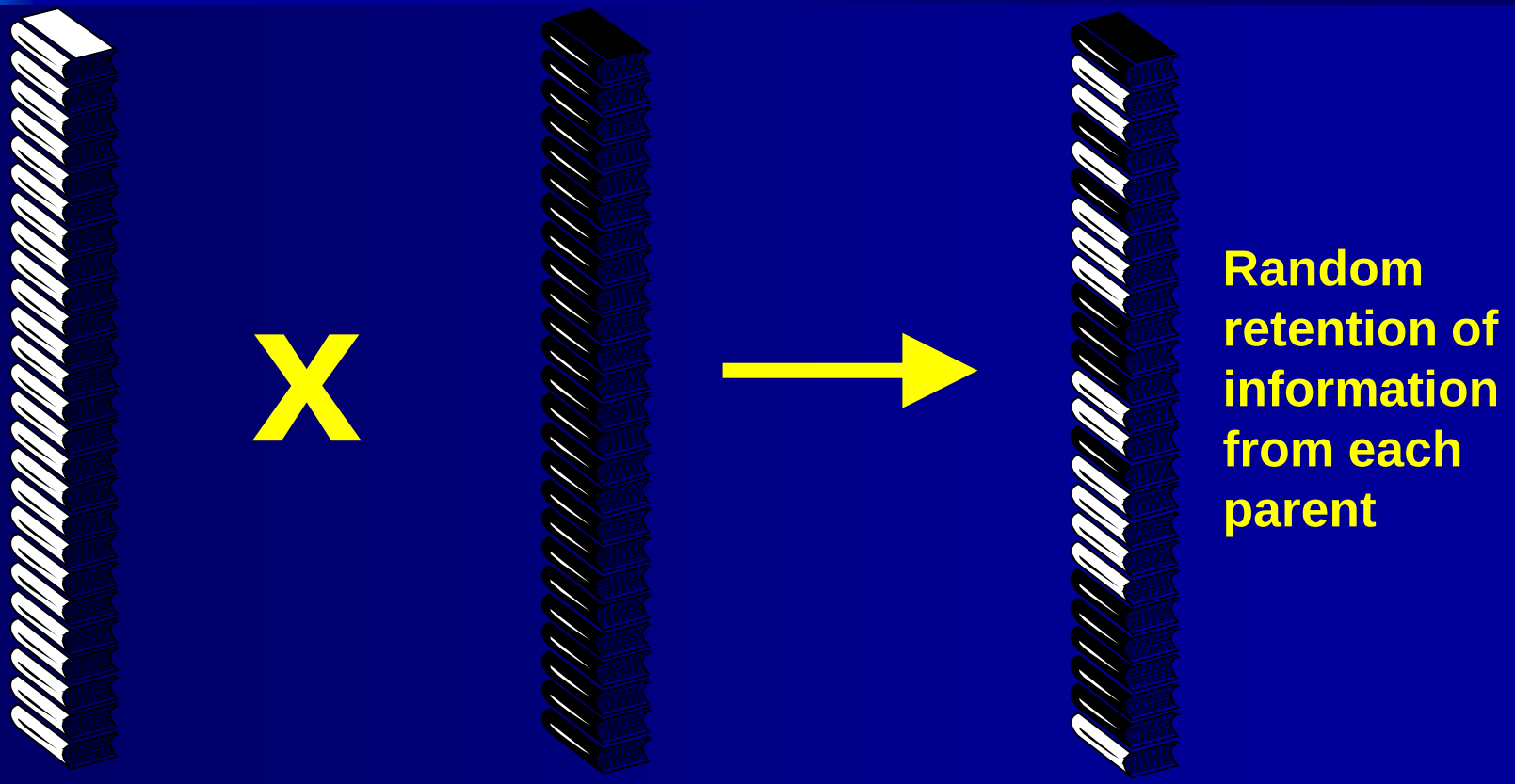
Ancient variety

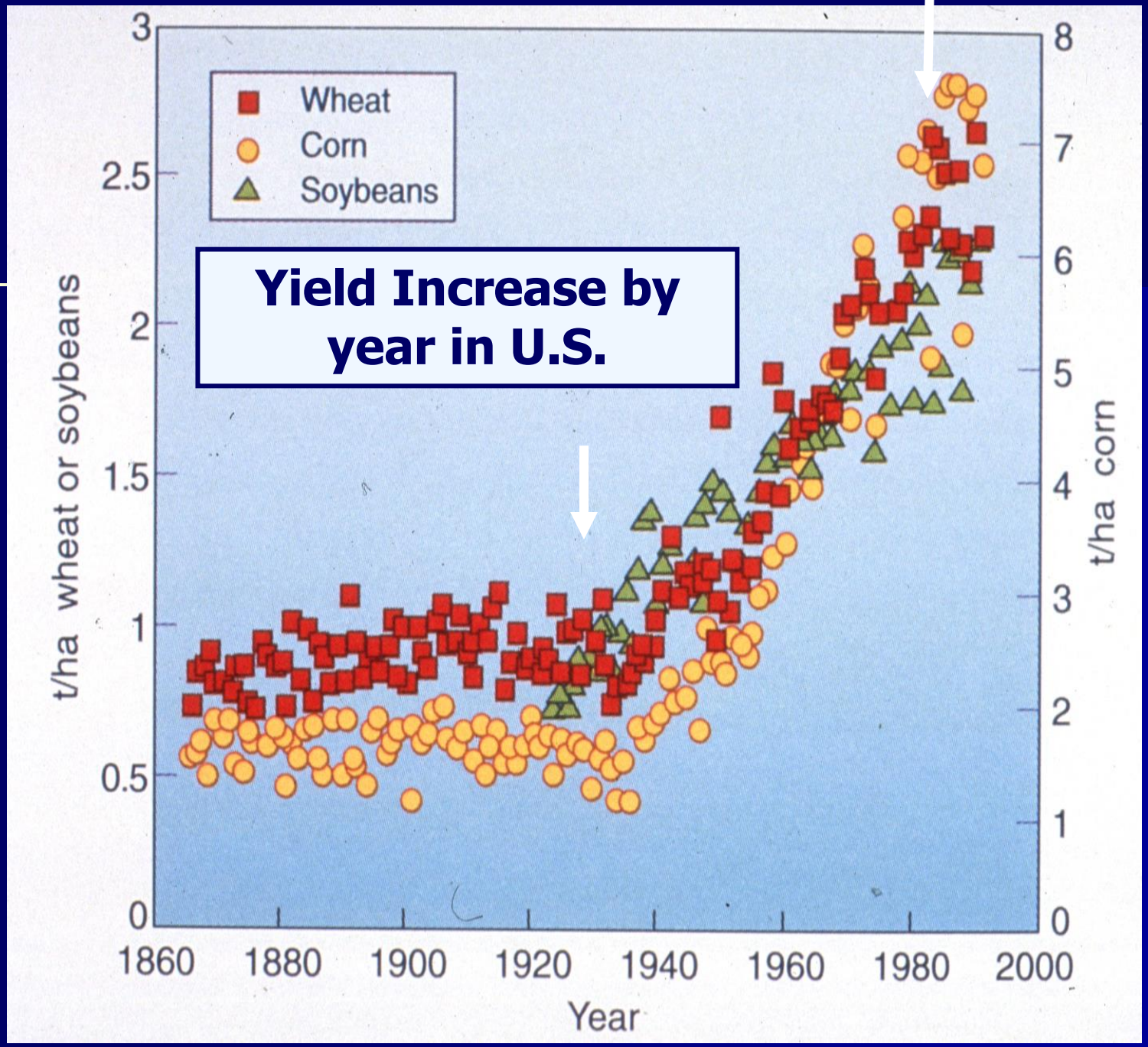
Triticum aestivum

Modern bread variety

Traditional breeders cross varieties to look for improved offspring

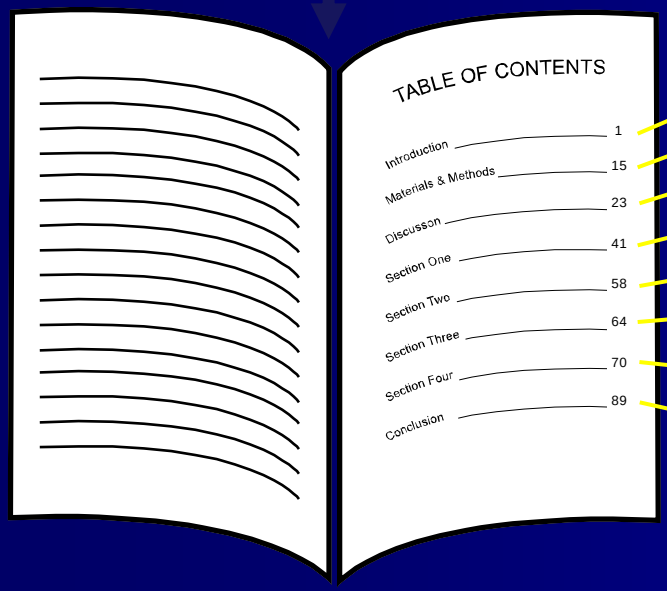


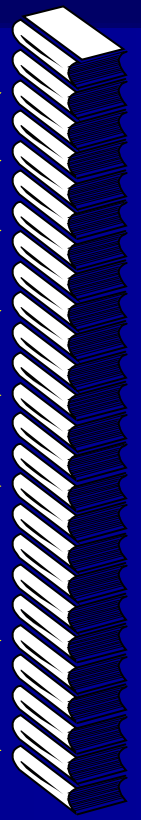



Wheat
Corn
Soybeans
Yield Increase by year in U.S.
t/ha wheat or soybeans
t/ha corn
Year
0
0.5
1
1.5
2
2.5
3
0
1
2
3
4
5
6
7
8
1860
1880
1900
1920
1940
1960
1980
2000

Genomics and the sequencing of genomes has enabled us to develop a "Table of Contents"

...CTGACCTAATGCCGTA...





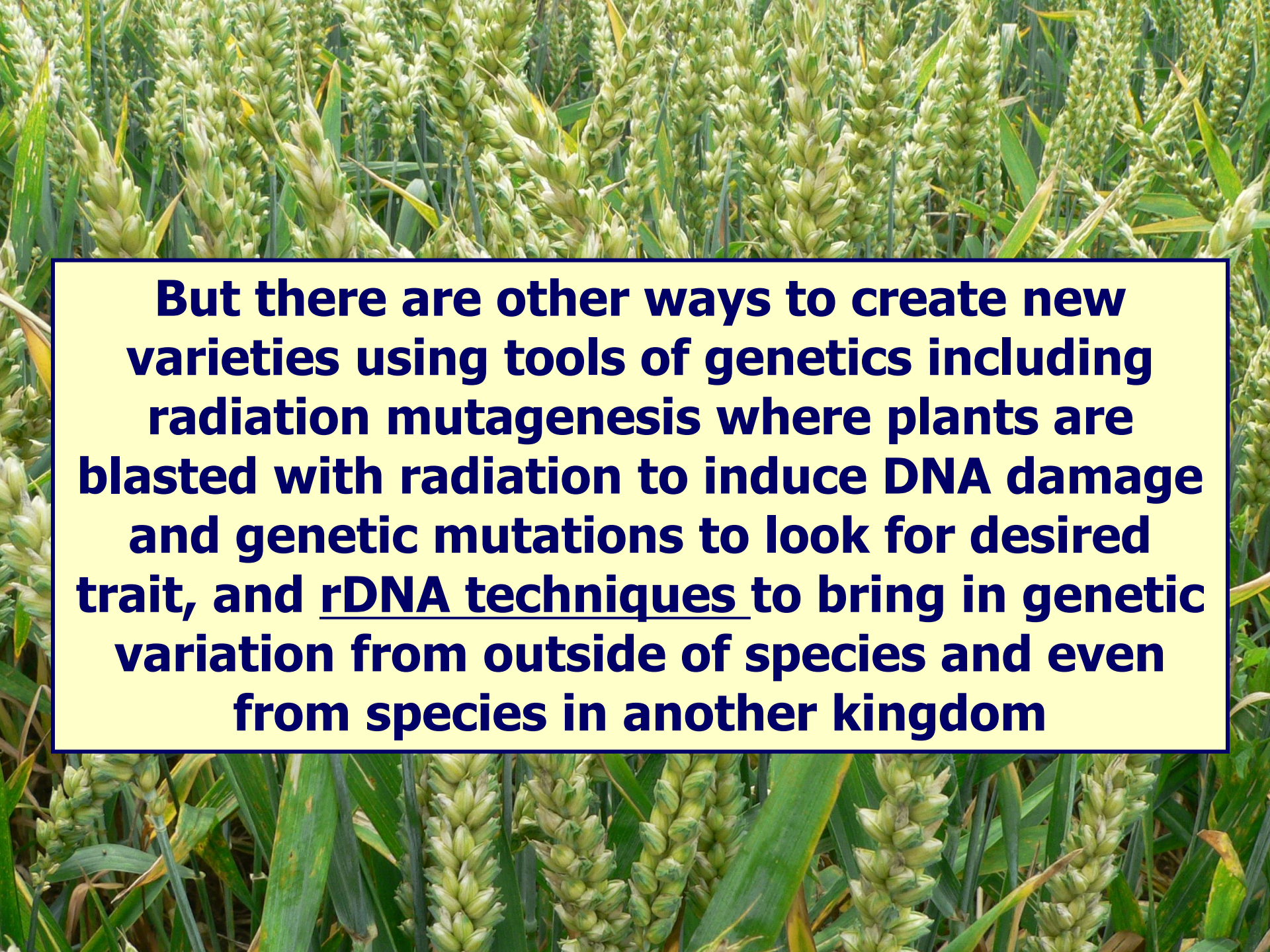
Used for Marker-Assisted Selection

Genomics

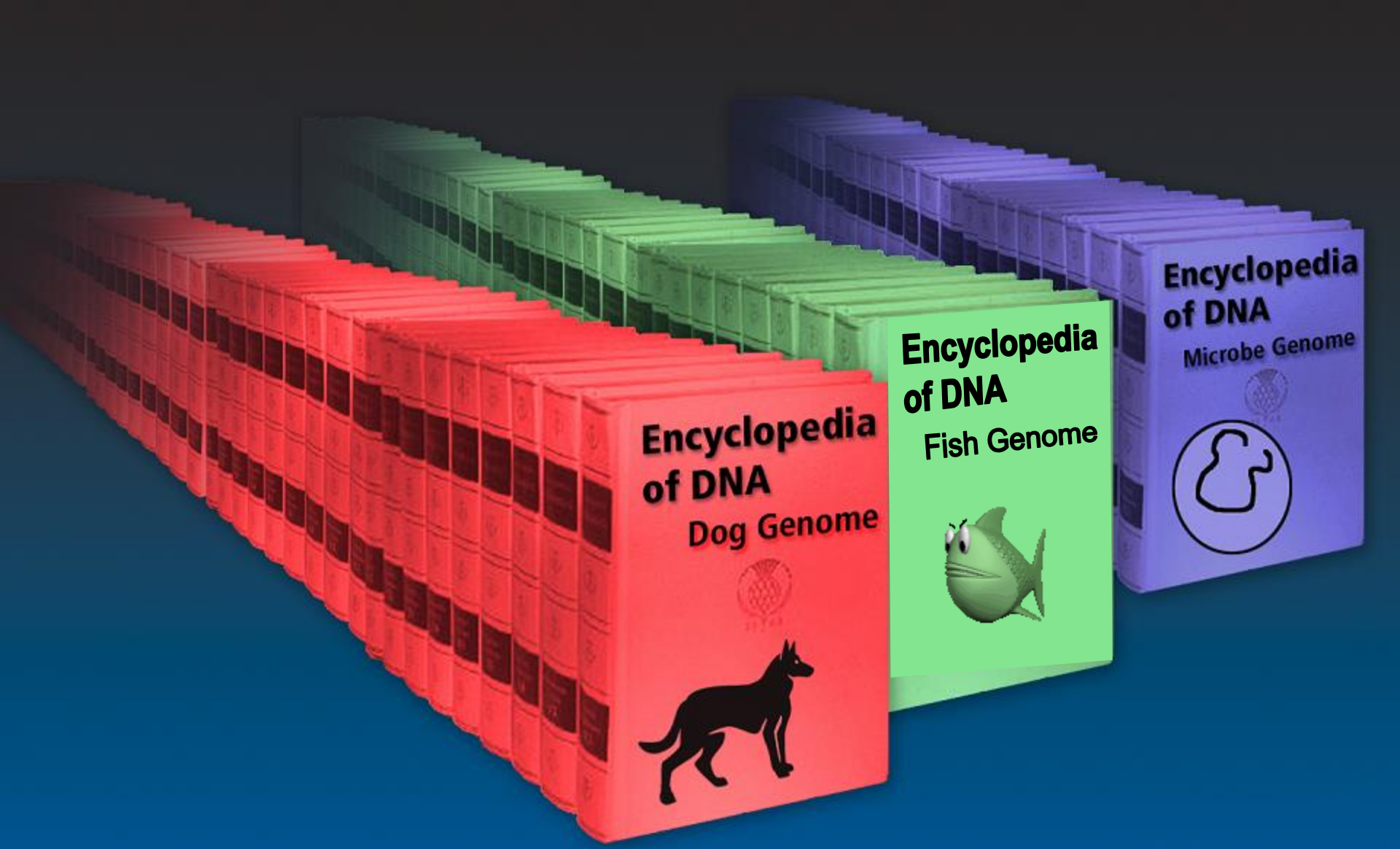
1700 books (or 1.7 million pages)

Marker-assisted selection used to protect rice against bacterial blight and blast disease

Protection limited to diversity in crop and compatible relatives

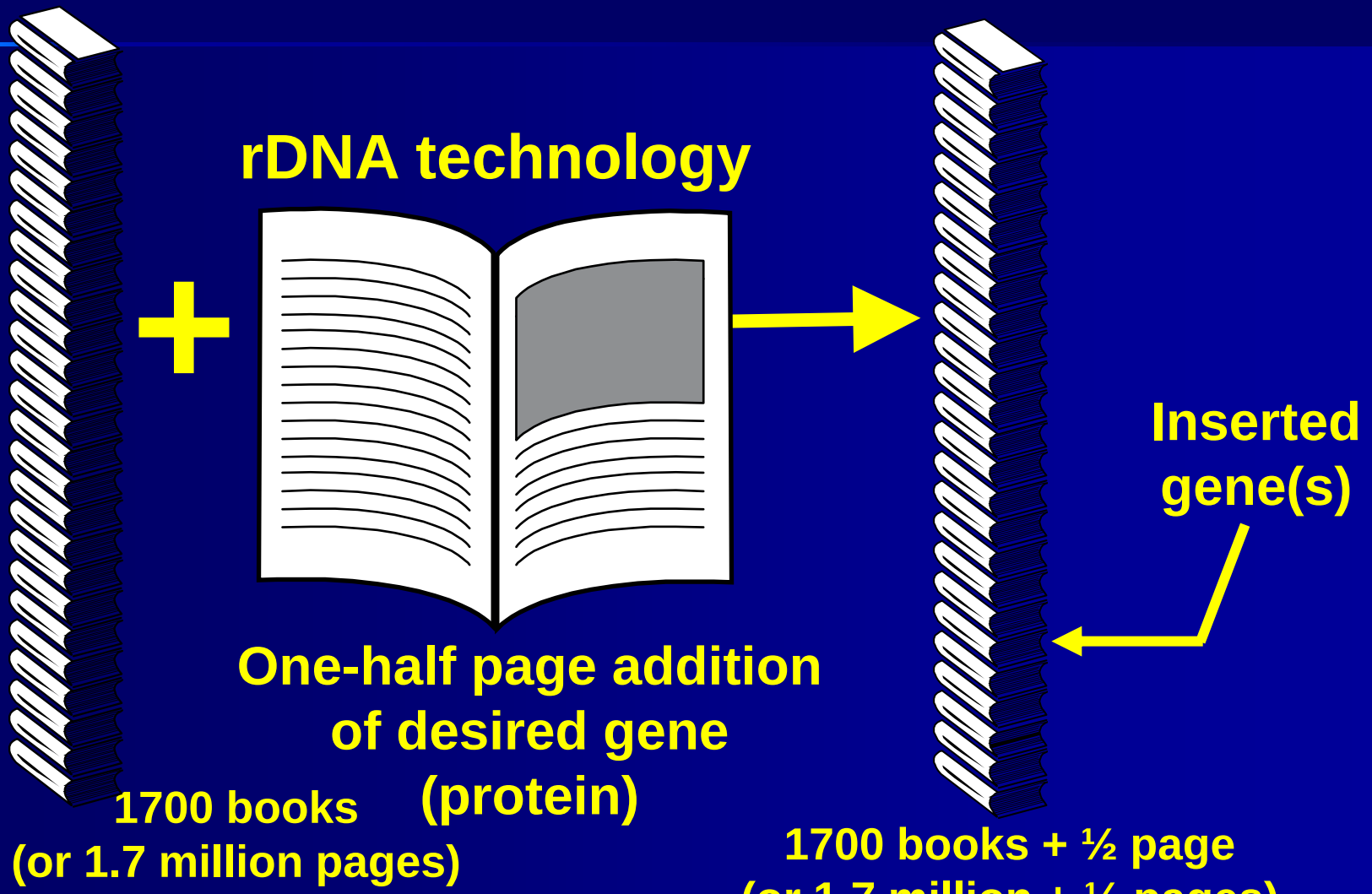


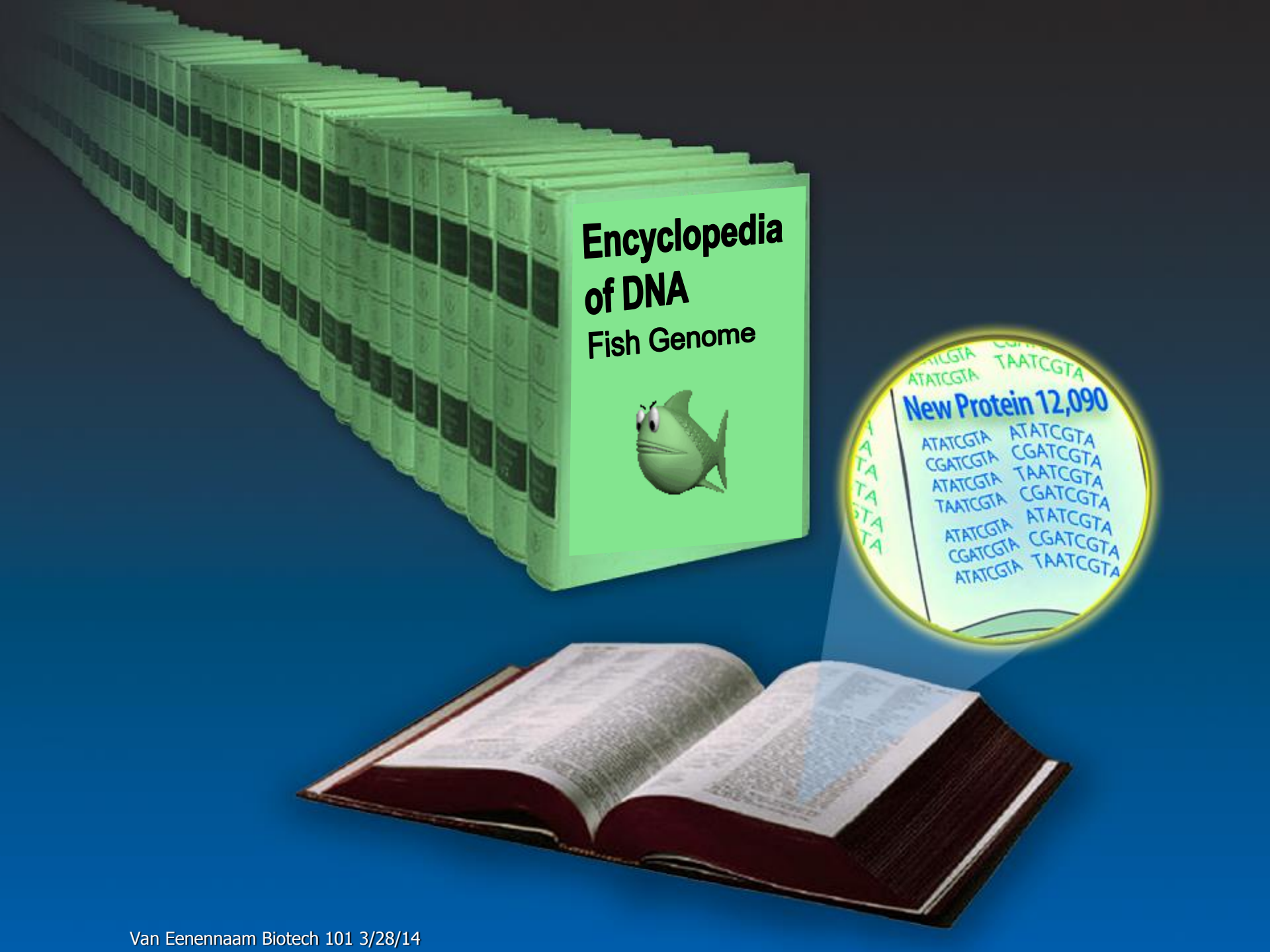
But there are other ways to create new varieties using tools of genetics including radiation mutagenesis where plants are blasted with radiation to induce DNA damage and genetic mutations to look for desired trait, and rDNA techniques to bring in genetic variation from outside of species and even from species in another kingdom



The triplet code is universal across the different kingdoms and so genes will be translated into the same protein irrespective of which species that gene is in

Genetic Engineering Methods



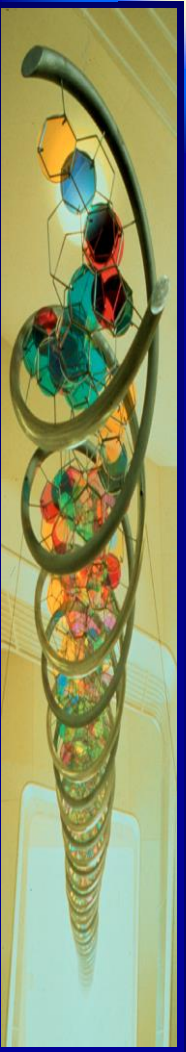

Encyclopedia
of DNA
Fish Genome
New Protein 12,090
ATATCGTA ATATCGTA
CGATCGTA CGATCGTA
ATATCGTA TAATCGTA
TAATCGTA CGATCGTA
ATATCGTA ATATCGTA
CGATCGTA CGATCGTA
ATATCGTA TAATCGTA

Classical Breeding

- Uses host machinery of recombination
- Gene exchange is random involving whole genome
- When/where gene expressed not controlled by breeder
- Source of gene primarily within genera
- Includes techniques like radiation mutagenesis

Genetic Engineering

- Uses host machinery and rDNA techniques in lab.
- Gene exchange is specific involving single or a few genes
- When/where gene expressed controlled precisely by promoter
- Source of gene from any organism or kingdom
- Is triggered solely by use of rDNA techniques

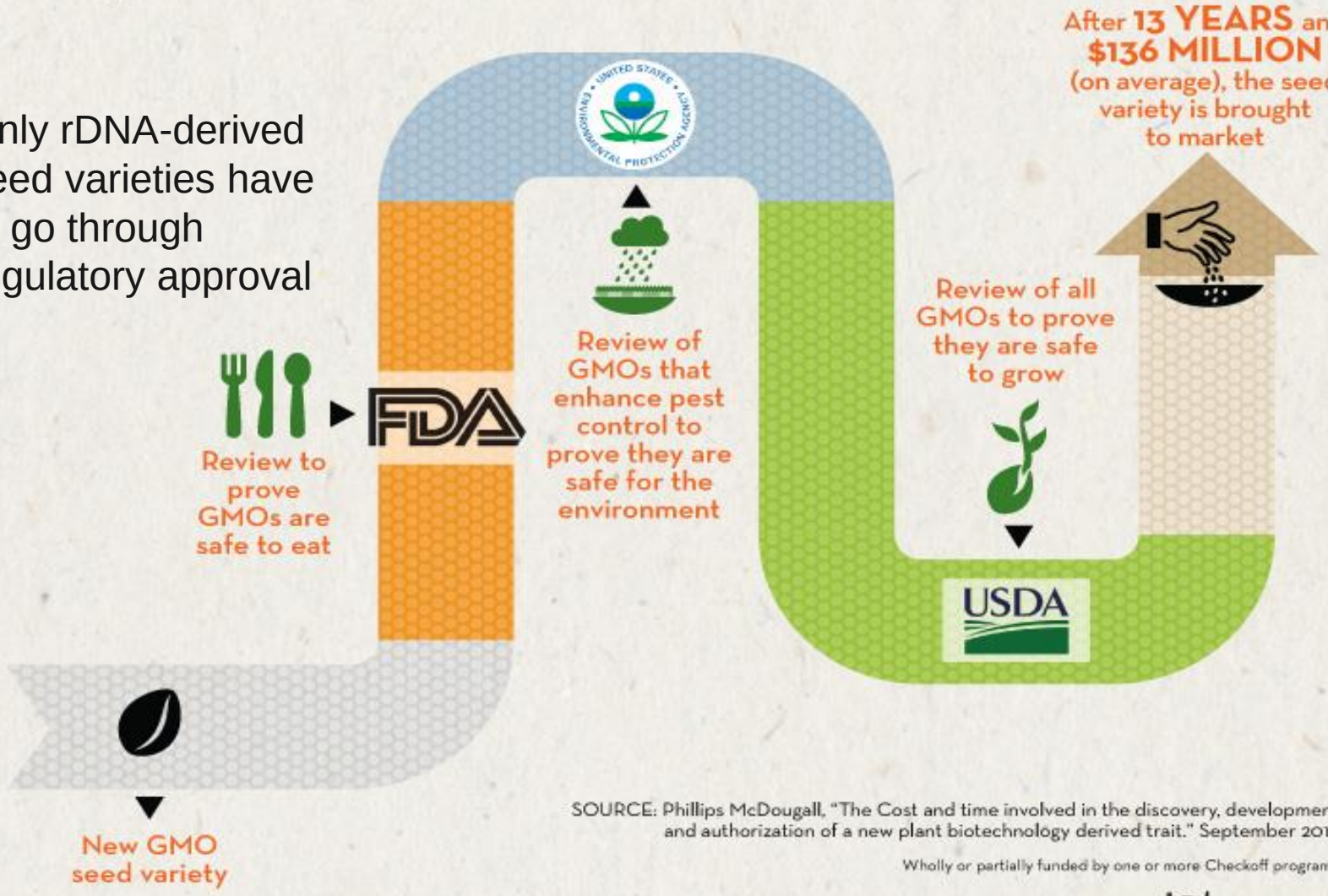


HOW A GM SEED GETS TO MARKET

No other type of new seed that comes to market from other breeding methods goes through regulatory approval, including the thousands of conventional and organic seeds developed from mutagenesis*. Only GMOs are required to be reviewed. Even before the new seed goes through the review process, years of testing and research take place.

*Deliberately engineered DNA mutations

Only rDNA-derived seed varieties have to go through regulatory approval



SOURCE: Phillips McDougall, "The Cost and time involved in the discovery, development and authorization of a new plant biotechnology derived trait." September 2011.

Wholly or partially funded by one or more Checkoff programs

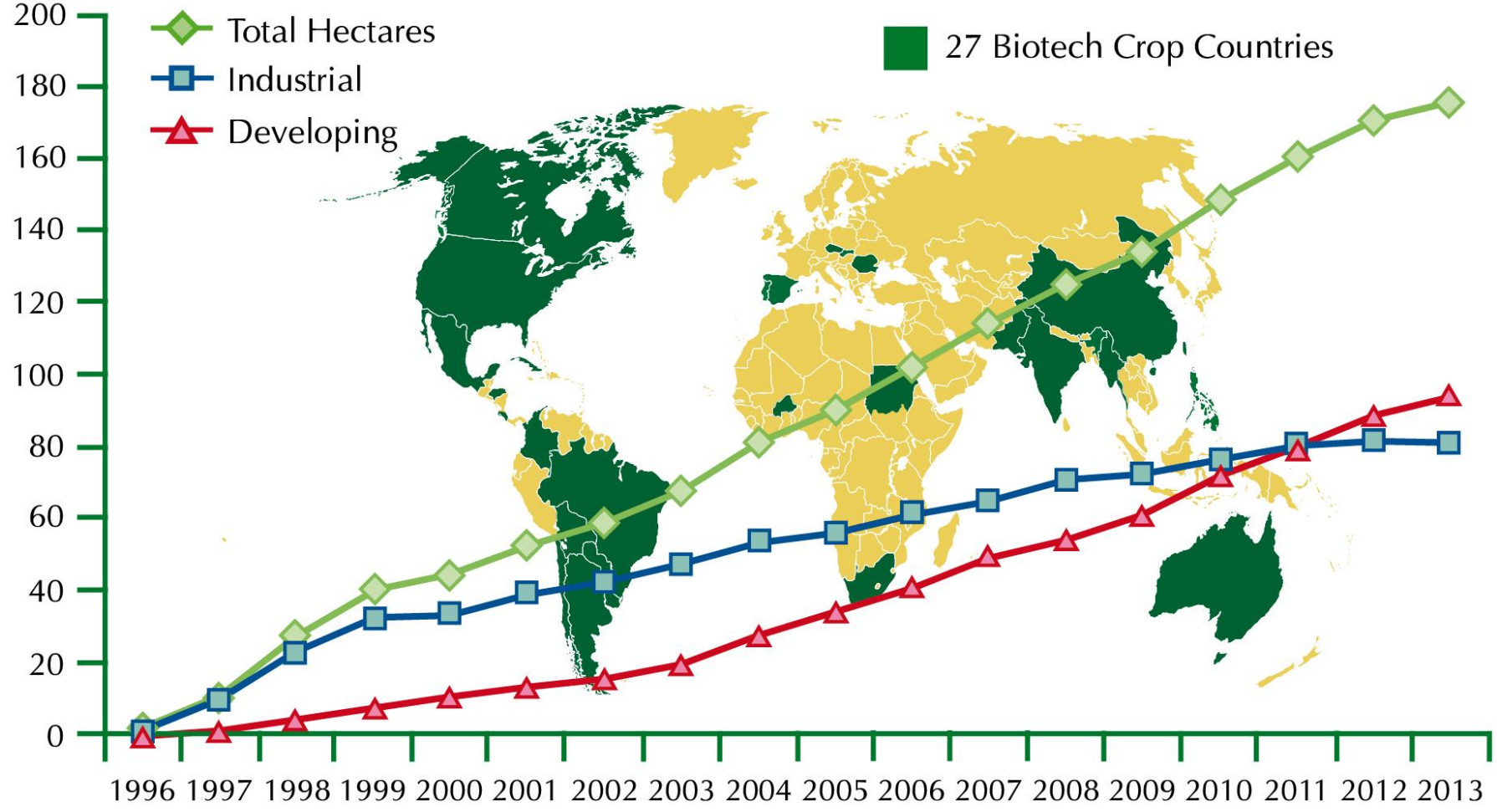
U.S. Farmers & Ranchers Alliance

www.FoodDialogues.com

Summary statements of leading science organizations regarding safety of genetic engineering

- "No effects on human health have been shown as a result of the consumption of such foods by the general population in the countries where they have been approved."(World Health Organization)
- "No adverse health effects attributed to genetic engineering have been documented in the human population." (National Academy of Sciences)
- "The science is quite clear: crop improvement by the modern molecular techniques of biotechnology is safe." (American Association for the Advancement of Science)
- "There is no scientific justification for special labeling of bioengineered foods. Bioengineered foods have been consumed for close to 20 years, and during that time, no overt consequences on human health have been reported and/or substantiated in the peer-reviewed literature." (American Medical Association)
- "No scientific evidence associating GMOs with higher risks for the environment or for food and feed safety than conventional plants and organisms." (European Commission)

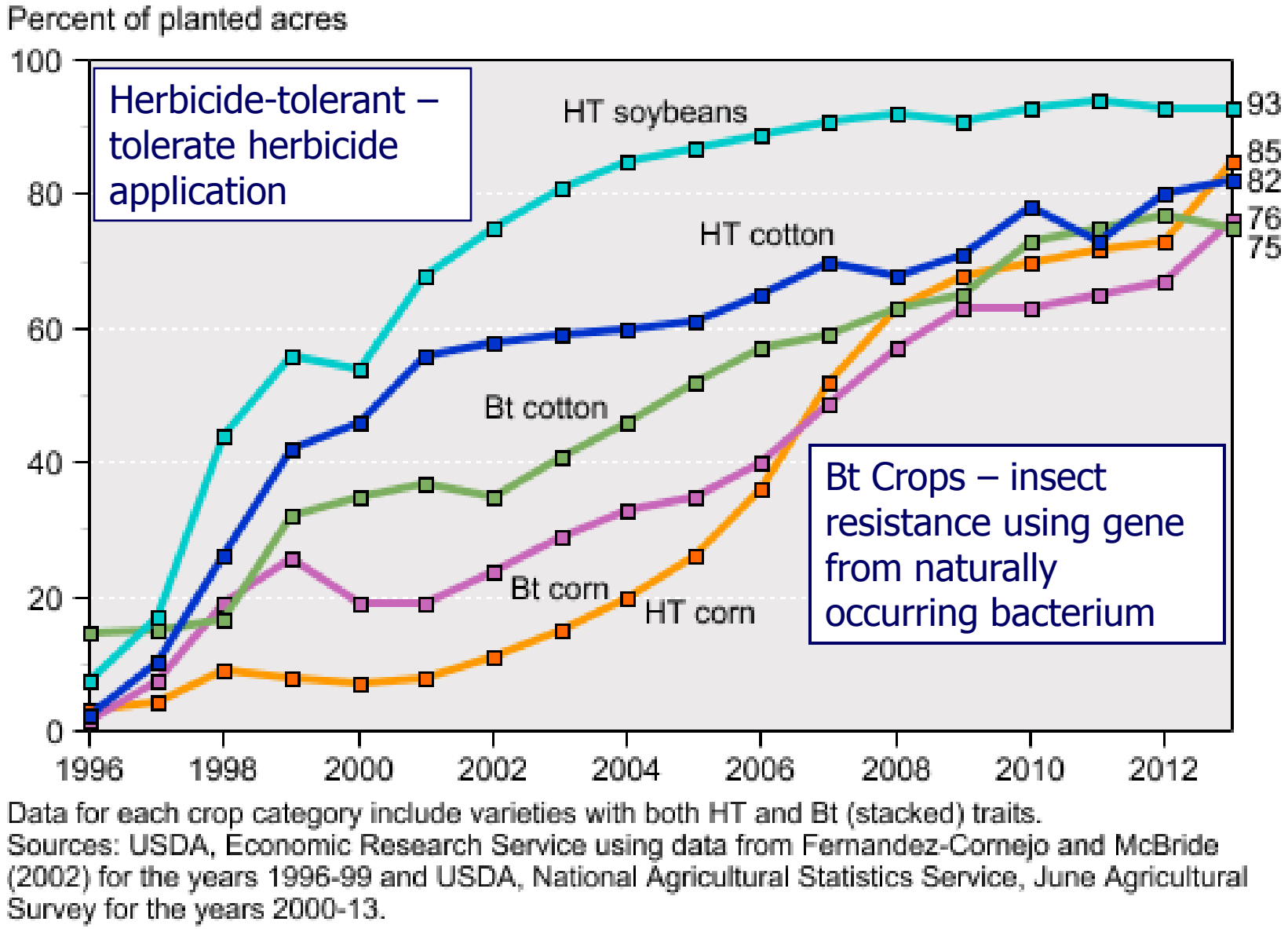
Global Area of Genetically Engineered (GE) crops
Million hectares (1996-2013)



A record 18 million farmers, in 27 countries, planted 175.2 million hectares (433 million acres) in 2013, a sustained increase of 3% or 5 million hectares (12 million acres) over 2012.

Source: Clive James, 2013 ISAAA Brief 46-2013

Adoption of genetically engineered crops in the United States, 1996-2013



Data for each crop category include varieties with both HT and Bt (stacked) traits.
Sources: USDA, Economic Research Service using data from Fernandez-Cornejo and McBride (2002) for the years 1996-99 and USDA, National Agricultural Statistics Service, June Agricultural Survey for the years 2000-13.

What crops are GE in US?

- ✓ 90% of all **corn** planted in U.S. was GE in 2013
- ✓ 90% of all **cotton** planted in U.S. was GE in 2013
- ✓ 93% of all **soybeans** planted in U.S. was GE in 2013
- ✓ 95% of all **sugar beet** planted in U.S. was GE in 2013
- ✓ 90% of all **alfalfa** seeds sold in US were GE in 2013
- ✓ Also canola, papaya, some squash, melons and sweetcorn

<u>NON-GE FEEDSTUFFS CURRENTLY INCLUDE</u>

- Wheat
- Sorghum
- Oats
- Rice
- Millett
- Barley

Genetically engineered citrus greening (also called huanglongbing or HLB)-resistant citrus trees – research lead by public-sector researcher (Texas A&M)

Engineering Innate GE potato to reduce levels of acrylamide, a potential carcinogen and known neurotoxin, developed by J. R. Simplot, Idaho

SOURCE: Wu, L., Bhaskar, P.B., Busse, J.S., Zhang, R., Bethke, P.C. and and Jiang, J. 2011. Developing Cold-Chipping Potato Varieties by Silencing the Vacuolar Invertase Gene. Crop Science 51: 981-990.

Non-browning “Artic” GE apple, developed by Okanagan Specialty Fruits in Canada

rDNA
gene construct

embryo

GE or transgenic animal

Research
- disease models

Biomedical
- pharmaceuticals
- xenotransplantation

Industrial
- spider silk

Agriculture
- none on market to date

GloFish™

FDA statement on Glofish (exercised "enforcement discretion")

"Because tropical aquarium fish are not used for food purposes, they pose no threat to the food supply. There is no evidence that these genetically engineered zebra danio fish pose any more threat to the environment than their unmodified counterparts which have long been widely sold in the United States. In the absence of a clear risk to the public health, the FDA finds no reason to regulate these particular fish."

December 9, 2003

The first product from a transgenic farm animal to become a registered drug in 2009 was Antithrombin III from GTC-Biotherapeutics, USA, produced in the mammary gland of transgenic goats for heparin resistant patients to prevent blood clots

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FDA Grants First-Ever U.S. Approval of GE Animal Product Printer Friendly

For Immediate Release
2/6/2009

Contact:
Contact Karen Batra
202-449-6382

WASHINGTON, D.C. (Friday, February 06, 2009) - Advances in human health care from the genetic engineering of animals are now being realized in the United States. The U.S. Food and Drug Administration (FDA) announced today the first approval of a product derived from a genetically engineered (GE) animal.

ATryn®, a recombinant form of human antithrombin developed by GTC Biotherapeutics, was approved by the FDA for the prevention of peri-operative and peri-partum thromboembolic events in hereditary antithrombin deficient patients. It is not indicated for treatment of thromboembolic events in hereditary antithrombin deficient patients. ATryn® is the first ever transgenically produced therapeutic protein and the first recombinant antithrombin approved in the United States.

Along with the approval of ATryn®, the FDA's Center for Veterinary Medicine also approved GTC's New Animal Drug Application, the first of its kind to regulate GE animals. This is now required for a recombinant technology used to develop transgenic animals, such as the goats that produce recombinant antithrombin. GTC has granted OVATION the right to market ATryn® in the United States and pursue further clinical development.

February 2009, First GE Animal Product

www.gtc-bio.com

Fast growing salmon

The founder female was generated in 1989 – 25 years ago

Nature Biotechnology 10:176 – 181. 1992

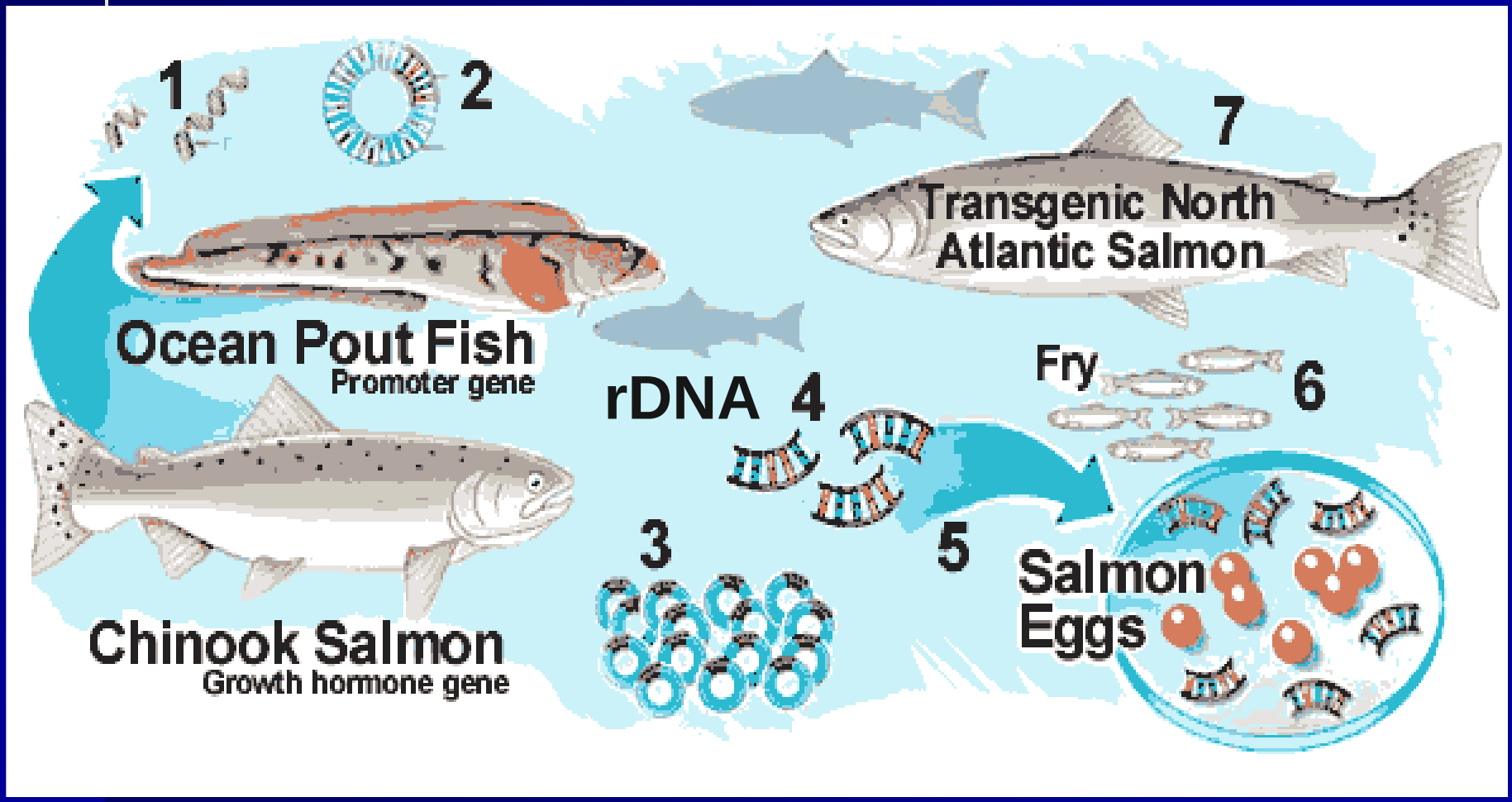
GROWTH ENHANCEMENT IN TRANSGENIC ATLANTIC SALMON BY THE USE OF AN "ALL FISH" CHIMERIC GROWTH HORMONE GENE CONSTRUCT

Shao Jun Du, Zhiyuan Gong, Garth L. Fletcher[1], Margaret A. Shears[1], Madonna J. King[1], David R. Idler[1] and Choy L. Hew*

Research Institute, The Hospital for Sick Children and Departments of Clinical Biochemistry and Biochemistry, University of Toronto, Toronto, Canada M5G 1L5. [1]Ocean Sciences Centre, Memorial University of Newfoundland, St. John's, Newfoundland, Canada A1C 5S7. *Corresponding author.

We have developed an "all fish" growth hormone (GH) chimeric gene construct by using an antifreeze protein gene (AFP) promoter from ocean pout linked to a chinook salmon GH cDNA clone. After microinjection into fertilized, nonactivated Atlantic salmon eggs via the micropyle, transgenic Atlantic salmon were generated. The presence of the transgene was

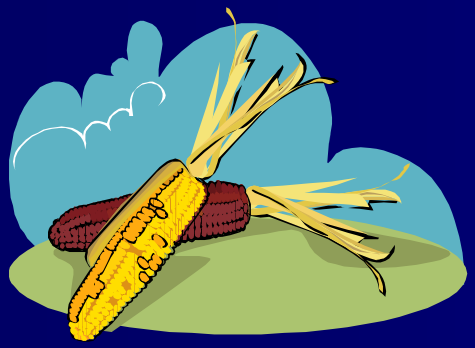
How was the AquAdvantage salmon made?



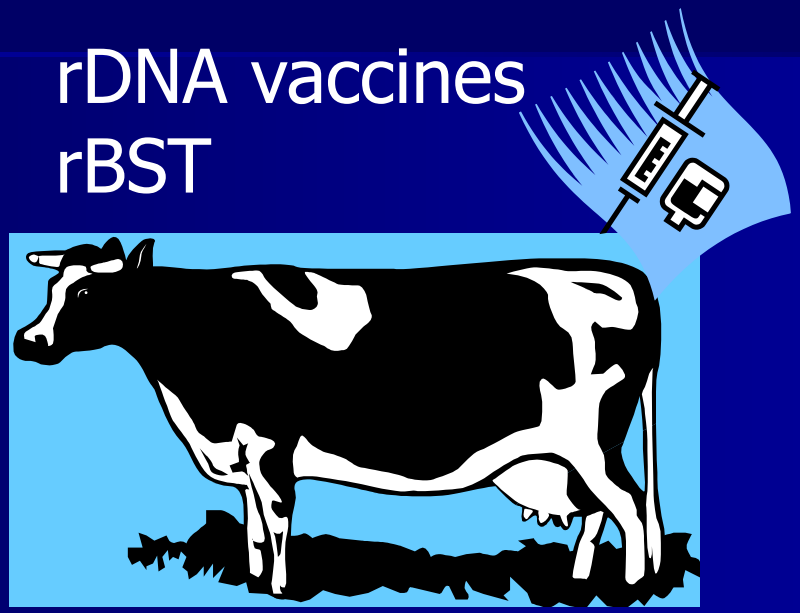
Where is GE used in Animal Agriculture?

GE products are used in animal feed, vaccines (chickens, pigs, horses, dogs, cats), pharmaceuticals, food processing aids, and food

GMO feed



rDNA vaccines
rBST



Currently no GM animals in market

GMO food & ingredients

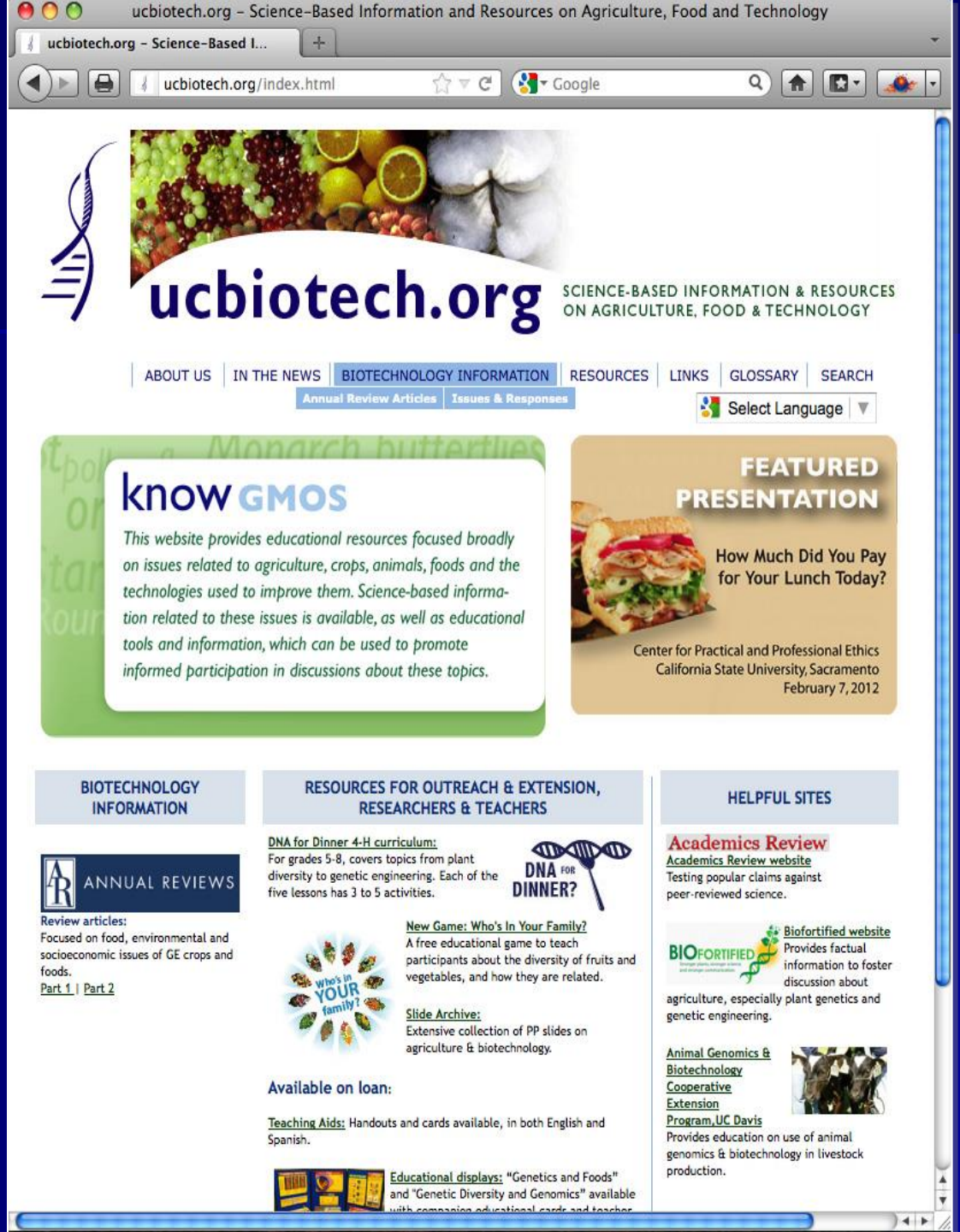
GE rennet, and other food processing aids

Summary

- GE refer to organisms produced using rDNA techniques
- GE organisms are used to make medicines (e.g. insulin), food processing aids (e.g. rennet to clot cheese), vitamins (e.g. riboflavin), vaccines (e.g. canine distemper), and GE crops for a limited number of species; no GE food animals
- To date no unique food safety concerns have been associated with the current applications of GE organisms despite intensive regulatory scrutiny and 20 years of data
- Adoption of GE crops has been rapid and extensive
- Agricultural applications of GE are more controversial than industrial and medical applications

Want to ask questions? Follow these easy steps in Biotech information section of http://ucbiotech.org

ucbiotech.org



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ucbiotech.org – Issues and Responses

ucbiotech.org – Issues and Res...

ucbiotech.org/search4.php

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SCIENCE-BASED INFORMATION & RESOURCES ON AGRICULTURE, FOOD & TECHNOLOGY

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Go to Issues and Responses section on drop-down menu from Biotechnology Information section. Chose category to see the issues or type your question in "search by phrase". Hit search.

Enter a keyword such as "food".
You can also search by combination of words such as "water and food".

bt corn safe to eat?

SEARCH

Alternatively, you may list all of the questions related to a category.
Select a category, and click "Display."

Agriculture

DISPLAY

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Responses to the issue you raised will appear and you can click on the Response that best addresses your question.

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ucbiotech.org – Issues and Res...

ucbiotech.org/search4.php

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Search Again?

Your search for *bt corn safe to eat?* returned the following results

Results are given in order of relevance

Are Food Safety Studies Conducted on GE Foods? Response

Besides Genetically Engineered Crops, Does Genetic Engineering Play a Role in Producing Food? Response

Were Foods Made From Bt Corn Removed from the Market Because of Allergenicity Concerns? Response

Is the Bt Protein Safe for Human Consumption?

Bt proteins, naturally occurring insecticides produced by the soil bacterium, B. thuringiensis, have been used to control crop pests since the 1920s (1), generally as microbial products. Many strains ... Read more...

Filed under [Food Risks] [Food Safety] [Pest Tolerance] [Regulation]

Can Federal Regulatory Agencies Stop Planting of Genetically Engineered Crops That Pose Environmental Risks? Response

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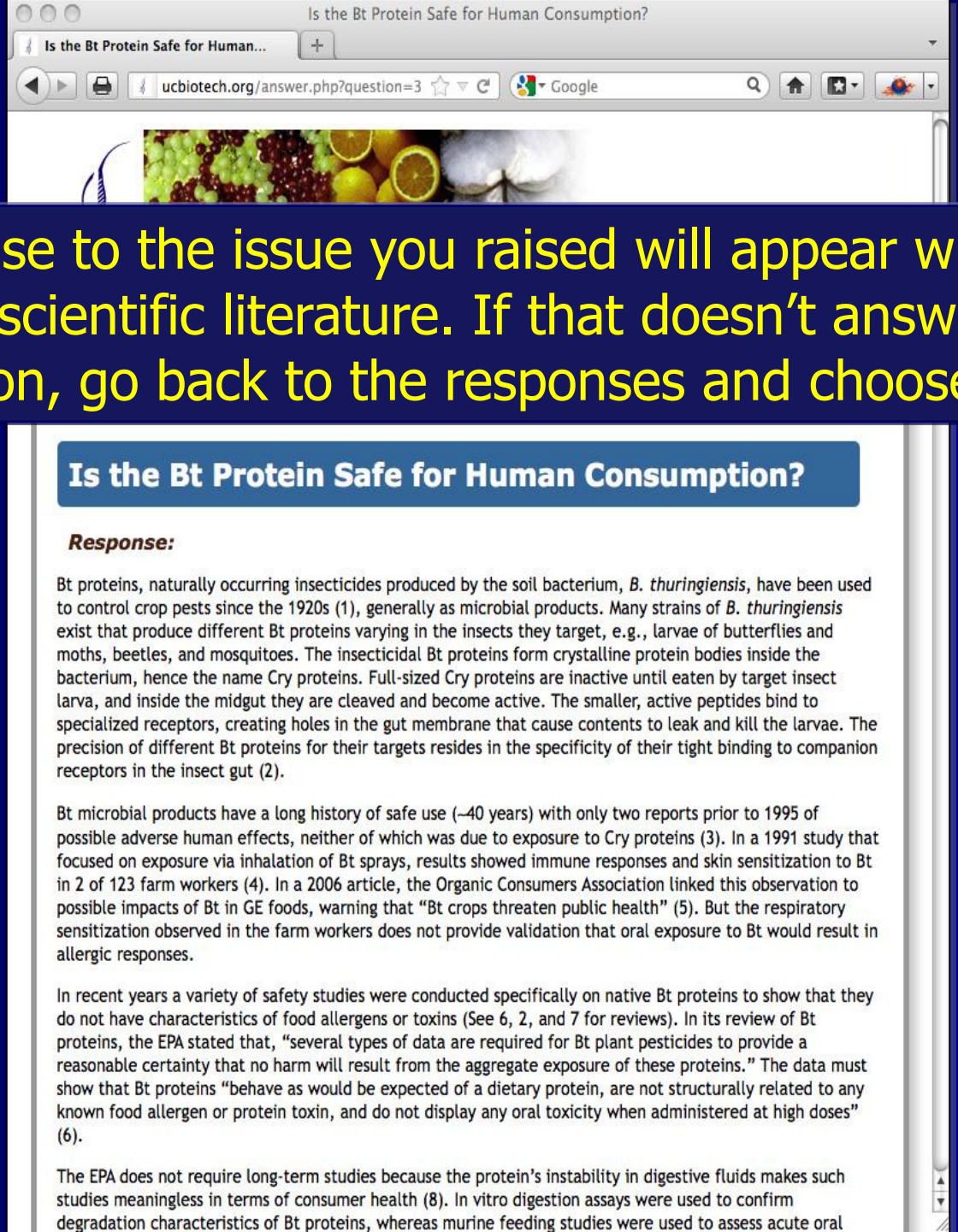
Response to the issue you raised will appear with links to the scientific literature. If that doesn't answer your question, go back to the responses and choose another.



Is the Bt Protein Safe for Human Consumption?

Response:

Bt proteins, naturally occurring insecticides produced by the soil bacterium, *B. thuringiensis*, have been used to control crop pests since the 1920s (1), generally as microbial products. Many strains of *B. thuringiensis* exist that produce different Bt proteins varying in the insects they target, e.g., larvae of butterflies and moths, beetles, and mosquitoes. The insecticidal Bt proteins form crystalline protein bodies inside the bacterium, hence the name Cry proteins. Full-sized Cry proteins are inactive until eaten by target insect larva, and inside the midgut they are cleaved and become active. The smaller, active peptides bind to specialized receptors, creating holes in the gut membrane that cause contents to leak and kill the larvae. The precision of different Bt proteins for their targets resides in the specificity of their tight binding to companion receptors in the insect gut (2).

Bt microbial products have a long history of safe use (~40 years) with only two reports prior to 1995 of possible adverse human effects, neither of which was due to exposure to Cry proteins (3). In a 1991 study that focused on exposure via inhalation of Bt sprays, results showed immune responses and skin sensitization to Bt in 2 of 123 farm workers (4). In a 2006 article, the Organic Consumers Association linked this observation to possible impacts of Bt in GE foods, warning that "Bt crops threaten public health" (5). But the respiratory sensitization observed in the farm workers does not provide validation that oral exposure to Bt would result in allergic responses.

In recent years a variety of safety studies were conducted specifically on native Bt proteins to show that they do not have characteristics of food allergens or toxins (See 6, 2, and 7 for reviews). In its review of Bt proteins, the EPA stated that, "several types of data are required for Bt plant pesticides to provide a reasonable certainty that no harm will result from the aggregate exposure of these proteins." The data must show that Bt proteins "behave as would be expected of a dietary protein, are not structurally related to any known food allergen or protein toxin, and do not display any oral toxicity when administered at high doses" (6).

The EPA does not require long-term studies because the protein's instability in digestive fluids makes such studies meaningless in terms of consumer health (8). In vitro digestion assays were used to confirm degradation characteristics of Bt proteins, whereas murine feeding studies were used to assess acute oral

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Literature cited will appear with links when possible to the articles so that you can see them yourselves.

Are Food Safety Studies Conducted on GE Foods?

Are Food Safety Studies Conduc...

ucbiotech.org/answer.php?question=2

Google

consume large amounts of food to obtain sufficient quantities of the GE ingredient. Compositional analyses and toxicity testing of individual components are actually more sensitive and accurate in assessing safety (15). Therefore, in addition to whole foods, safety tests are conducted on individual products of introduced genes, both target and selectable marker genes, on the basis of the food additive provision (Section 409) of the 1992

References:

1. Food Drug Adm. (FDA). 2005. Guidance for industry: Pharmacogenomic data submissions. http://www.fda.gov/downloads/.../Guidances/ucm126957.pdf Last accessed 2011-11-26. PDF

2. Food Drug Adm. Cent. Food Saf. Appl. Nutr. 2007. Biotechnology. http://usbiotechreg.nbii.gov/database_pub.html. Last accessed 2011-11-26. PDF

3. Environ. Prot. Agency Off. Sci. Coord. Policy Biotechnol. Team. 2006. *Regulatory framework.* http://www.epa.gov/scipoly/biotech/pubs/framework.htm. Last accessed 2011-12-8. PDF

4. Kuiper HA, Kleter GA, Noteborn HPJM, Kok EJ. 2001. Assessment of the food safety issues related to genetically modified foods. *Plant J.* 27:503-28

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Thanks for inviting me

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