

# **Biotechnology Regulatory Services Update**

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**Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service  
United States Department of Agriculture**

**National Plant Board  
July 29, 2014**



**Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service**

# Paul Eggert



# Outline

- BRS FY14 Goals & Organization
- Regulatory Activities
  - FY14 Decisions
  - CBI Sharing Rule
- Inspections & State Partnership
- Hot Issues
- County Level Statutes



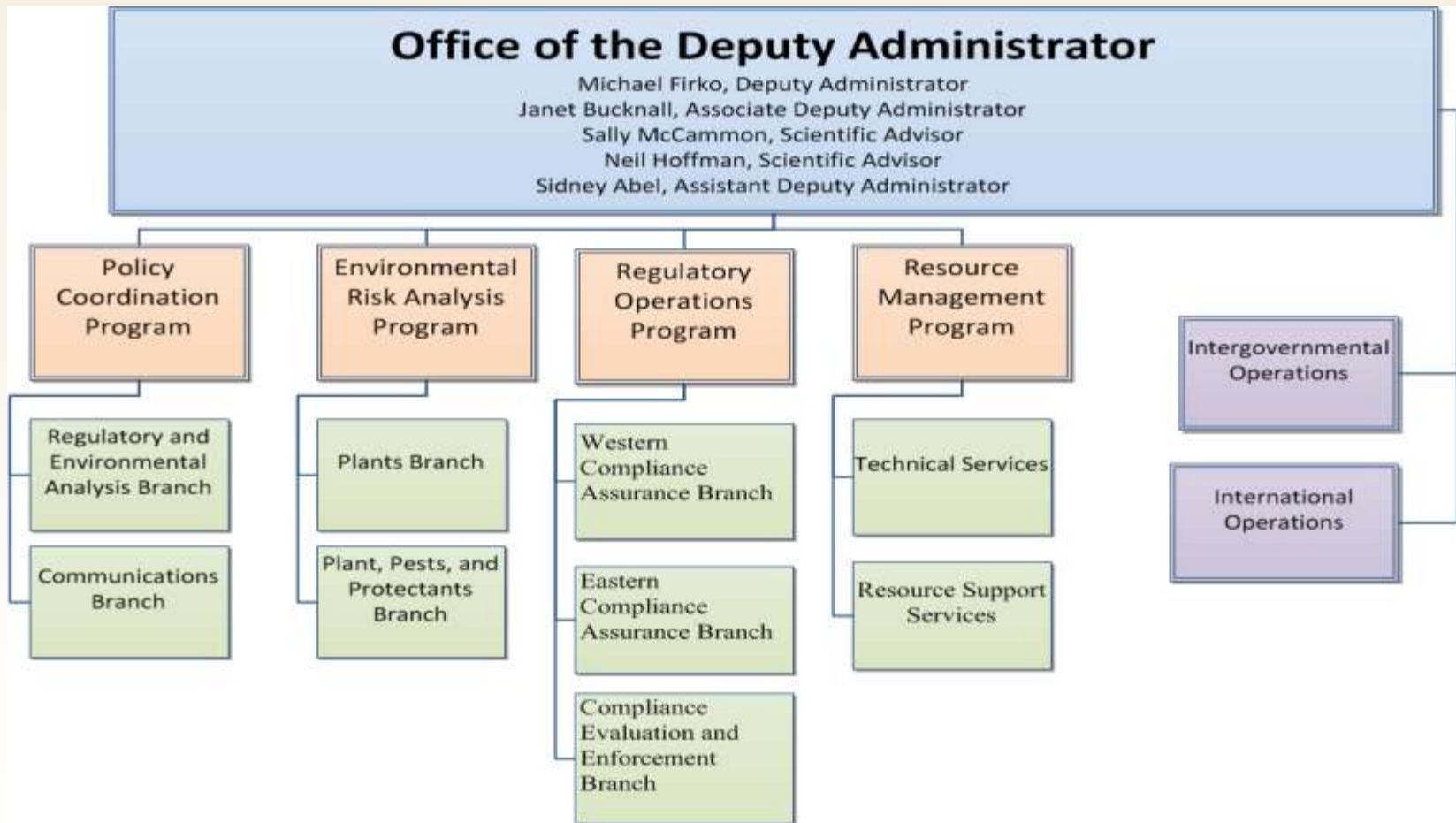
# BRS FY14 Operational Goals



1. Maintain and Enhance Compliance
2. Balance Oversight and Risk
3. Ensure the Best Science is used in Decision-making
4. Create a Highly Effective Organization



# Organizational Chart





# Improved Petition Process

<b>Step</b>	<b>New Process ( # Completed)</b>	<b>New Process (# Ongoing)</b>	<b>Target (Days)</b>	<b>Actual (Days)</b>	<b>Diff. (Days)</b>	<b>Previous<sup>1</sup> (Days)</b>	<b>Savings (Days)</b>
Completion of initial petition review	9	0	35	29	-6	205	-176
Response from petitioner	9	0	30	26	-4	107	-81
Completion of final petition review	11	0	21	29	+8	39	-10
Preparation of draft PPRA	12	1	60	90	+30	143	-53
60-Comment on petition	15	0	60	60	0	n/a	+60
Preparation of draft EA	11	2	180	275	+95	213	+62
Preparation of final EA	2	1	44	40	-4	91	-51

<sup>1</sup> Average of all petitions using old process since 2005



# FY14 Regulatory Decisions



## Recent Approvals (4)

- Monsanto Increased Yields Soybean
- BASF Herbicide (imidazolinone) Resistant Soybean
- Dow Insect Resistant and Herbicide Tolerant Soybean
- Syngenta mesotrione and glufosinate Tolerant Soybean



# CBI Sharing Rule

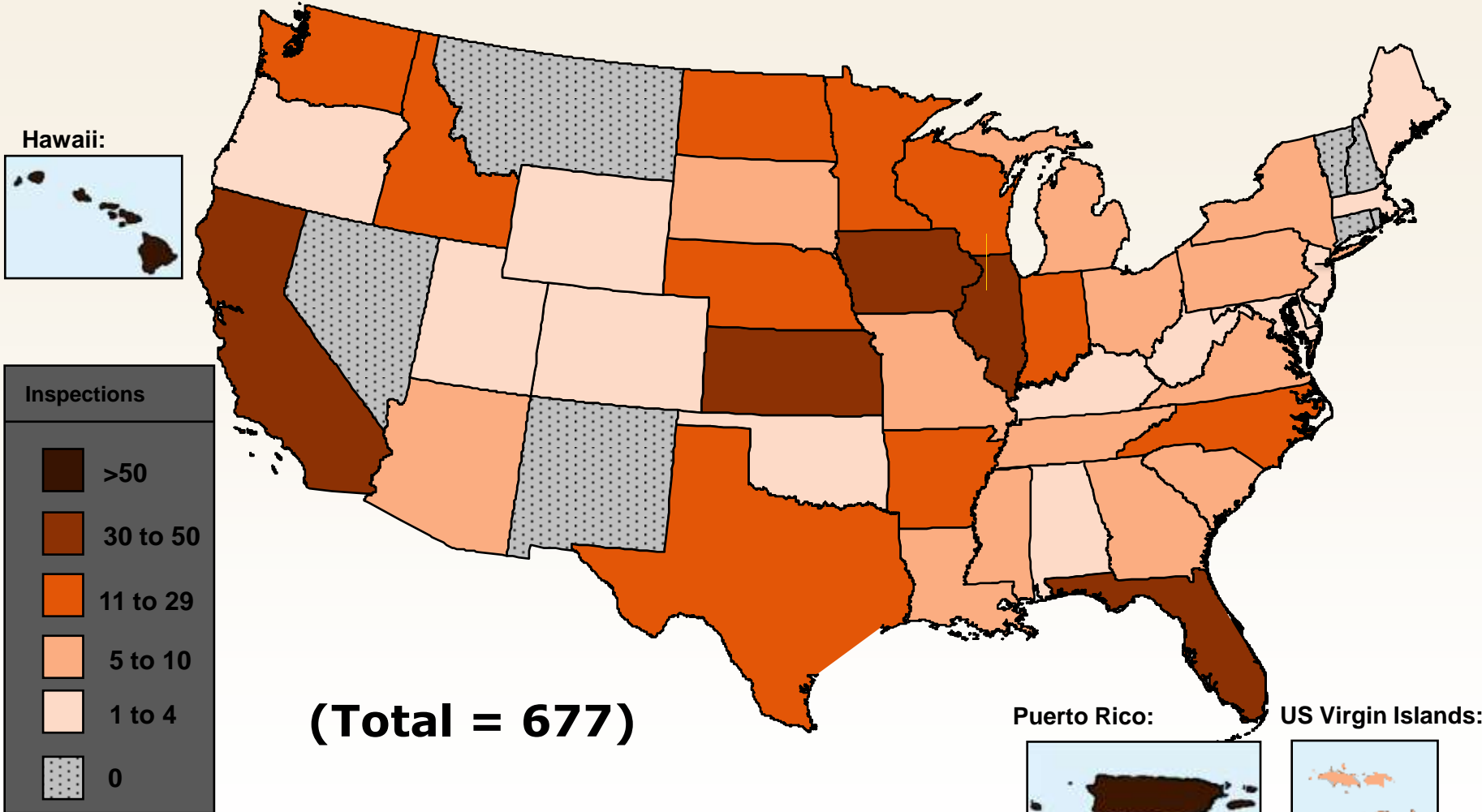


- Withdrawal of CBI Sharing Rule published on July 18, 2014
- Potential vulnerability associated with FOIA was identified.
  - Under FOIA, States and Tribes are considered members of the public
  - Once APHIS discloses information to one member of the public, information may be subject to release to other members of the general public through FOIA.





# FY 2013 USDA Biotech Inspections Completed



# Inspection Partnership



## State Inspection Program

- 2013 participant States
  - Arkansas, Kansas, Florida, North Carolina, Minnesota

<b>FY</b>	<b>States</b>	<b>Total Inspections</b>
08	AR, KS	26
09	AR, KS, FL, NC	35
10	AR, KS, FL, NC	47
11	AR, KS, FL, NC	64
12	AR, KS, FL, NC, MN	60
13	AR, KS, FL, NC, MN	79
14	AR, KS, FL, NC, MN	35 (as of July 21)



# FY13 State Inspections

<b>State</b>	<b>Inspections conducted by State</b>	<b>Total Inspections</b>	<b>% conducted by State</b>
Florida	27	37	73
Minnesota	8	12	67
Kansas	26	33	79
North Carolina	7	16	44
Arkansas	11	11	100



# Other Topics of Interest



- 2,4-D resistant corn and soybean EIS
- Dicamba resistant soybean and cotton EIS
- Report of Investigation for OR GE Wheat



# County GE Regulation



## Enacted

- Mendicino, CA (2004)
- Marin, CA (2004)
- Trinity, CA (2004)
- San Cruz, CA (2004)
- San Juan, WA (2012)
- Kauai, HI (2013)
- Hawai'i, HI (2013)
- Jackson, OR (2014)
- Josephine, OR (2014)

## Pending

- Maui, HI
- Benton, OR
- Lane, OR
- Humboldt, CA



# For More Information



## **USDA-APHIS-BRS:**

[http://www.aphis.usda.gov/biotechnology/brs\\_main.shtml](http://www.aphis.usda.gov/biotechnology/brs_main.shtml)

## **EPA:**

<http://www.epa.gov/pesticides/biopesticides/pips/index.htm>

## **FDA-CFSAN:**

<http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/ucm2006889.htm>







# Questions?



**Biotechnology Regulatory Services  
Animal and Plant Health Inspection Service**

# History of Plant Breeding



Before 1900

Classical Breeding

1900

Cell Fusion  
Chemical Mutants  
X-ray Mutants



1980

Add Specific DNA  
(Genetic Engineering)



# GE Plant Development

**LABORATORY / GREENHOUSE**  
**(not regulated by APHIS)**



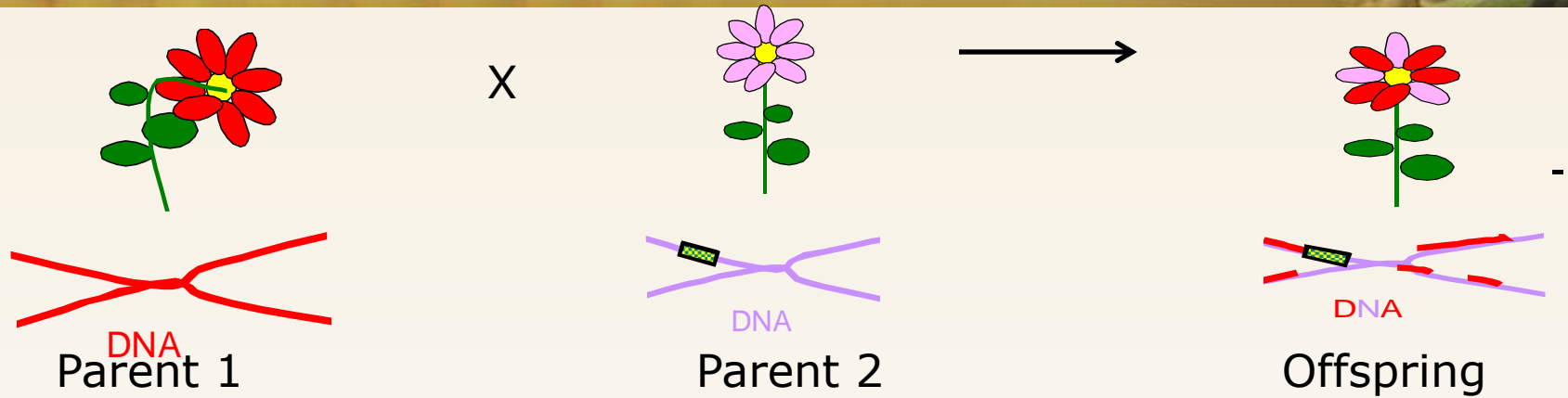
**FIELD TESTING**  
**(regulated by APHIS)**



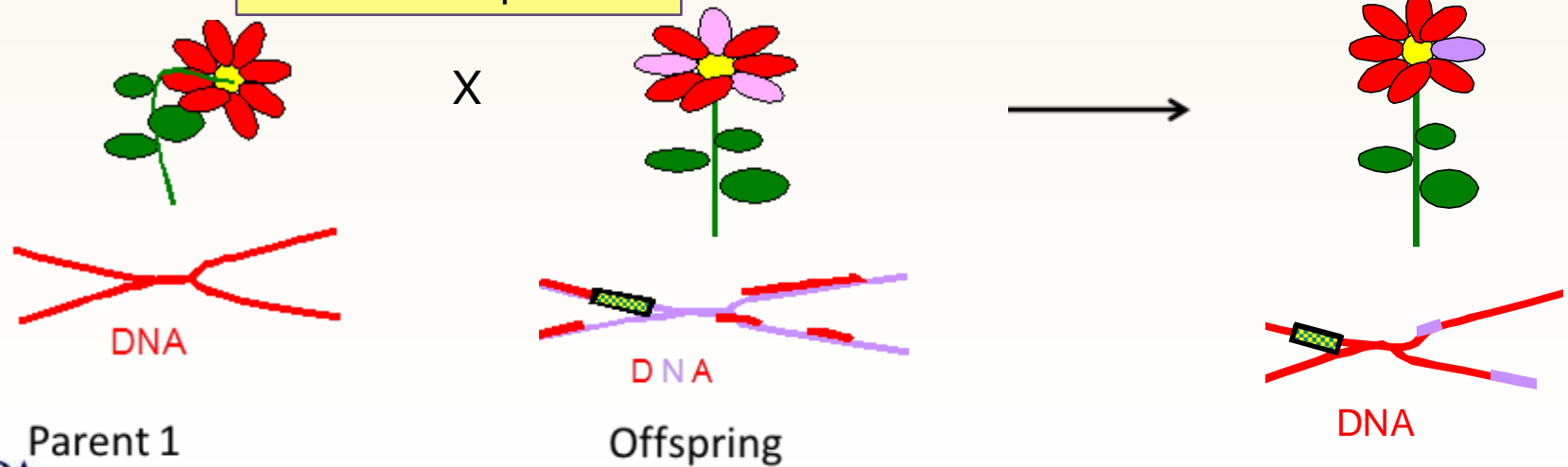
**COMMERCIALIZATION**  
**(not regulated by APHIS)**



# Classical Breeding



Backcross to Parent 1 multiple



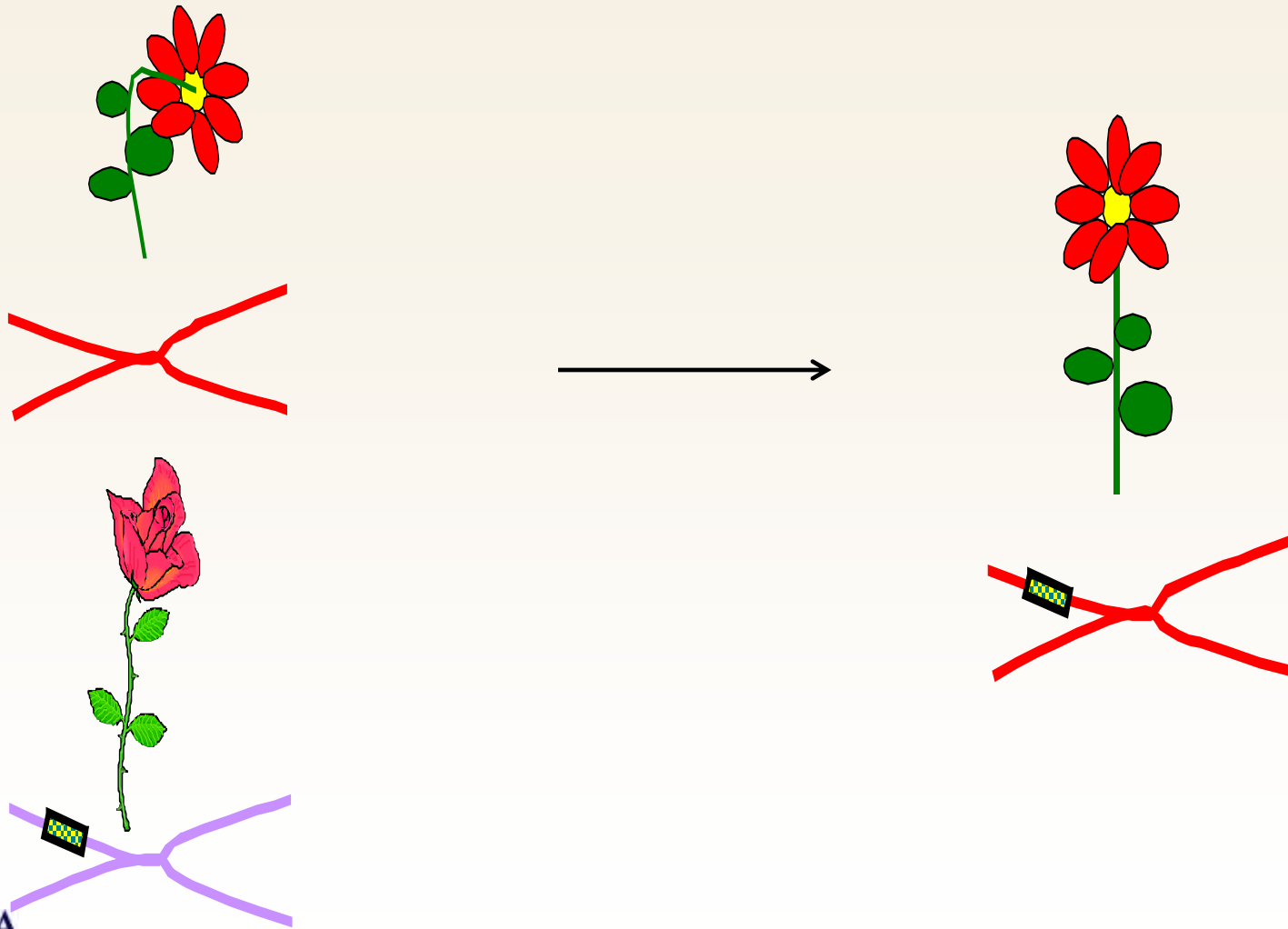


# Chemical Mutagenesis/ X-Ray Mutants



Select for different traits for breeding or marketing

# Genetic Engineering





# History of Plant Breeding



## Not Regulated

**Classical Breeding  
(Before 1900)**

**Cell Fusion  
Chemical Mutants  
X-Ray Mutants  
(After 1900)**

## Regulated

**Add Specific DNA from  
Certain Hosts  
(After 1980)**

