

# **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



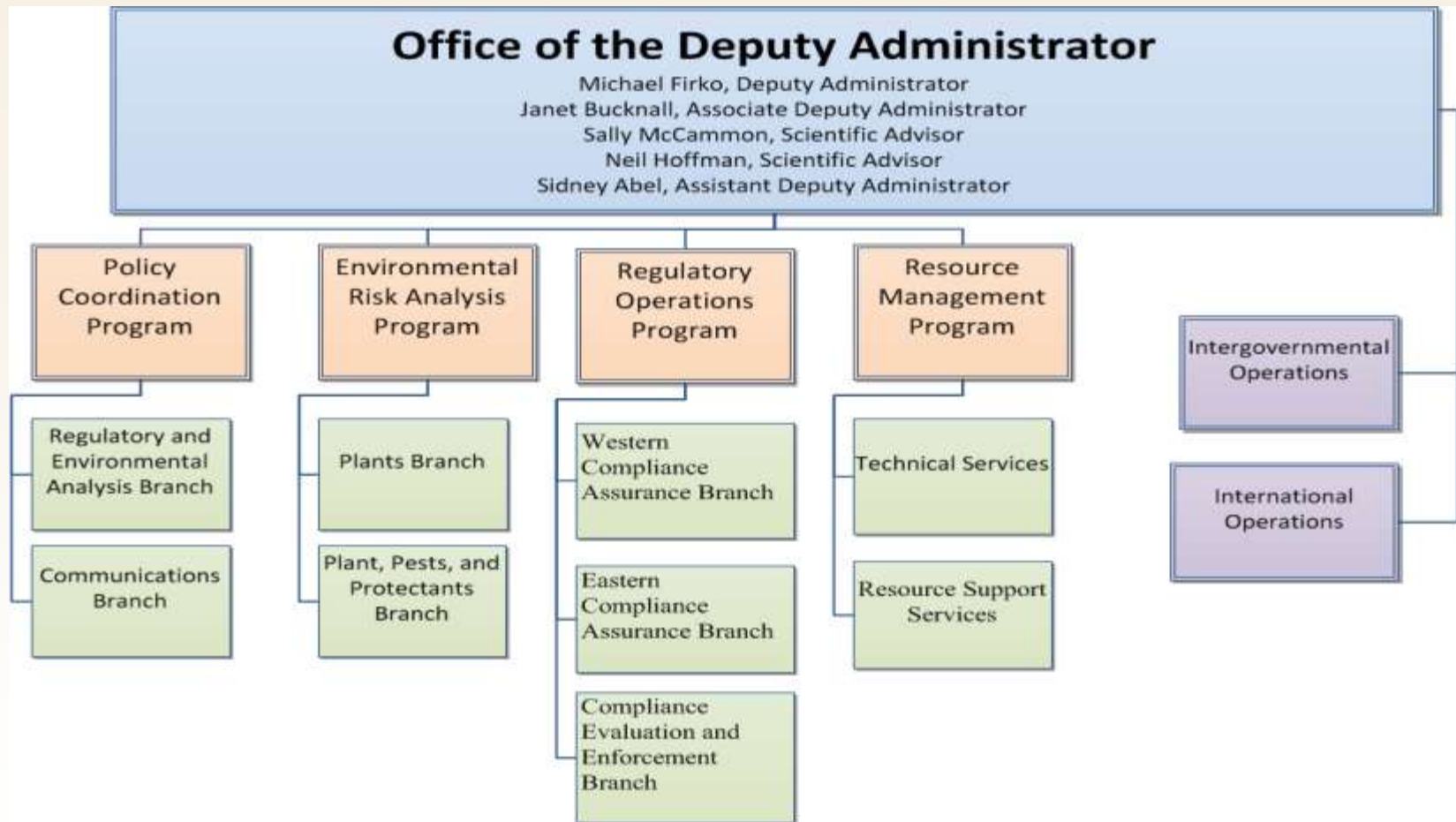
# BRS FY14 Operational Goals



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<br/>( # Completed)</b> | <b>New Process<br/>(# Ongoing)</b> | <b>Target<br/>(Days)</b> | <b>Actual<br/>(Days)</b> | <b>Diff.<br/>(Days)</b> | <b>Previous<sup>1</sup><br/>(Days)</b> | <b>Savings<br/>(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



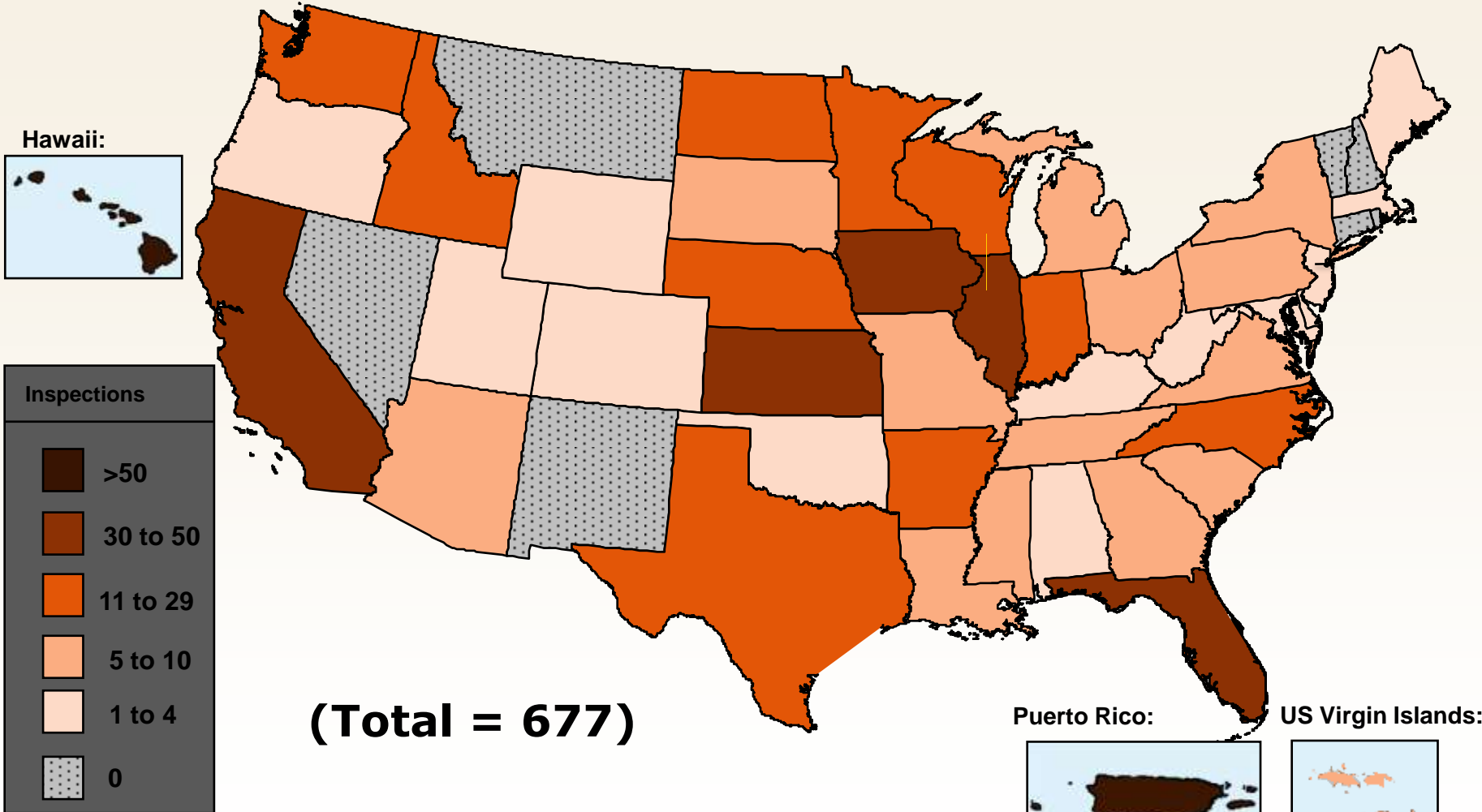
# CBI Sharing Rule

- 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<br>(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)





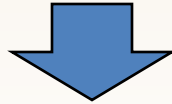
# GE Plant Development



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



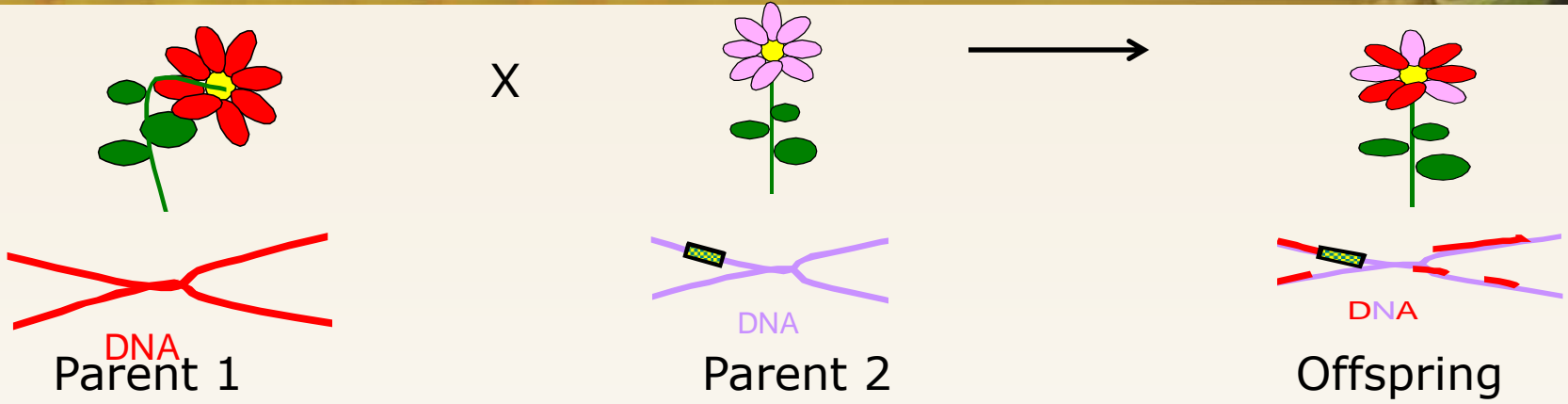
**FIELD TESTING**  
(regulated by APHIS)



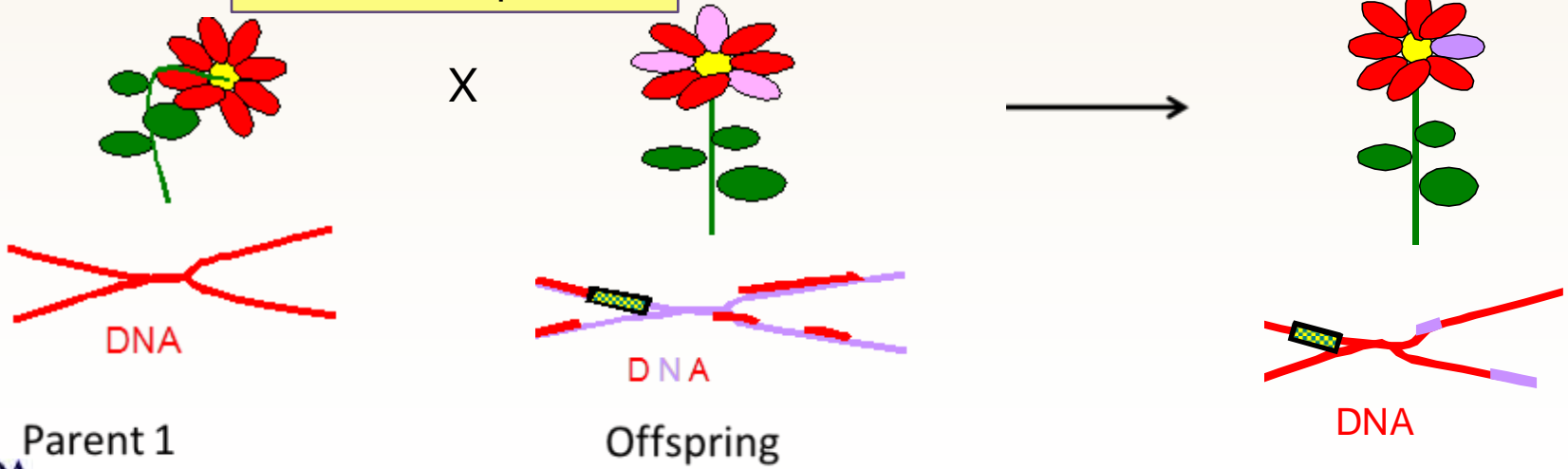
**COMMERCIALIZATION**  
(not regulated by APHIS)



# Classical Breeding



Backcross to Parent 1 multiple

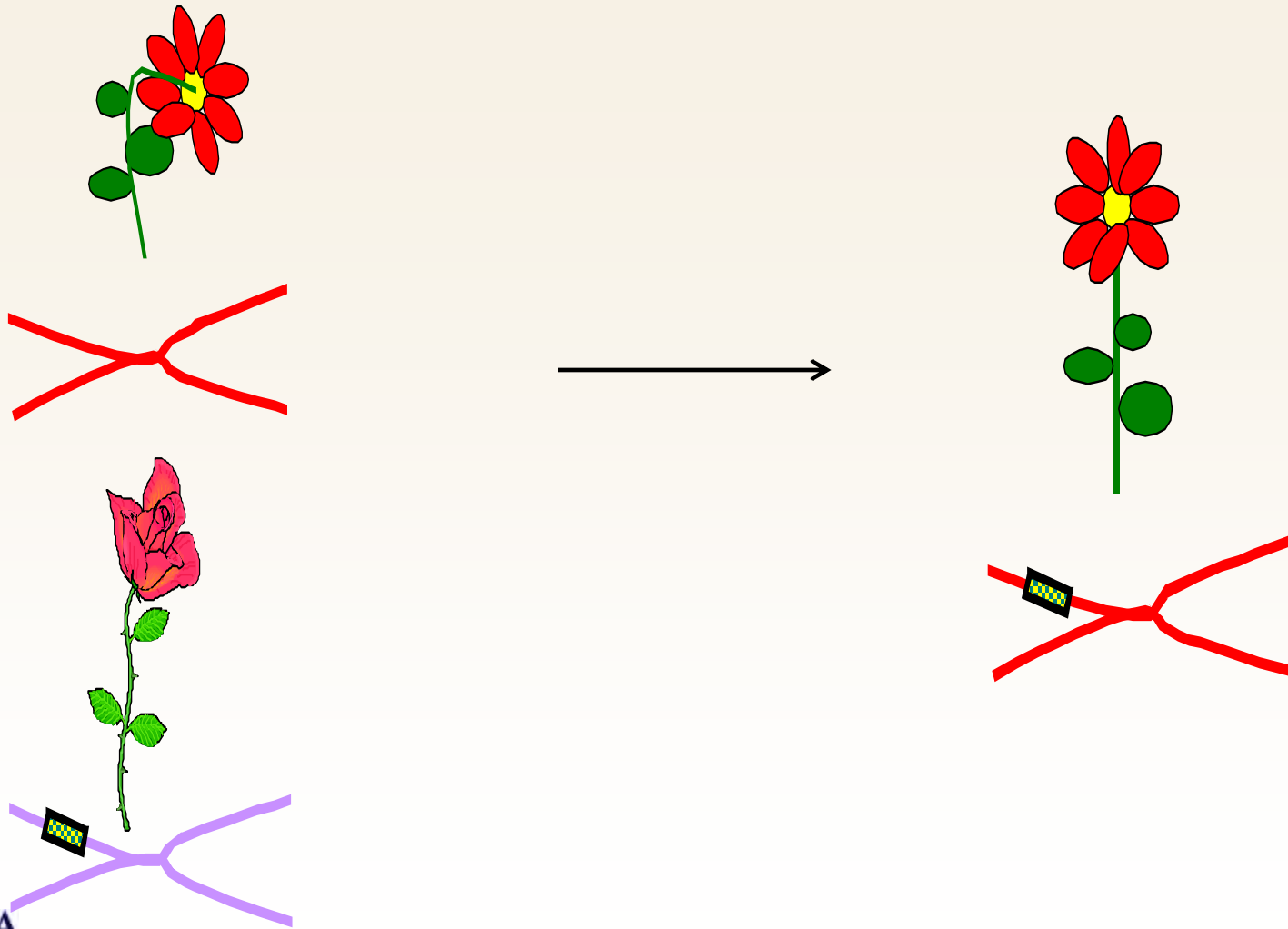


# Chemical Mutagenesis/ X-Ray Mutants



Select for different traits for breeding or marketing

# Genetic Engineering



# History of Plant Breeding



| <b>Not Regulated</b>   | <b>Regulated</b>  |
|--|---|
| <b>Classical Breeding<br/>(Before 1900)</b>                                | <b>Add Specific DNA from<br/>Certain Hosts<br/>(After 1980)</b> |
| <b>Cell Fusion<br/>Chemical Mutants<br/>X-Ray Mutants<br/>(After 1900)</b> |   |