

Regulatory Structure for GE Crops

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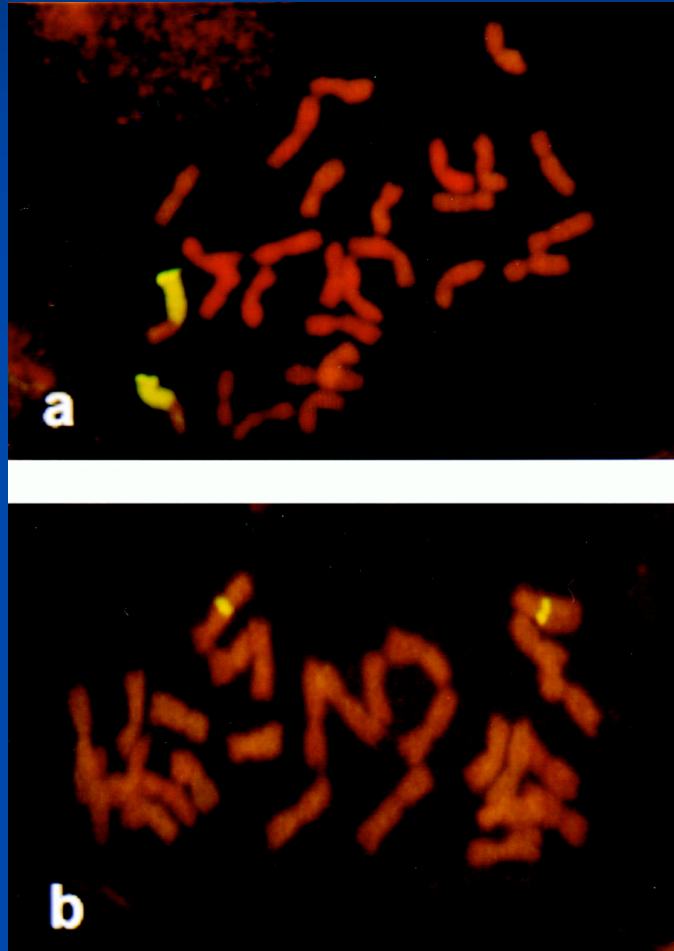
Arguments to ban GMOs...

- **GMOs are hazardous because...**
- GE breaks the “species barrier”; Nature never allows genes from one species to move to another
- GE involves random insertions into genome
- GE crops and foods are untested and unregulated
- Once released, GMOs can never be recalled
- ...or other claims of danger?

USA: Theory of risk assessment

- Science based risk analyses
 - Other factors applied later
- Product vs process
 - rDNA processes are not inherently risky
 - Any breeding process may result in risky products
- Labelling
 - Product composition, not process

Foreign Genes in Wheat



Friebe et al., Crop Science 39:1692-1696 (1999)

Variety release requirements: genetically engineered crops

- USDA (APHIS) - environmental issues
- HHS (FDA)- food and feed safety
- EPA- pesticide usage issues

Variety release requirements: genetically engineered crops

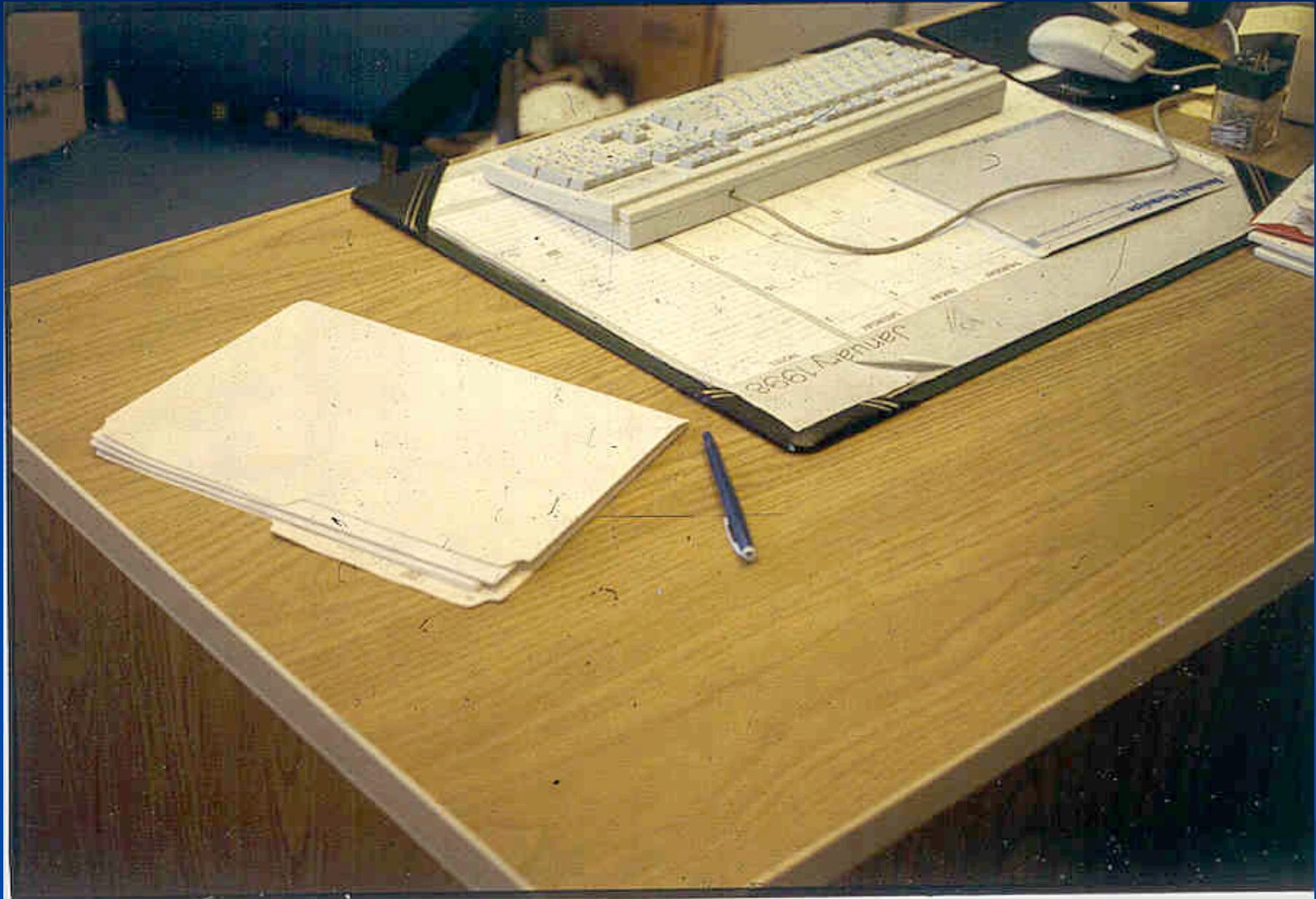
- USDA- environmental issues
 - Plant Protection Act (PPA, 2000); *also administers*
 - Plant Patent Act (*for asexually propagated plants*)
 - Plant Variety Protection Act (PVPA)

USDA/APHIS procedures

- Notification
 - Simplest means for least hazardous GE plants
 - Must meet six criteria (non-weedy; stable; known function; non-infectious/toxic/pharmaceutical/industrial; non-virulent; non-human or animal pathogenic source)
- Permit (for field testing release)
 - More complex GE plants, requires greater scrutiny
- Petition for nonregulated status (commercialization)
 - Complete risk analysis

US field trials, 1986-present

- 12,000+
 - <http://nbiap.biochem.vt.edu/cfdocs/fieldtests1.cfm>
- 47,000
 - Environment Maine (PR 8/18/2005)
 - “...once released, can never be recalled.”





Variety release requirements: genetically engineered crops

- FDA- food and feed safety
 - Federal Food, Drug, and Cosmetic Act (FFDCA)
 - GRAS (substantially equivalent)
 - Food Additive

Variety release requirements: genetically engineered crops

- EPA- pesticide usage, food safety issues
 - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
 - Federal Food, Drug, and Cosmetic Act (FFDCA) and
 - Toxic Substances Control Act (TSCA)

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- GE involves random insertions into genome
- GE crops and foods are untested and unregulated
- Once released, GMOs can never be recalled...
- **The same “hazards” as other breeding methods.**