# Safety Regulations for Stacks and New Technologies


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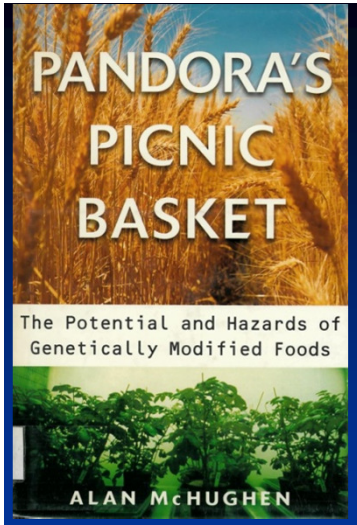
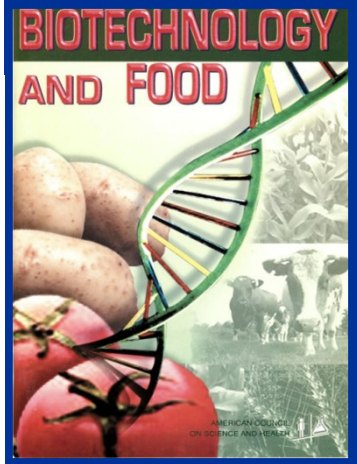
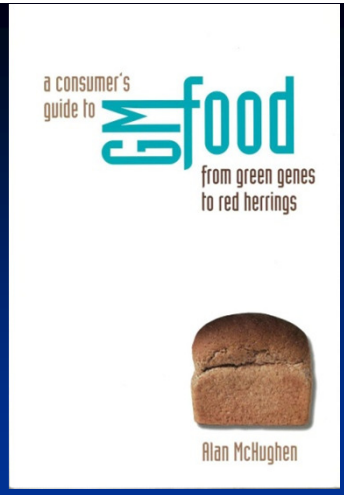
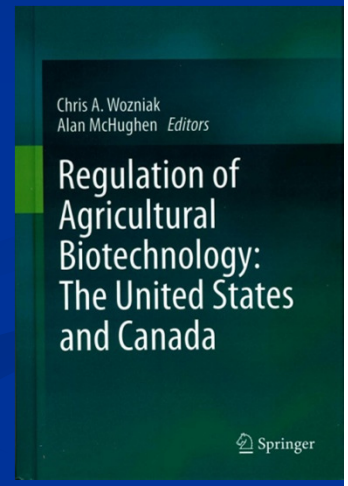
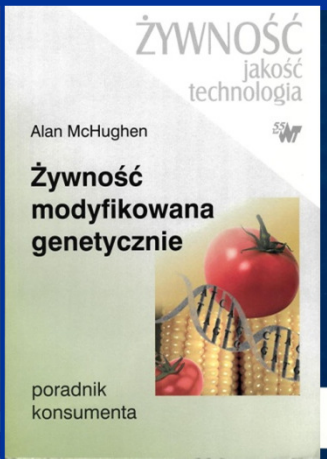


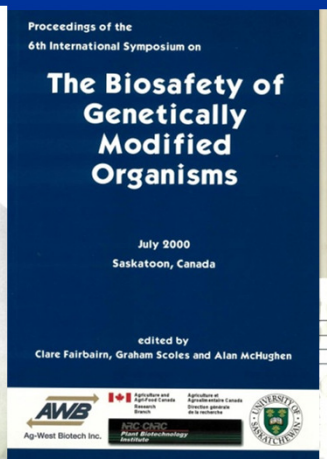



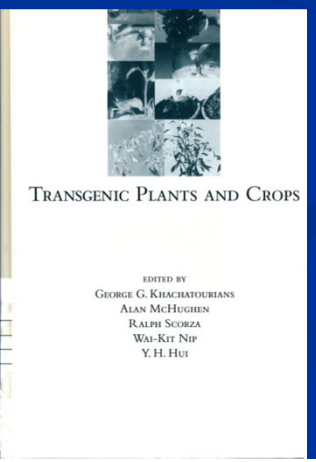



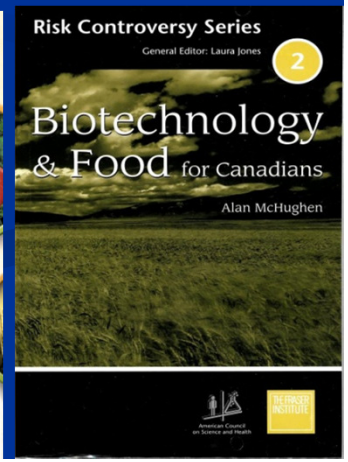








# Need for science based regulations

- Product vs Process assessment trigger
  - Risk is carried by products, not processes
  - Science based trigger looks at features of a product
  - Non-science looks at process (of rDNA, etc.)
- Hazards are overcome using **science,** not emotion
  - Fail to address actual problems
  - Processes are constantly changing; outdating laws
  - Products maintain features; no need to update laws
- Trade obligations:
  - WTO requires scientific evidence to support differential treatment of GMO products.

# Regulating New Technologies

- *Agrobacterium tumefaciens* Natural rDNA
- Particle gun- physical rDNA
- Stacks- combining two independent GE traits
- Cisgenics- no foreign DNA
- Talen-Crispr-RNAi: no foreign DNA, modification
- Zinc Finger
  - Nuclease (exact locus DNA insert)
  - Transcription factor (no DNA modification)
- Synthetic Biology: fabricate new gene/protein.

# Regulatory Maxim

- Degree of regulatory scrutiny should be commensurate with degree of risk
- Tiered approach is often appropriate
- Relax scrutiny with increased familiarity and comfort
  - Especially with clean safety record of prior products
- Expend regulatory resources on actual threats.

# Safety issues with 'Stacks'

## Conventional breeding to combine two or more Transgenic (GM) 'events'

- **USA**- if parent 'events' were approved: No regulation of derived genotypes/cultivars
- **EU**- full regulatory review as if stacks were entirely new GMO 'events'
- **Canada** – Stacked PNT events: Notification only
  - But may require added data if:

# Canada - Stacks

- The novel traits of the parental PNTs are expressed differently in the stacked plant product (e.g. greater or lower expression), or
- The stacked product expresses an additional novel trait not already approved
- New stewardship requirements may be imposed

*http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/stacked-traits/eng/1337653008661/1337653513037*

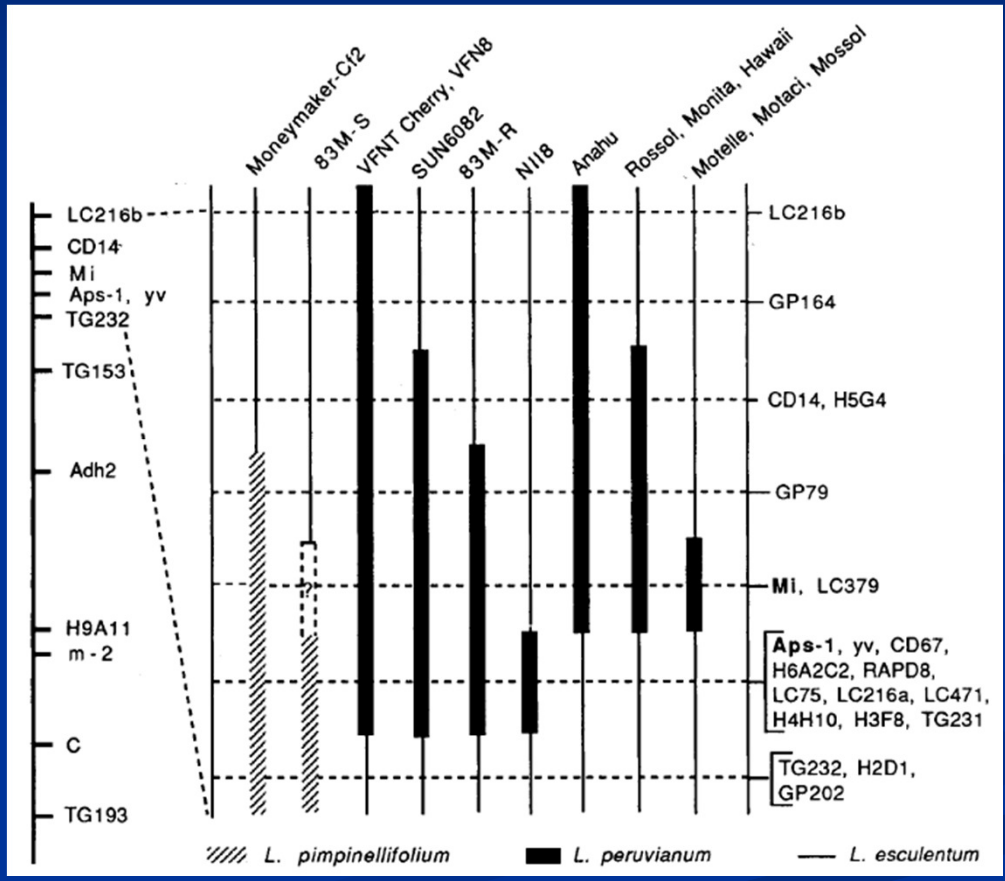
| | USA | EU | Canada | Scientific community |
|---|---|---|---|---|
| *Agrobacterium* | Yes | Full | Depends on novel traits | Depends on novel traits |
| Biolistic | Depends on plant pest component | Full | Depends on novel traits | Depends on novel traits |
| Stack | None (EPA reviews stacked PiPs) | Full | Notification | Only if traits interact in a new way |
| Cisgenic | None? | Full | None | None |
| Zinc Finger | Depends on plant pest component | Full | Depends on novel traits | Depends on novel traits |
| Irradiation mutagenesis | none | none | Depends on novel traits | Depends on novel traits |
| Introduction from distant region | none | none | Depends on novel traits | Depends on novel traits |

# Genomic alterations from traditional breeding approaches

Introgression of Mi locus in tomato accompanied by dozens to hundreds of genes (Ho et al. 1992)

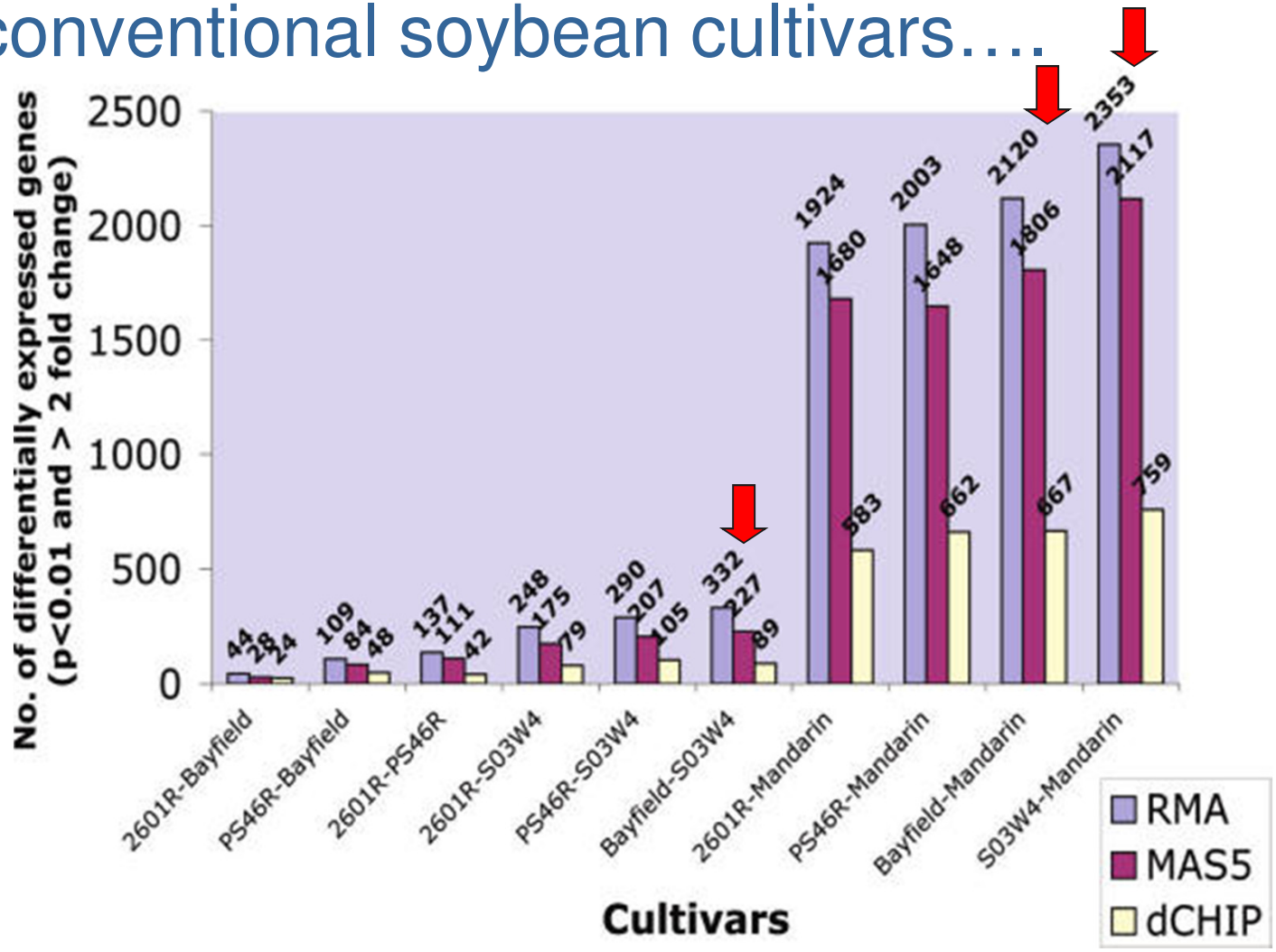
Rapid sequence elimination observed following allopolyploidization (Ozcan et al. 2001. Plant Cell 13: 1735-1747)

Also disproves "species barrier" fallacy; these are NOT GE!



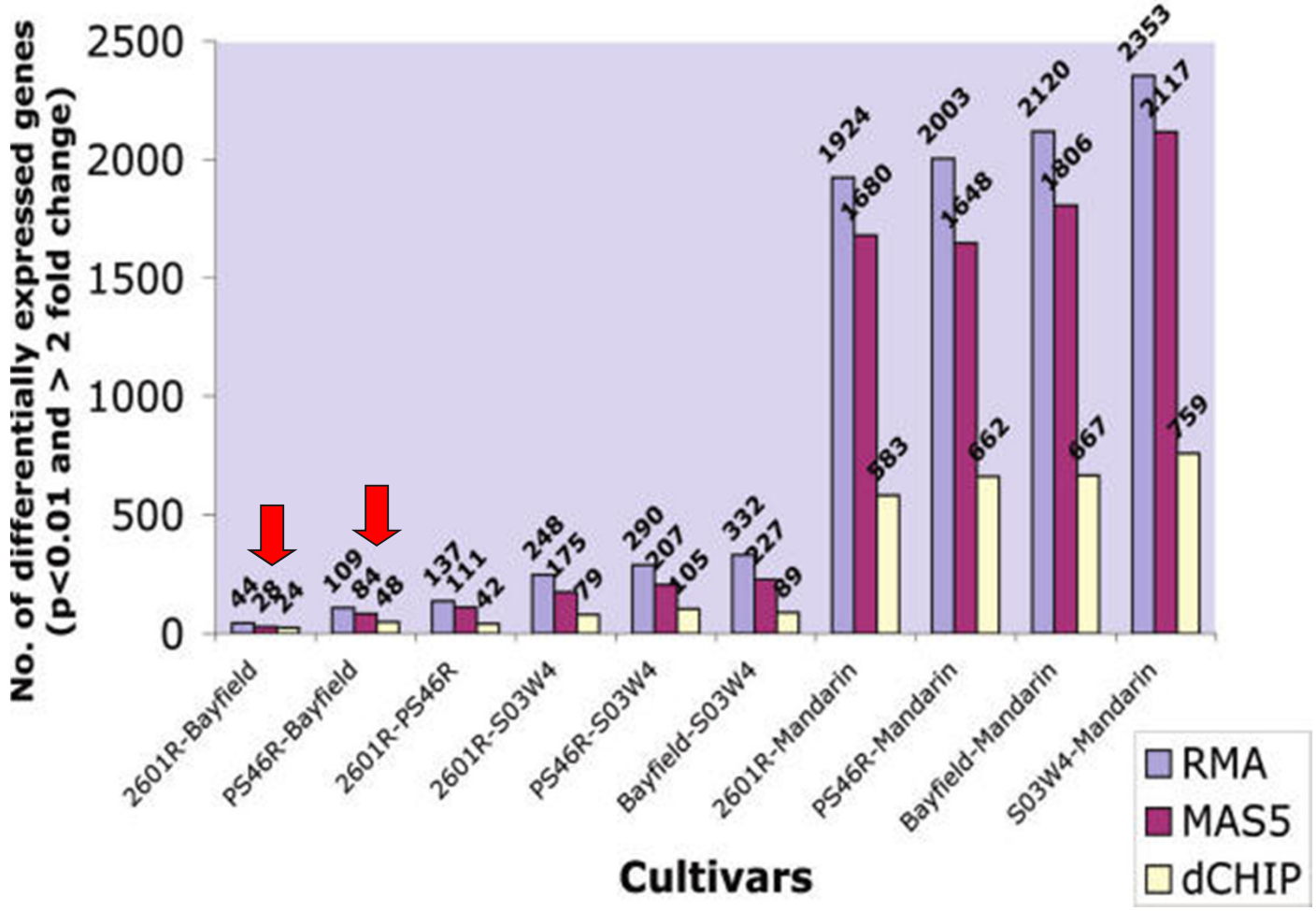

*Next three slides from*: Schnell, J. 2010. Canadian Food Inspection Agency (CFIA)

# Gene expression differs more between two conventional soybean cultivars….




Cheng et al 2008. J Agric Food Chem 56: 3057-3067

# …than between transgenics and their closest conventional cultivars

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# Similar products, similar risks ?

| HT Canola: | Group |
| --- | --- |
| Sulfonylurea | 2. ALS/AHAS inhibitor |
| Trifluralin | 3. Mitotic inhibitor |
| Bromoxynil | 4. PGR |
| Triazine | 5. Photosynthetic inhibitor |
| Glyphosate | 9. EPSP Synthase inhibitor |
| Glufosinate | 10. Glutamine Synth. inhibitor |

# Conventional Non-SE examples

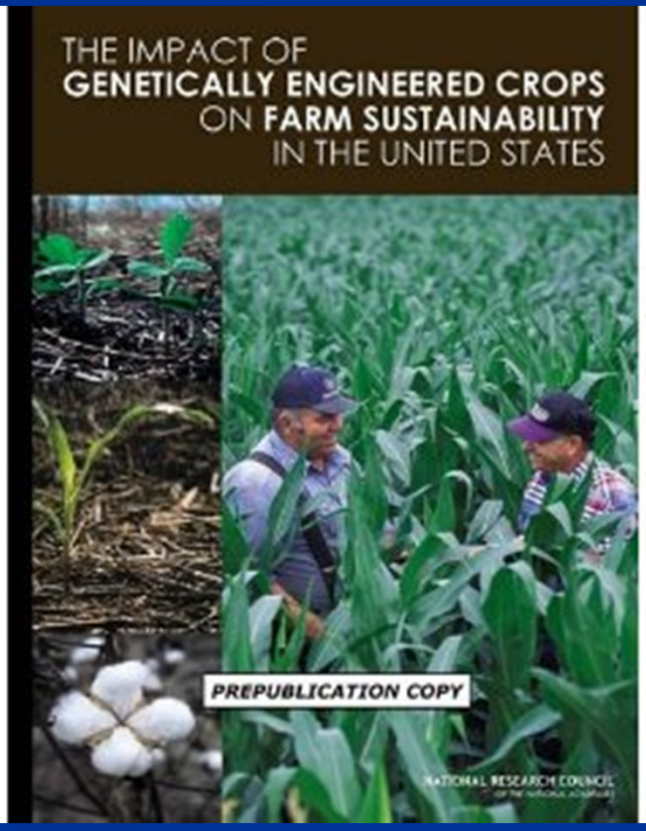
- Celery with excessive psoralin content
- Tomatoes: excessive tomatine content
- Potatoes: Lenape,  excessive solinine content
- Canola: reduced erucic acid, glucosinolates
- Solin: flax with reduced omega-3 f.a., increased linoleic acid (profile equivalent to sunflower oil)

Other mutants: >3200 cultivars worldwide

Mutant database: http://mvgs.iaea.org/

# *'Is AgBiotech farming sustainable?'*

- US: NAS, 2010. Impact of GE crops on farm sustainability in the US
  - *Also see:*
- Brookes and Barfoot, 2014
- Bonny, 2011
- Qaim, 2009



# Sustainability Impacts in the USA

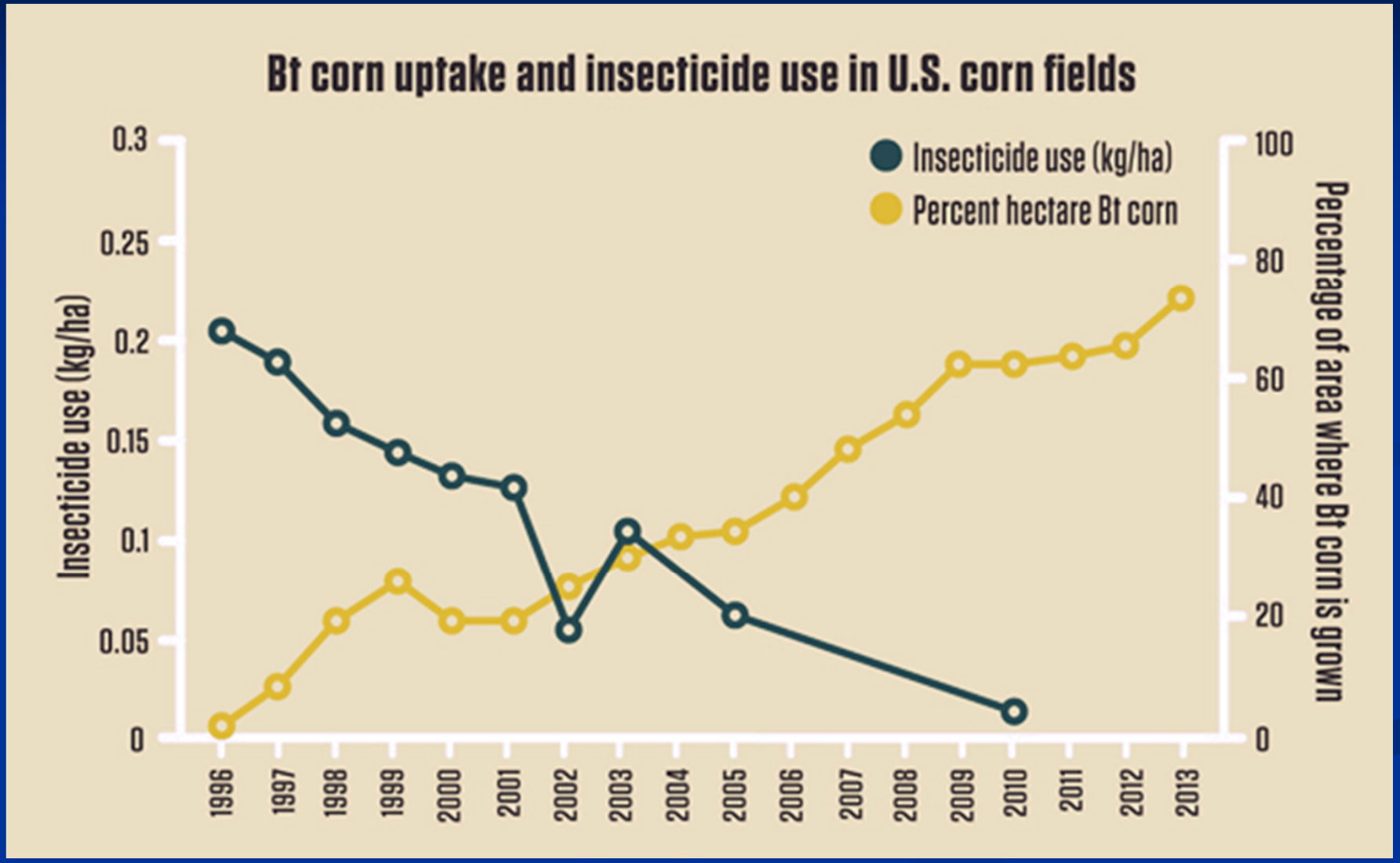
- NAS Conclusions: Planting GE crops *generally* :
  - Is better for the environment than conventional crops
  - Uses less pesticide
  - Uses safer pesticides than those used in conventional cropping systems
  - Reduces tillage, leading to improvements in
    - Soil
    - Water
  - BUT: may lead to reliance on a single pesticide.

# USDA-ERS (2014)

- Insecticide use has decreased with the adoption of insect-resistant crops
- Herbicide-tolerant crops have enabled the substitution of glyphosate for more toxic and persistent herbicides
- Overreliance on glyphosate and a reduction in the diversity of weed management practices have contributed to the evolution of glyphosate resistance in some weed species.

www.ers.usda.gov/publications/err-economic-research-report/err162.aspx

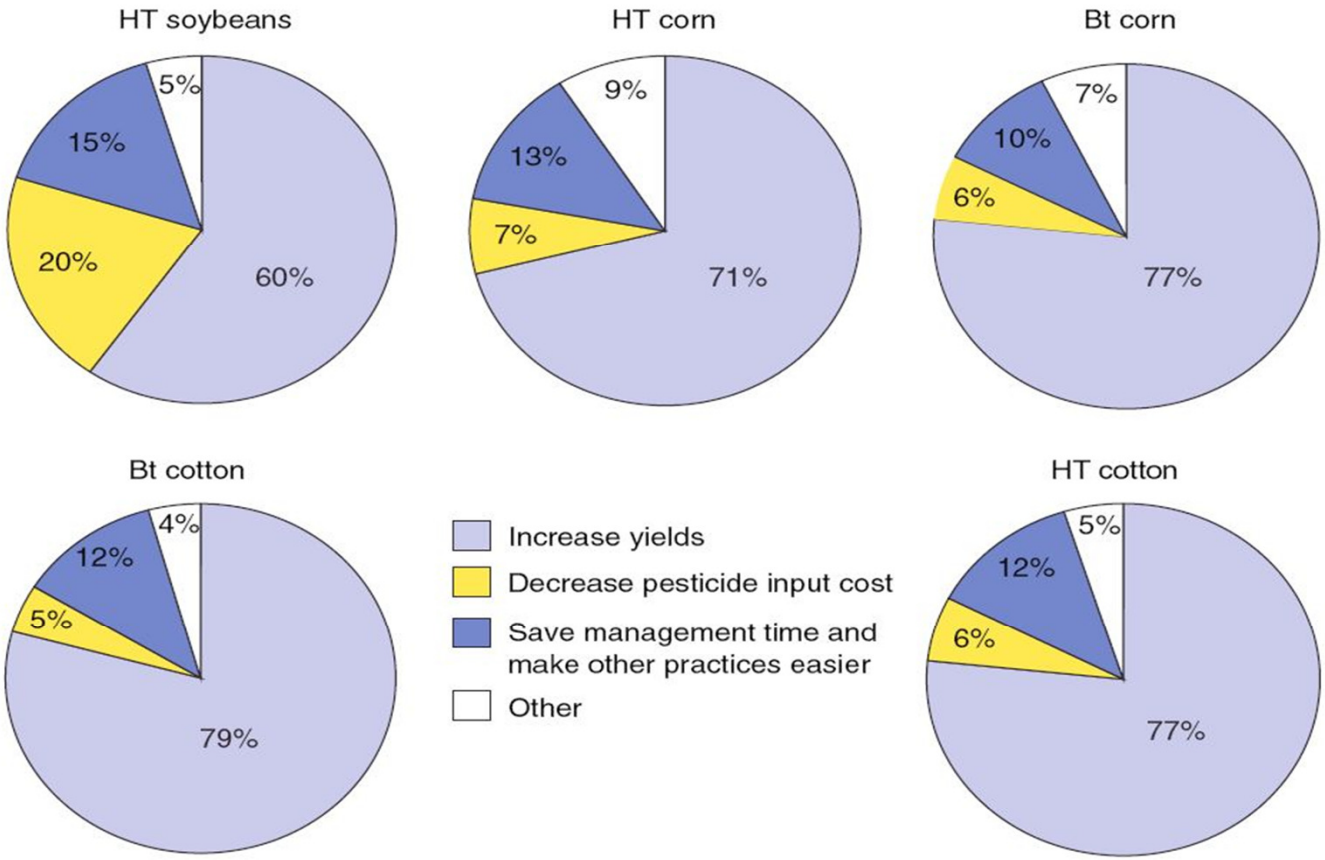
# GM maize and pesticide usage



# No yield increase with GM crops?

Figure 7

**Farmers' reasons for adopting genetically engineered crops**




Bt crops have insect resistant traits; HT crops have herbicide tolerance traits.

Sources: USDA Economic Research Service using data from Agricultural Resource Management Survey (ARMS) Phase II surveys: 2010 for corn, 2007 for cotton, and 2006 for soybeans.

www.ers.usda.gov/publications/err-economic-research-report/err162.aspx

# Resources

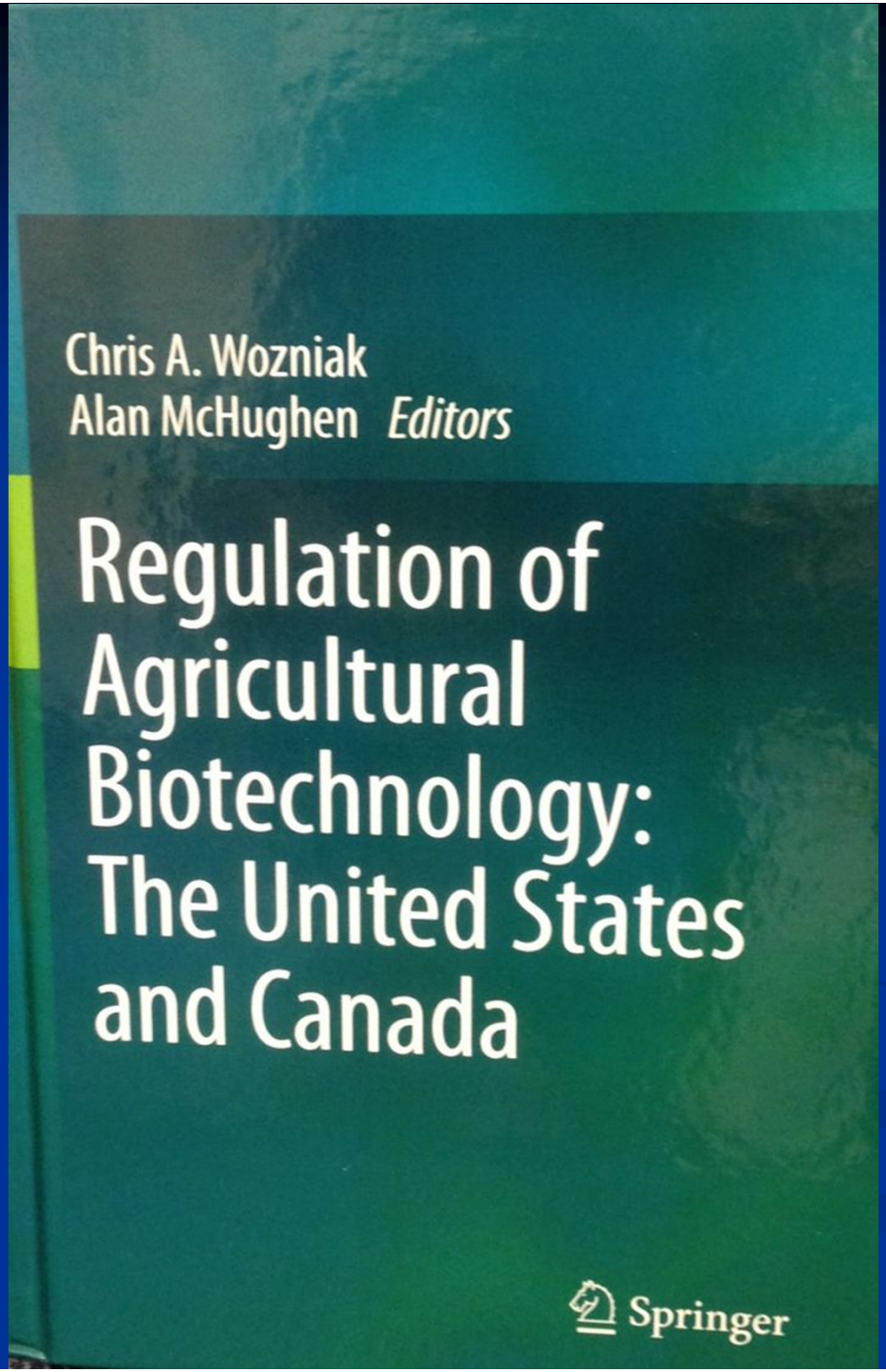
- GM Crop Databases

  http://www.cera-gmc.org/GMCropDatabase (ILSI)

  http://www.isaaa.org/gmapprovaldatabase/

  http://www.gmo-compass.org/eng/gmo/db/ (EU only)

  http://ec.europa.eu/food/dyna/gm_register/index_en.cfm
- GM Crop Detection database
  http://gmdd.shgmo.org/index/search
- EU- EFSA http://www.efsa.europa.eu/en/topics/topic/gmo.htm
- Canada Guidance, Biology and Decision Docs
  http://www.inspection.gc.ca/guidance-document-repository/eng/1374161650885/1374161737236?gp=3&gc=25&ga=0#gdr_results
- Canada Stacks http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/stacked-traits/eng/1337653008661/1337653513037
- ILSI Crop composition database: https://www.cropcomposition.org/


Chris A. Wozniak
Alan McHughen Editors
Regulation of Agricultural Biotechnology: The United States and Canada
Springer

# Conclusion

- Regulatory scrutiny should be based on risk
  - And revised with experience and familiarity
- Risk resides in Products, not Process
- Process based regulations are not scientifically sound; misallocation of resources
- Process based regulations become obsolete
- AgBiotech has documented benefits
  - And downside risks are manageable
- We (ILSI and others) already know how to conduct risk assessments on stacks and other new products