Implications of *process* vs *product* regulatory triggers

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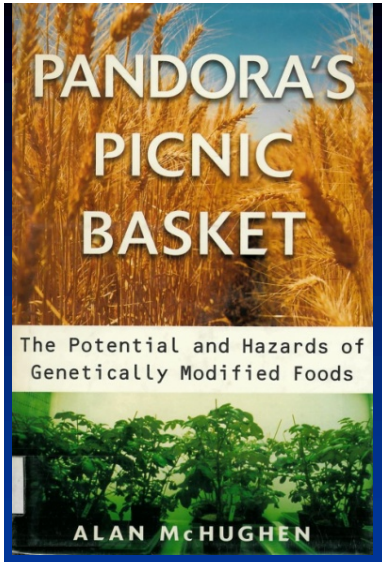

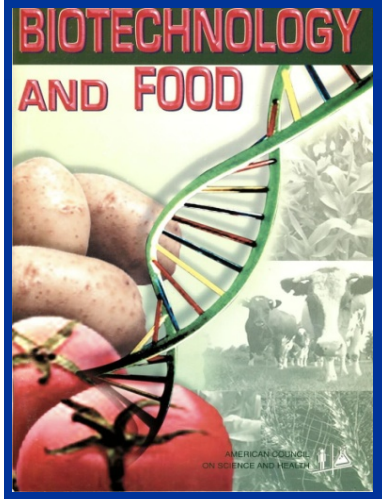

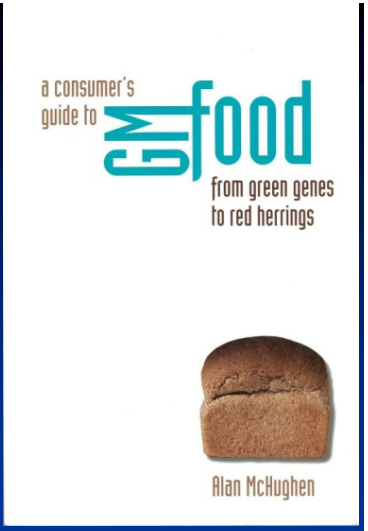

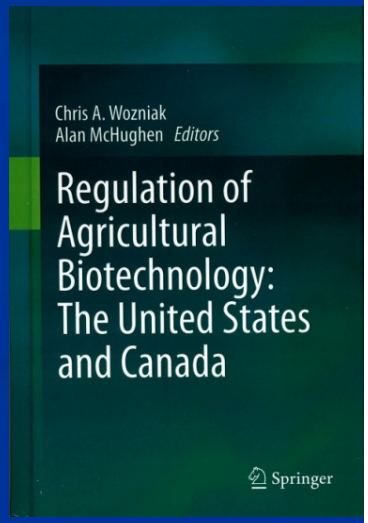

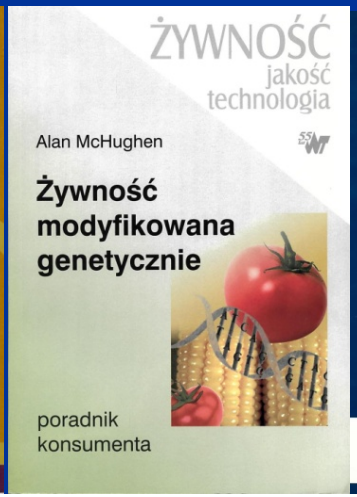

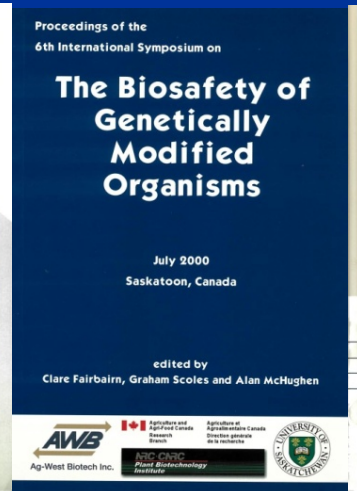

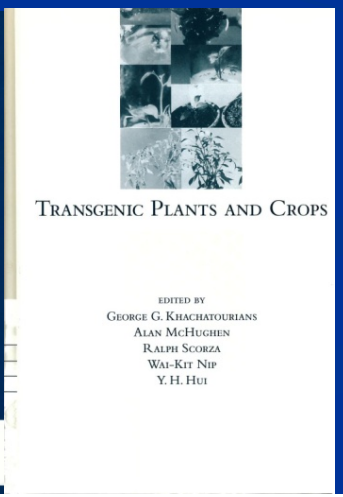

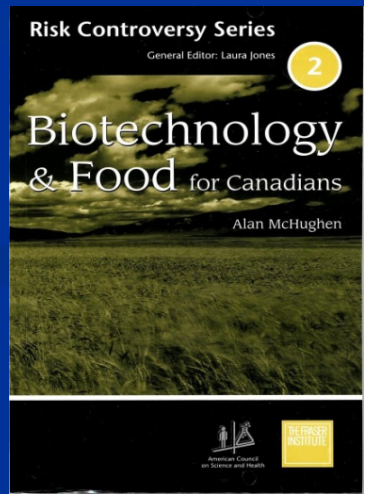

Regulations? What regulations?

- US
  - USDA: Plant pest features
  - FDA: Food and feed safety
  - EPA: Pesticidal properties, including PiPs
- Canada
  - CFIA and HC: Plants with Novel Traits (PNTs)
- Argentina: NBT does not trigger regulatory review
- EU
  - EFSA scientific assessment and advice
  - Routinely ignored by EU political system.

Varied Recommendations…

- US NAS (2017) Move to product and 'familiarity'
  - USDA- 'NoForn' DNA – exempted >30 GE crops
    - *e.g.*, CRISPR- Corn, Mushrooms
- Australia: FSANZ: exempt 'simple deletions'
  - Capture for regulation those crops with 'inserted genes'
- European Academies (*e.g.* EASAC) (2017): NoForn
  - Anti-GMO NGOs: NBTs = 'stealth GMOs'
- Canada CFIA: PNT: no change; no need to change
- New Zealand: EPA said some may be exempt… but
  - Overturned by NZ High Court.

Confusion and Disarray?

- USDA, FDA- New regulatory proposals
  - 2017 Regulatory reform in the USA = elimination?
- UK- post Brexit… anyone's guess
- EU- various EU scientific societies: *Regulate Product*
  - Anti-GMO activists: *"NBT are 'Stealth GMOs!"*
- Scientists: Regulate products, not processes
- Differing definitions: e.g.
  - "What is 'foreign' DNA?"
  - "Who says what Nature can or cannot do?"

Impact of incompatibility

- Technology voting with feet. *Will developers move to 'easier' regulatory sphere?*
- International trade disruptions
  - Commodity crops cannot be fully 'contained'
  - If US exempts a certain NBT crop, will it be captured by foreign regulators who still sees it as a 'GMO'?
  - Any lessons from Canada's 'PNT' trigger policy?
    - Yes, because PNT is product based
    - No, there aren't any PNTs that aren't also new 'events'

What are GMOs?

- GMO = Genetically Modified Organism
- A.k.a. Genetically Engineered (GE), Transgenic, Bioengineered, Biotech, PNT, etc.
- **No standard scientific OR political definition**
  - Process based: the use of recombinant DNA or other 'modern' techniques, e.g. cell culture
  - Product based: food contains 'foreign' DNA, novel protein or other new substances
- In practice, a GMO is the result of using rDNA.

Other + New AgBio Products

- GE PRSV-resistant Papaya in Hawaii
- GE Soy with enhanced oil profile
  - Vistive™, Plenish™ (GM and non-GM versions of oils)
  - Non-GM: Canola, Linola, High Oleic Sunflower, etc.
- "Golden Rice", ↑ β-Carotene to combat VAD
- Non-browning "Arctic Apples" "Innate potato"
- "Non-transgenic" cisgenic, gene editing techniques, Zinc finger, CRISPR-Cas9, RNAi, etc. All = NO transgenes, No species barrier, NO foreign DNA

New Technologies (NBTs)

- Various gene editing methods, under development or in practice, focuses regulatory trigger debate back to Product vs Process
- Gene editing allows changes to as little as one nucleotide to the genome, or deletions
- No 'foreign' DNA insertions (NoForn)
- Virtually undetectable
- Virtually indistinguishable from mutation breeding
- Similar risk profile to 'conventional' breeding.

Refined sugar in the USA

- Cane sugar: ~ 50%
- Sugar beet: ~ 50%
- In both cases, refined sugar is sucrose: $C_{12}H_{22}O_{11}$
- No GE sugar cane on the market
- 99% sugar beet; so ~ half US sugar is 'GE'
- No current label to specify cane vs beet source
- Cannot verify GE source of sugar in foods.

Process Fallacy: *GE sugarbeet*

- Plants, *e.g.* GE sugarbeet, undergo Photosynthesis
- The resulting Sucrose (sugar) is sequestered and stored in the tuberous root
- Upon harvest, the sucrose is extracted and purified, packaged and sold to consumers.
  - No rDNA, protein or other 'substances' remain
  - Yet in EU, the sugar is regulated (labeled) as 'GMO'
- Other products from (GE) plant photosynthesis
  - $6CO_2 + 6H_20 + (light) \rightarrow C_6H_{12}O_6$ (sugar) + $6O_2$
  - 4B acres of GM crops worldwide since 1996 pumping unregulated GMO O_2 into the Global atmosphere.

Real Food Safety Hazards

- Organic
  - Mycotoxins (fumonison, aflatoxin, etc.)
  - Botulinum, etc.
- Microbial
  - E coli
  - Salmonella
  - Listeria
  - Clostridium, etc.
- Inorganic and other contaminants
  - Glass fragments, heavy metals, soil, filth, etc.

Conclusions

- Real hazards are presented by products, not processes
- Regulatory oversight should be commensurate with degree of risk posed
- Many jurisdictions continue to regulate 'GMOs' based on process instead of product
- This policy maintains inefficient regulatory structure and exposes consumers and the environment to greater risks than necessary
- Don't expect much change with NBTs.