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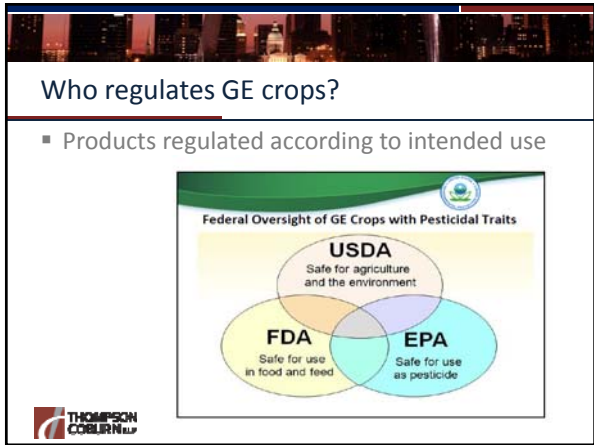
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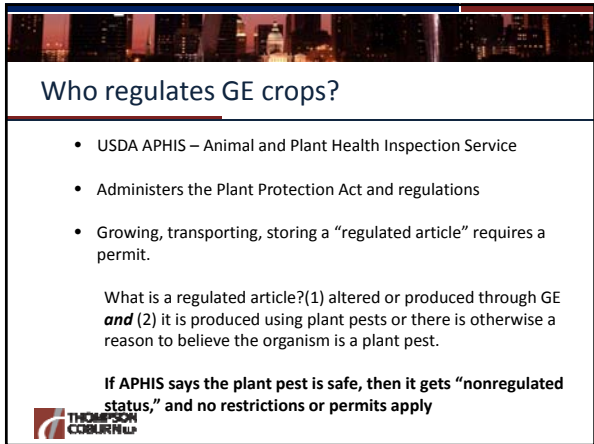
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**Who regulates GE crops?**

- FDA
  - Human drugs, animal drugs, plants and animals if related to food use
- EPA
  - Pesticide microorganisms – some plants are pesticides (plant-incorporated protectant (PIP)) – ex. Bt Cry1Ab protein
  - Chemicals put on plants for herbicide-resistant plants
  - Registration of pesticides under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) and tolerances for residues under FD&C Act (Federal Food, Drug and Cosmetic Act)
  - TSCA – catch all category for items not regulated by FIFRA/FD&C




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**After APHIS approval & commercialization**

- GE plant gains deregulated status
- APHIS no longer regulates
- The plant/seed can be bought and sold just like all non-GE plants/seeds




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**After APHIS approval & commercialization**

- *Commercialization of Commodity Crops*
  - Commodities are co-mingled in the supply chain
  - Usually no restrictions in place by federal government
  - Company decision as to when to sell, where to sell, how to sell
  - Company can choose to commercialize regardless of approval to export to other markets (reality is they wait for approval in certain countries)
  - Once plant is released, you can't take it back
  - Commingled in supply chain many ways




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### Issues with commercialization

- U.S. grain companies export a very large percentage of commodities to many countries
- Asynchronous approval issue –countries do not approve new GE crops at same time
- Some countries are zero tolerance for non-approved GEs
  - Some countries have other standards – “adventitious presence” or “low level presence”
  - CropLife International: “When used in relation to plant biotechnology, the term refers to the incidental presence of biotech-derived material in food, feed or grain at levels that are consistent with generally accepted agricultural and manufacturing practices.”



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### Challenges faced by agribusinesses

- Segregation of commodities to a “zero degree tolerance” is impossible / impracticable
- Economics don’t favor segregation – low profit margins (low even for specialty crops)
- Requires buy-in and transparency throughout supply chain (growers, seed dealers, grain companies)
- Corn and other crops cross pollinate – even if there’s buy-in, you may still not contain the trait
- Export markets and regimes unpredictable (e.g., China)



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### Lessons from past litigation – StarLink Corn

- StarLink Corn
  - First major GE “escape” litigation
  - StarLink corn was a pesticide – toxic to certain insects
  - StarLink given a limited registration, allowed only for use in non-human food, industrial purposes
  - Wound up in taco shells
  - Clear liability – Aventis pays hundreds of millions to farmers, Taco Bell, allergy sufferers, and for recall
  - Set the stage for all future GE litigation



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**Lessons from past litigation – Liberty Link Rice**

- Liberty Link Rice –
  - Late 2006 *regulated rice strain* found in commercial rice supplies – liability for manufacturer fairly clear, challenge to find out where escape occurred
  - 300 cases filed by rice farmers and other businesses that sell rice
  - MDL & common benefit fund established
  - class not certified (individual damages)
  - Loss of EU rice market
  - Liability to farmers based on decreased CBOT price– theory of damages was a regression study, event analysis.
  - Liability to cooperatives based on “margin squeeze” damages
  - Over \$1 billion in damages
  - Punitive damages awarded in state court cases, but not MDL cases
  - Common benefit attorneys’ fees battle continues over a decade after detection




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**Lessons from current litigation – Viptera & Duracade**

- Syngenta commercialized Viptera with no channeling
- At the time, no China import approval
- Chinese corn market – sleeping giant awoke
- Syngenta warned not to commercialize by grain companies
- Grain companies refuse receipt of Viptera
- Syngenta attempts preemptive strike against Bunge




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**Lessons from current litigation – Viptera & Duracade -- market volatility**





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Lessons from current litigation – Viptera & Duracade -- market volatility

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Lessons from litigation – Viptera & Duracade

- Comingling happens
- China approval stalled for months – Viptera sales continue; Duracade put on the market
- China eventually rejects vessels
- Nearly 4,000 lawsuits pending – farmers and grain companies
- Grain companies sued as well
  - Claims preempted
- Class certified

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What measures can grain companies take?

- Contractual provisions – indemnity agreements; grower agreements requiring channeling
- Record keeping – where was product sold? where was product planted?
- Channeling to non-export markets
- Channeling to approved export markets

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What measures can seed companies take?

- Engage the supply chain
- Delay commercialization until “major markets” approve
- Strong grower agreements
- More transparency



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