

Chapters 21 & 22-Regulating, Patenting & Ethics of Biotechnology

Regulatory agencies
Regulating food and food ingredients
Deliberate release of GMOs
GMO controversies
Patenting
Ethical principles
Let's discuss some case studies

Regulations-note that the product, not the process, is evaluated for safety

- **IBC** (Institutional Biosafety Committee)-regulates all recombinant DNA experiments
- **NIH** (National Institutes of Health)-regulates human gene therapy research
- **EPA** (Environmental Protection Agency)-regulates all microbial pesticides (including genetically engineered ones), genetically engineered organisms for pest and pollution control
- **USDA** (United States Department of Agriculture)- regulates genetically engineered organisms released into the environment for agricultural purposes
- **FDA** (Food and Drug Administration)-regulates all foods and drugs produced using recombinant DNA technology

Regulating food and food ingredients

Recombinant Chymosin

- an enzyme used in cheese production (hydrolyzes casein in milk to curds for cheese)
- rChymosin produced in *E. coli*/K-12 & approved by the FDA
- identical to calf chymosin, pure & safe (animal tests)
- 85% of all cheese made in the US use rChymosin

Tryptophan

- an amino acid used as a dietary supplement; produced by GE of microbes (Chap 12)
- in 1989-90 "tainted" Trp caused severe muscle pain and potentially fatal respiratory arrest
- "tainted" tryptophan traced to an "enhanced" bacterial strain & small purification change

Recombinant Bovine Somatotropin or Growth Hormone (rBST or rBGH)

- injecting cows with rBST will dramatically increase milk production
- rBST approved by the FDA; 15% of US dairy farmers use Monsanto's rBST ("Posilac")
- Health Canada and the European Union refused approval saying it increases the risk of mastitis, causes leg and foot disorders, reduces reproductive capabilities, and causes severe reactions at injection site
- "hot button" issue for small scale dairy farmers

Deliberate release of GMOs

- Ice-minus *Pseudomonas syringae*-a naturally occurring mutant form of this bacteria lowers the freezing temperature of plants since it lacks the ice nucleation (crystallization) protein
- Open field tests of other GMOs including GE plants (>6,000), fish, and animals



Frostban being sprayed onto strawberry plants in a 1987 field trial in California.

Some GMO controversies

- Ice-minus bacteria
- GM plants (Bt, Roundup Ready, virus resistance)
- Bt plants and the monarch butterfly (see <http://www.colostate.edu/prod/ams/life/sci/news/TransgenicCrops/current.html>)
- Bt gene from StarLink corn found in taco shells
- Roundup Ready turf grass for golf courses
- Flavr savr tomato
- "Golden rice"
- Transgenic fish overexpressing growth hormone genes
- Use of rBST to increase milk production
- Labeling of GM foods (US vs. Europe)



A Quick Recipe for "Frankenfood" Frenzy
Combine lots of emotionally-charged doomsday rhetoric with a good amount of anti-capitalist sentiment. Add just a pinch of scientific uncertainty about safety and you've created enough "Frankenfood" Frenzy to serve the world. **Caution:** This dish can be ruined if contaminated by facts about the health or environmental benefits of genetically modified foods.

Patents

- Patents are legal documents which give the owner exclusive rights to market a product or invention and thereby earn substantial profits
- Patents encourage companies to take greater risks and invest more funds into research and development
- Three criteria for patentability: the invention, which can be a product or a process, must be 1) new, 2) useful, and 3) nonobvious to one skilled in the field
- In the US, patents end 20 years after the patent application is filed
- The US Supreme Court ruled that "anything under the sun that is made by man" is patentable; this includes GMOs

Ethics

Major Ethical Principles

1. Do no harm (nonmaleficence)
2. Do good (beneficence)
3. Do not violate individual freedom (autonomy)
4. Be fair (justice)

Ethics

Secondary Ethical Principles

1. Tell the truth (truth-telling)
2. Keep your promise (fidelity and promise keeping)
3. Respect confidences (confidentiality)
4. Use the principle of proportionality; risk/benefit ratio (how much harm can be justifiably risked to effect good)
5. Attempt to avoid undesirable exceptions, also known as the wedge principle, the slippery slope or the camel's nose

Ethics

- Although these rules are simple, they represent fundamental values associated with respect for human dignity that most people agree to. These are the principles to which one should refer when making and justifying ethical decisions.
- Let's look at and discuss some case studies, as you will see it is not usually simple and straightforward.