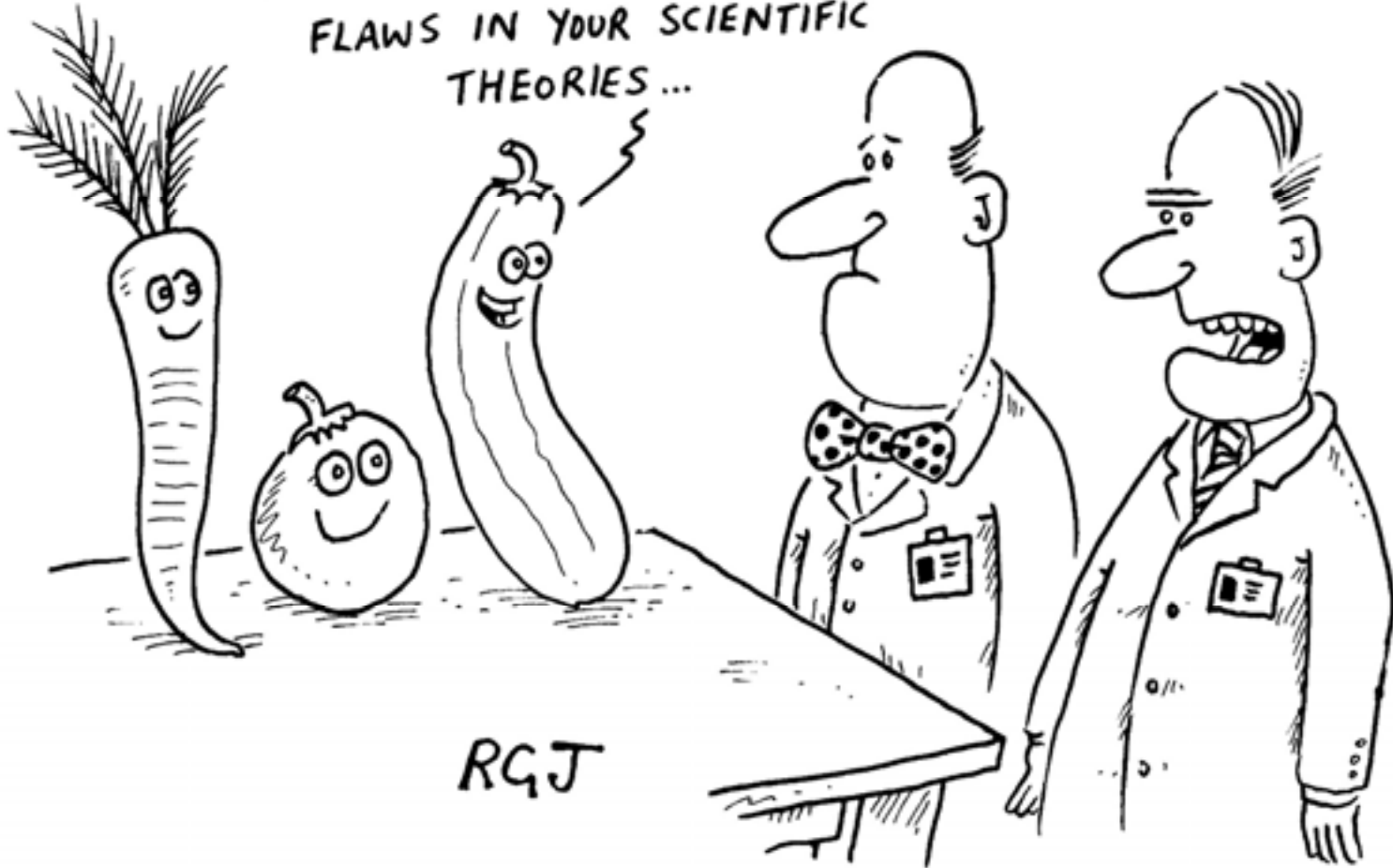


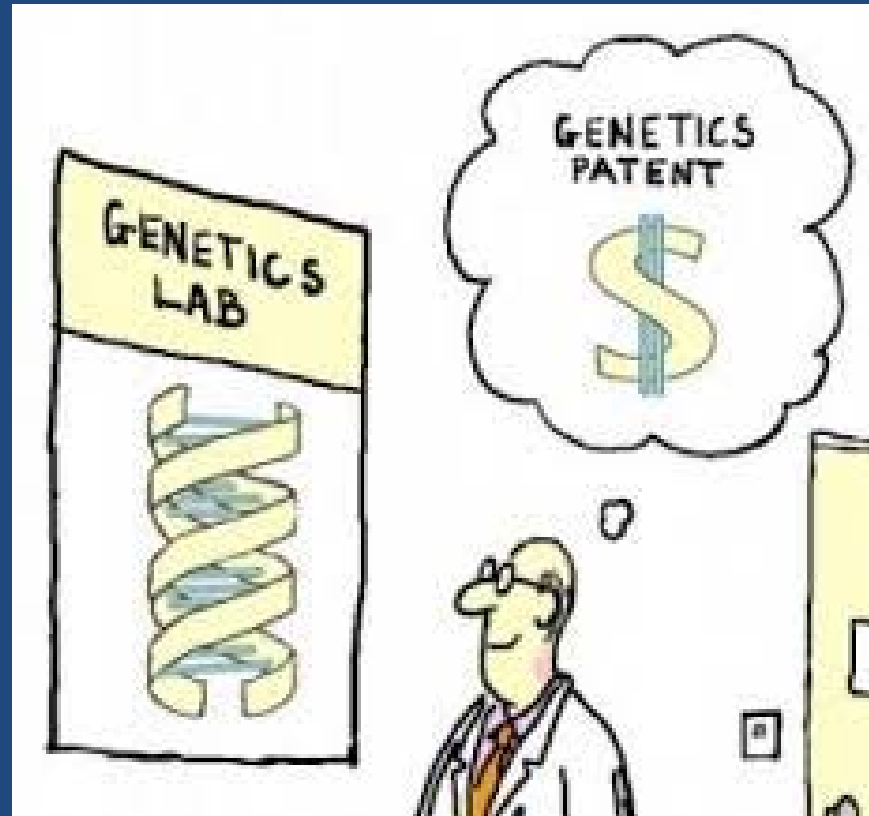
Understanding Social Controversies about Ag Biotech

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PROFESSOR... WE'D LIKE
TO DISCUSS CERTAIN
FLAWS IN YOUR SCIENTIFIC
THEORIES...



"That's it. We've taken this genetic engineering too far"



Hypotheses

- The development path of the agricultural biotechnology industry, including novelty of the technologies, has resulted in rapid deployment and adoption, while at the same time created a strong resistance movement to the technology.

Outline of Talk

1. IP Regimes Resulting from Chakrabarty versus Diamond & J.E.M. Ag Supply versus Pioneer HI-Bred International Supreme Court Decisions.
2. Integration of Seed and Pesticide Firms → Concentration Levels in the Resulting Life Science Sector.
3. Transgenes Seem Scary.
4. Permissive Regulatory Framework: Substantial Equivalence and G.R.A.S.
5. *Framing* the Debates over Safety and Efficacy and Risk Assessment.
6. Discussion and Conclusions: Whither the Industry.

1. U.S. Supreme Court: *Diamond v. Chakrabarty*

- Held that a genetically altered microorganisms can be patented- though there was relevant earlier case law regarding plants, bacteria etc.,
- Prior to *Diamond*, general interpretation was that altered natural organisms that were no longer living could be patented.

Close Ruling

- In a 5-4 ruling the court ruled in favor of Chakrabarty and upheld the patent, holding that:
 - *A live, human-made micro-organism is patentable subject matter under [Title 35 U.S.C.] 101. Respondent's micro-organism constitutes a "manufacture" or "composition of matter" within that statute. –*
- This decision, and subsequent J.E.M. Ag Supply versus Pioneer HI-Bred, gave plant patent applicants the option of seeking utility patents under 35 U.S.C. § 101 to protect a novel variety.

Difference in Kind

- Utility patents offer broader protection than the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970.
- The Plant Patent Act applies only to asexually reproduced and non-tuber-propagated plants.
- The Plant Variety Protection Act allows a farmer's exemption and a research exemption.
 - Farmers can save and replant seeds.

2. Commercial Impacts

- The decisions were an extremely critical building block for the biotechnology or life sciences industry.
- Made possible the current development trajectory of the biotechnology since patenting provided sufficient protection for agricultural chemical firms to finance shift to life science industry.

- Chemical firms purchased seed companies to use seed intellectual property as vehicle for delivering transgenic technology in agriculture.
- Shifted seed industry from one of dispersed ownership, lots of small firms, to a few firms controlling the industry.
- St. Louis, Missouri-based Monsanto Co. was not a seed firm until after the decision and now is the largest seed firm.

Top Four Seed Firms in 2011

Source: ETC Group

Rank	Company	Seed Sales (\$US mil)	% Market Share
1	Monsanto	8,953	26.0
2	DuPont Pioneer	6,261	18.2
3	Syngenta (Switzerland)	3,185	9.2
4	Vilmorin (France) (Groupe Limagrain)	1,670	4.8
	Total (CR4)		60.2

3. Early Commercial Successes were Transgenic

- Transgene: Genetic material (DNA) that is inserted into the genome of a cell via gene splicing techniques across species lines into the genome of a host organism.
- Perceived as novel compared to conventional breeding.
- Cisgenic techniques might have been a more strategic approach- closely related organisms.

4. Biosafety Regulation

- U.S. regulatory theory is 'substantial equivalence' and 'generally recognized as safe.'
- If GE food characterized as substantially equivalent to its 'natural' antecedent, it can be assumed to pose no new health risk.

G.R.A.S.

- “Any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use...

(<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/default.htm>).

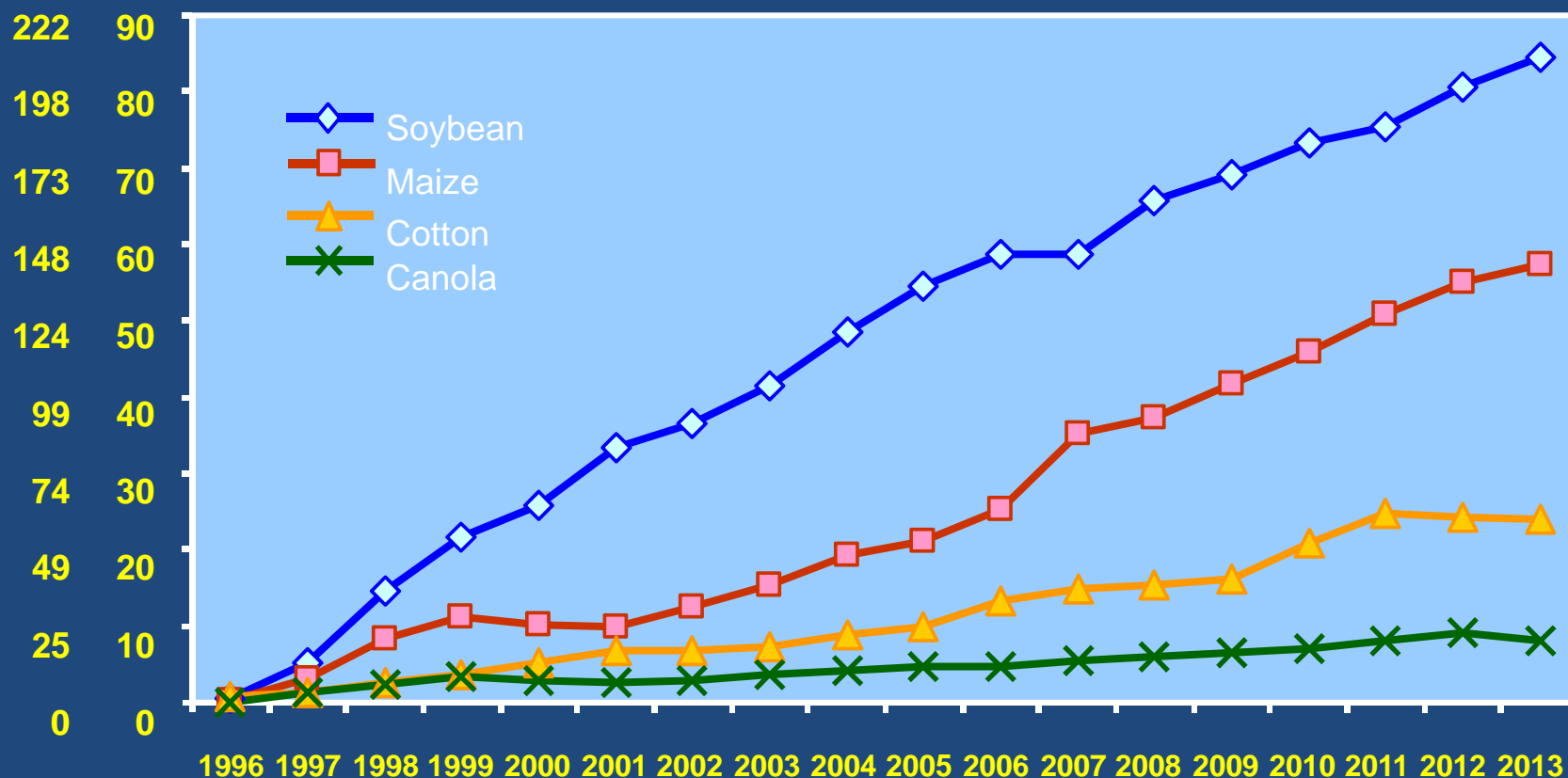
- Permissive approach to technology commercialization.

- U.S.: risk-based system with burden of proof on environmental health risks, i.e., it controls for the (type I) error of rejecting the null hypothesis of no harm when it is in fact true.
- EU: precautionary approach uses same science, but controls for the (type II) error of accepting the null hypothesis of no harm when harm will in fact occur.

Global Area of Biotech Crops, 1996 to 2013: By Crop (Million Hectares, Million Acres)

ISAAA

M Acres

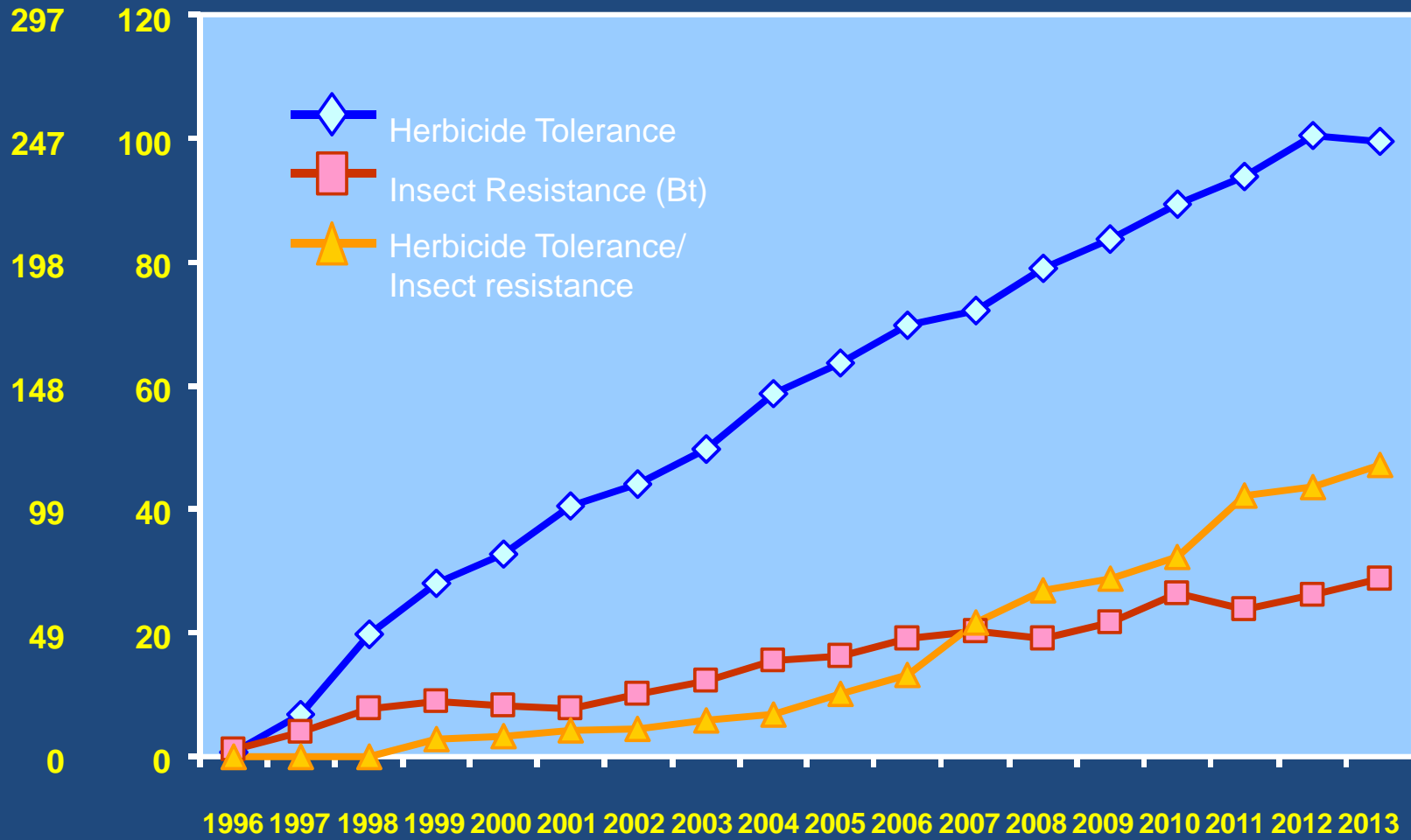


Source: Clive James, 2013

Global Area of Biotech Crops, 1996 to 2013: By Trait (Million Hectares, Million Acres)

ISAAA

M Acres



Source: Clive James, 2013

Controversial

- The commercialization of transgenic crops in created a conflict over their efficacy, safety, environmental impact and economic effects.
- Resulting concentration and integration of seed and pesticide industry criticized.
- Stricter IP protections inhibited risk assessment research (Glenna et al., 2015).

5. Two Sides

- Most scientists, industry, government officials argue the technologies are safe and effective with benign environmental and economic effects.
- Environmental, food safety groups and a minority, but growing(?), number of scientists argue the opposite.
- Both sides attempt to wield discursive power to promote their positions: *framing*.

Industry frame

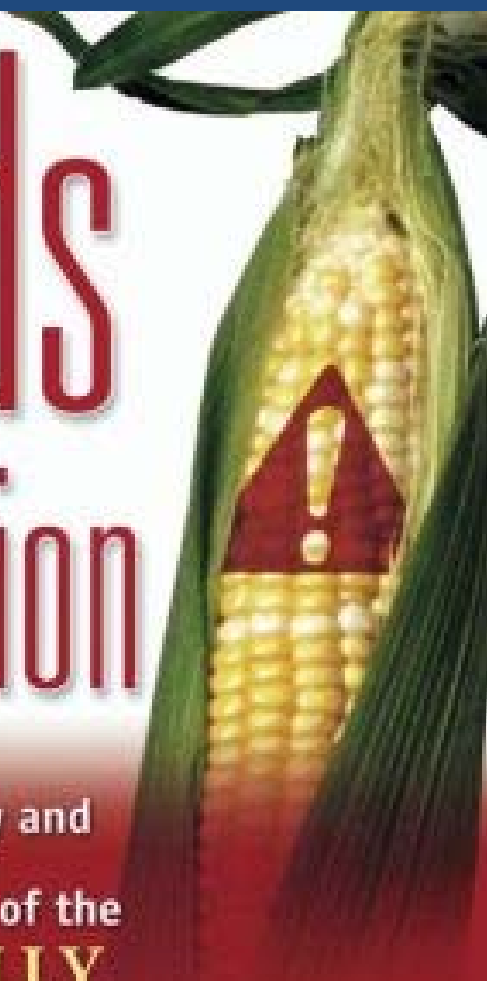
- Embedded in increased food security and environmental sustainability
- Less pesticide use
- Higher yields
- Increased nutritional intake



Biotechnology...
Fields of Benefits

Anti-biotech Frame

- Major environmental groups opposed to commercialization of most transgenic crops.
 - Cite lack of available data- food safety a question still not answered.
 - Lack of sufficient regulations from EPA, FDA and USDA- regulate as food additive.
 - Biodiversity loss: non-target organisms
 - Resistance development



Seeds *of* Deception

Exposing Industry and
Government Lies
About the Safety of the

**GENETICALLY
ENGINEERED FOODS**

You're Eating

Jeffrey M. Smith

FOREWORD BY **FRANCES MOORE LAPPE**

MONSANTO

HUNGRY-MAN

FRANKEN-FOOD

Frozen Dinner

MICROWAVABLE
for added carcinogens!



**GENETICALLY
MODIFIED!**
TRIPLE MSG

FDA
APPROVED

Promotes Excessive Brain Tumors and Premature Death!

**Box Raised
Tortured
Chicken**

With
TASTY GM Corn,
Tomato and
Trout Genes,
Snail Broccoli,
Human Gene
Spliced Potato

Results- competing discourses

- Polarized dialogue with industry generally successful → commercialization and adoption rates.
- Anti-biotech groups employ provocative symbols to turn consumers away from the technology.
- GMO labeling campaigns part of this strategy.
- Industry responds with PR campaigns and *Safe and Accurate Food Labeling Act (HR 1599)*.

6. Conclusions

- In the U.S. the regulatory process has favored industry as evidenced by approvals and commercializations.
- Opposition groups attempts to break off consumers from industry frame.
- Opponents have been successful to some extent- support for labeling.
- Long-term social sustainability will require reaching a greater social consensus.

Social Consensus Outcomes?

- One side wins the framing contest-
 - GMOs labeled and become irrelevant like rBST.
 - Opposition groups do not prevail- GMOs regularized.
- Or, try a different approach...

- Engineer traits that mimic ecological processes and natural defenses that confuse, avoid or deter pests.
- Transform the crop to minimize gene flow.
- Return to prior intellectual property (IP) arrangements such that farmers can save and replant but not resell seeds.
- Fund public research institutions to develop these types of *public good* traits and incentivize industry to do the same through regulatory mechanisms (Ervin and Welsh, 2010).

Questions?

Impact Factor for Renewable Agriculture and Food Systems

