Regulation and Innovation

Jim Vercammen

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Objectives of this Talk

- Facilitate a discussion about the impact of regulation on innovation
- Discuss several relevant papers
- Direct questions to panel members to obtain their thoughts on this topic
- Identify research priorities for CAIRN

Types of Regulation

- Regulatory approval for new products and technologies initiated by industry
  - e.g., novel plant material from biotechnology
- New regulations on industry resulting from concerns over consumer safety, the environment, animal welfare, etc.
  - e.g., new rules governing transport of livestock
- Changes to existing legislation to address evolving needs of society

Applications by Industry for Approval

- Plant variety
- Pesticide and other plant health
- Applications of biotechnology
- Food products, packaging, labels, processing procedures
- Nutraceuticals, functional foods, bioproducts
- Other technologies (e.g., bio-energy)

Panel: Are there other categories and do you have specific info about the procedure for approval?

Canadian Food Inspection Agency

- Canada Agricultural Products Act
- Consumer Packaging and Labeling Act
- Food and Drugs Act (as it relates to food)
- Health of Animals Act
- Meat Inspection Act
- Plant Breeders' Rights Act
- Plant Protection Act
- Others

Regulating Agricultural Biotechnology

- CFIA assesses the safety of plants, animal feeds, fertilizers, etc.
- Health Canada assesses the human health safety of products derived through biotechnology (e.g., foods, drugs, cosmetics, pesticides)
- CFIA manages non-health and safety food labeling regulations and policies
- CFIA regulates:
  - Animal Biotechnology
  - Labeling of novel foods derived from genetic engineering
  - Plants with novel traits

Health Canada

- Natural health products fall under the *Natural Health Products Regulations* of the *Food and Drugs Act*
- Includes vitamins and minerals; herbal remedies; homeopathic medicines; traditional medicines; probiotics
- About 40,000 products currently available
- Regulations include a product licensing system, clinical trial procedures and labeling requirements

Falling Between the Crackers!

- Natural health products and foods are regulated under the Food and Drugs Act (FDA)
- Natural health products (as defined in the Natural Health Products Regulations) are subject to the FDA as it applies to a drug
- Foods (as defined in the FDA) are subject to the FDA as it applies to food; pre-established health claims are allowed
- A product, that is both a NHP and a food is subject to the NHPR but is exempted from the food-based FDA

To be or not to be (a food)

- Distinction between NHP and food product is important (evaluation protocol, product claims, etc.)
- Since implementation of NHPR in 2004, Health Canada has received hundreds of new applications for products that appear to be a food

  e.g., energy drink
- Many products that meet the definition of "natural health product" are currently being offered for sale without a product license
- Delays in approvals can stretch out for many years

Panel Question

- *Do panel members have anything to add concerning the confusion over the regulation of NHPs versus foods and the delay in the approval process?*

Standards

Industry Canada (Office of Consumer Affairs)

- Standards are technical specifications/criteria for a product, process or service
- Standards development organizations may submit to Standards Council of Canada
- Currently more than 7000 national standards
- Companies adopt voluntary standards or comply with mandatory standards (majority are voluntary)
- Governments may draft new standards or incorporate existing standards into legislation

Standards; Cont'd

- Performance specifications: products meet prescribed test requirements (e.g., strength)
- Prescriptive specifications: identify product characteristics such as type of material
- Design specifications: set out the specific design or technical characteristics of a product
- Management specifications: specify process and procedural requirements

Voluntary Codes

- Include codes of conduct, codes of practice, voluntary initiatives, guidelines and non-regulatory agreements
- Codes supplement and sometimes replace regulation
- Typically inexpensive, flexible and effective
- Used for environmental protection, health and safety, advertising, quality, etc.
- Failure to comply can result in civil liability

Regulatory Delay in New Approvals

- Why, in general, are approval delays so long?
- Answer appears to be a commitment to “due process” and lack of consensus amongst scientists
- Is due process a mechanism for others to achieve delay for strategic reasons?
- Could a scientific court be used to fast-track approval process and regulations be structured after technology has matured?

Does Uncertainty in Regulatory Approval Time Hurt Innovation?

- Longer delays unambiguously reduce the incentives to innovate
- However, because long delays are discounted more heavily than short delays, the expected value of innovation is higher with more uncertainty over the timing of regulatory approval
- This builds on a Jensen's convexity argument, which is common in economics
- This work ignores the cost of coordination when the regulatory approval times are uncertain

Innovating around Regulations

- Panel Discussion
  - *Examples of regulations you face when managing graduate students and research grants?*
  - *Examples of personal innovations that have made you more effective at these activities?*
  - *Are your innovations constrained by regulations? Are they an attempt to lower cost of complying?*
  - *If all regulations were dissolved, would your department develop equally (or more) efficient codes of conduct?*

Innovation and Beneficial Regulation: "Squeezing the Lemons"

Ariel Katz, *Michigan Telecommunications and Technology Law Review* (2007)

- Conventional wisdom is that lengthy and costly approval processes reduces innovation
- Approval time (avg. of 8 years for drugs) also eats into life of the patent
- Recent reforms have extended patent lives to deal with approval delay
- Purpose of the paper is to show that regulation may increase rather than decrease the incentive to innovate

Why Regulation?

- Worry is that firms will overstate benefits and understate hidden costs of a product to obtain a first mover advantage
- This is especially problematic for drugs
- Regulation protects ill-informed consumers
- Peltzman (1973) concluded that consumer savings on ineffective drugs was far outweighed by the cost of reduced innovation

Patents and Regulation

- The relationship between patents (promote innovation) and drug regulation (stifle innovation) is more complicated
- Perhaps regulatory review is similar to investment in education – the shorter time horizon is more than offset by higher returns
- Regulation solves the lemons problem and therefore raises expected profits for quality drugs
- Firms would need to invest in certification anyway – gov't may be more effective because of trust

Summary

- Regulation impacts low quality products more than high quality, so regulation may be efficient at achieving separation
- The real cost regulation is the difference between the actual cost of regulation and the industry's cost of dealing with lemons problem (e.g., private standards)

Panel: Which industries in the agri-food sector are most likely to benefit from the lemon-reducing effects of regulation?

Private Standards

Enabling Lighter Touch Regulation (BSI Group)

- Traditional model of regulation is blanket treatment for all regulated activities
- Now recognized that regulation should be aimed at highest risk cases and responsible industry should be allowed to operate with private standards
- Examples: "Kitemark Certification" for automotive repair in Britain
- Standards can be developed with consensus of all stakeholders

Standards as an Indicator of Risk

- Those who fail to comply with rigorous industry standards have the highest risk of not complying with regulation
- Inspection should target firms who do not comply with standards
- If this process is known, firms will have a strong incentive to comply with standards
- Well-designed standards can provide flexibility, transparency and a strong incentive to innovate

Panel Discussion

- *For years the food processing industry made extensive use of hydrogenated oils despite growing evidence about the health effects of trans fats. Legislation was eventually required.*
- *A similar scenario with sodium appears to be emerging*
- *Can industry be trusted to develop their own standards that will replace regulation?*

Regulation and Technological Change in the American Meat Industry

John Sink

Technovation 2 (1984)

Study Objective

- What impact has new regulations in meat packing had on the rate of innovation and the types of innovation?

Neoclassical Theory of Regulation and Innovation

- Regulation may increase revenue stream, reduce the cost of innovation and quicken commercialization
- Regulation ➔ higher cost of producing new product, administration, regulatory delay
- Regulatory delay ➔ more discounting, missed opportunities
- Regulation may induce firms to seek lower costs of compliance ➔ possibly lower operating costs
- Regulation can reduce buyer uncertainty and speed up early adoption

X-Efficiency Theory of Regulation and Innovation

- A regulatory shock induces firms to focus attention on "taken as given" practices
- Firms uncover cost savings which were previously available but unobservable
- The added costs associated with compliance may be partially or fully offset by new cost savings

Exogenous Technological Change

- Technological innovation may be exogenous ("right place at the right time") rather than driven solely by economic considerations
- Exogenous innovation will be less impacted by regulation than endogenous innovation

Meat Packing in the U.S.

- Subject to about 41,000 regulations
- Most new equipment (design and materials) adopted from non-food industries
- Regulations on humane killing met with resistance, but lots of new inventions followed
- Regulations on precision concerning fat content of ground beef induced innovation
- Applications for equipment modification approvals rose sharply between 1975 and 1978

Industry Interviews

- Main concern was the uncertainty about standards being used to judge compliance
- More complicated approval processes ➔ incremental improvements versus adoption of new designs
- New technologies often have more stringent standards, so firms may be better off with old
- Regulatory uncertainty probably speeding rate of mergers in industry ➔ less aggregate R&D

Causal Relationships

- Does innovation follow regulation, or does regulation follow best practices?
- Relevant where private standards are common
- Firms may innovate in anticipation of new regulations
- These factors complicate econometric work
- Countries with less stringent regulation do not appear to be innovating more than the U.S.

Product Design

- Designs by external consultants were typically not suitable because nuances of regulation were not considered
- In house design superior because parameters of approval process better understood
- Knowledge pertaining to understanding regulations has high industry valuable
- Firms have so internalized regulations that it is hard for managers to estimate the cost of compliance

Panel Discussion

If you believe the X efficiency argument or the argument that innovation is largely exogenous, then the negative impact of innovation on regulation maybe overstated. What do you think?

In agri-food, does innovation follow regulation or does regulation follow best practices?

CAIRN Research Priorities

- Cost-benefit analysis for regulatory approval of ambiguous products and technologies
- Examine the extent that firms innovate to lower the cost of regulatory compliance
- Develop econometric procedures for examining the impact of regulation on innovation
- Develop formal models of private standards as a replacement for regulation
- Test X-efficiency and exogenous innovation hypothesis of innovation and link to regulation