



CAPI

*The Canadian Agri-Food
Policy Institute*



ICPA

*L'Institut canadien des
politiques agro-alimentaires*

Regulation and Competitiveness

David Sparling
Institute Of Agri-food Policy Innovation
February 13, 2006

Outline

Rational for regulation

The case for reform

Regulation – Function and Flexibility

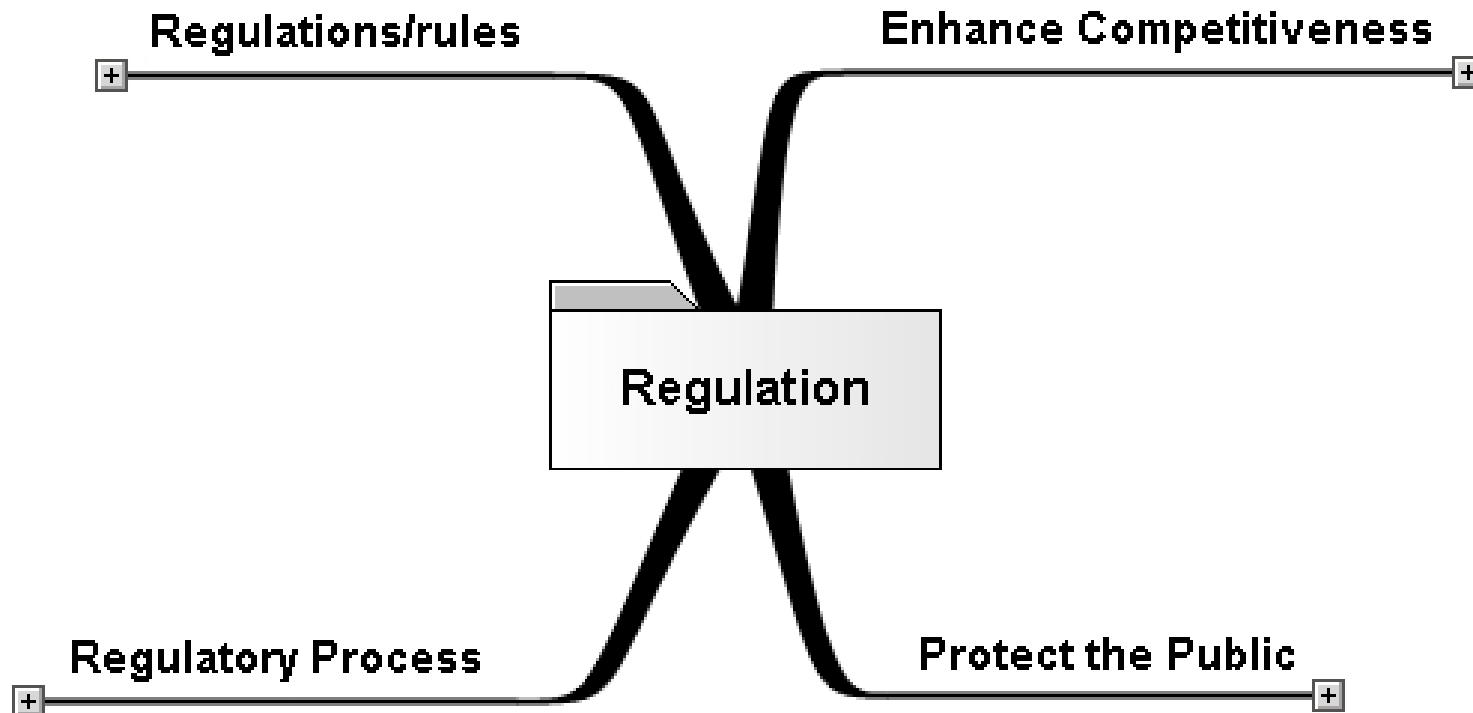
**Case Study – Functional Food/
Nutraceuticals**

Recommendations

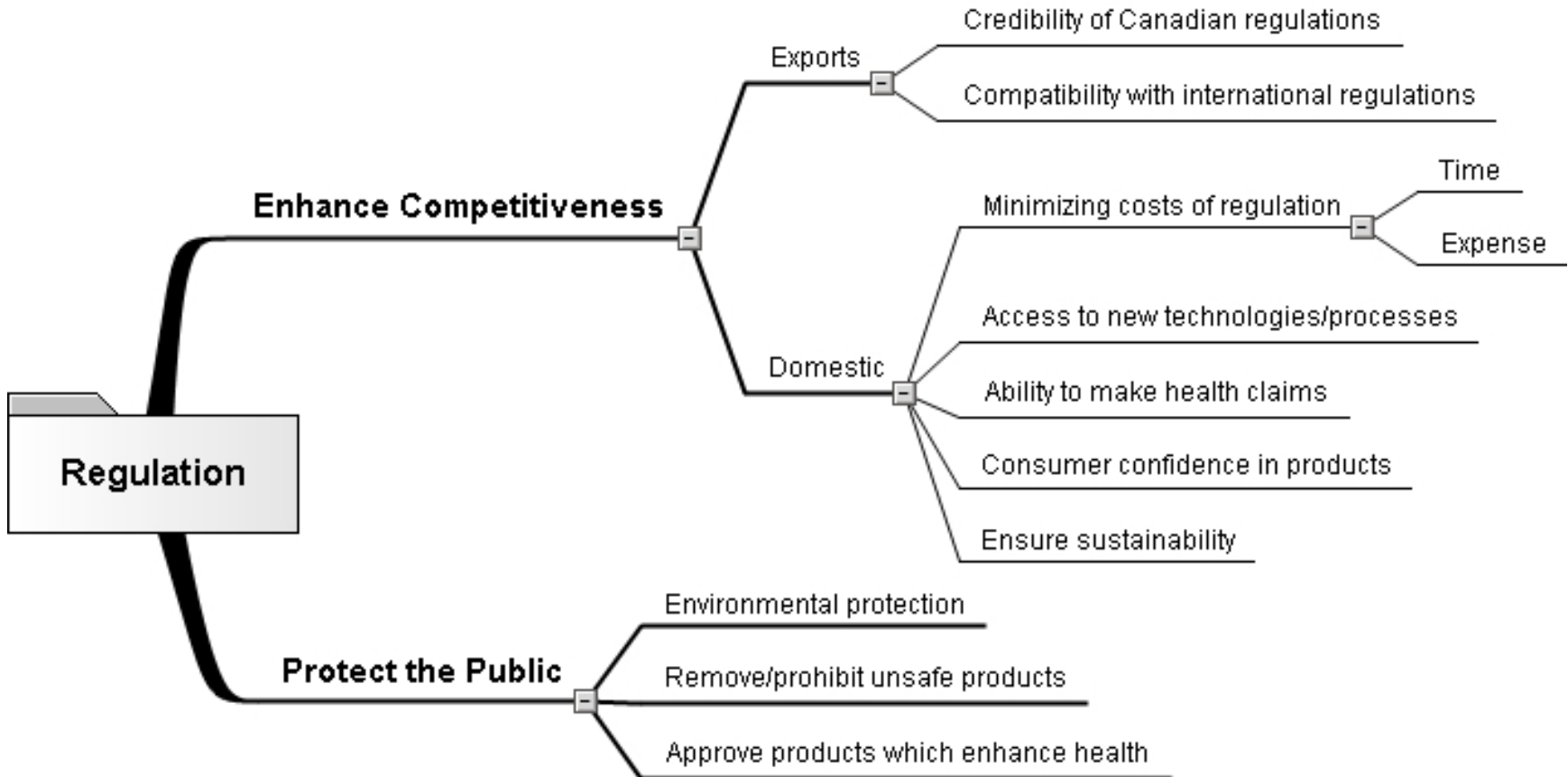
Analytical Framework

Approach to regulation

Objectives for Regulation



Rationale for Regulation



The Case for Reform - Is Regulation Achieving It's Objectives?

Protecting the public

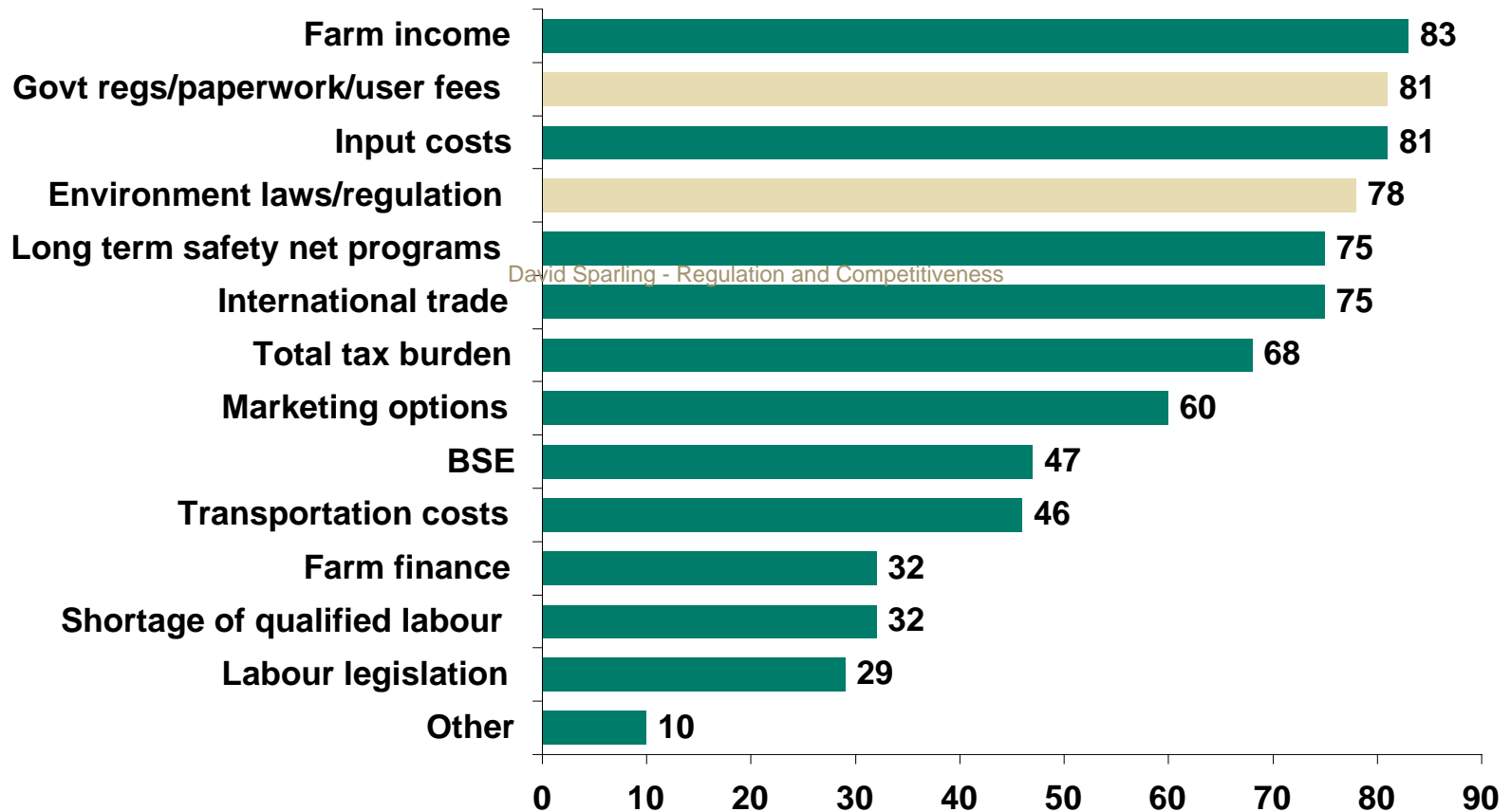
- From unsafe products – Yes
- From products which might be beneficial to public health – Also Yes!

Enhancing competitiveness

- Industry evidence points to problems

CFIB Survey of Agribusiness - 2004

High Priority Concerns for Agri Businesses in Ontario



Canadian Bioproducts Survey 2003

Province	Accessing Capital	Regulatory Approval	Transportation	Raw Material Prices
Atlantic Canada	X	X		
Quebec	X	X		
Ontario	X	X		
Manitoba			X	X
Saskatchewan	X			X
Alberta	X			X
British Columbia	X	X		

Regulation and Flexibility

- Regulations constrain firm activities to achieve business goals but also to meet regulatory objectives
- The approach to regulation has been evolving to increase flexibility to achieve both business and regulatory goals

Evolution of Regulation and Flexibility

Period	Changes in Approach to Regulation	Level of Flexibility
1970's & early 1980's	Economic regulations dismantled.	<i>Economic flexibility</i>
	Social regulations initiated Technology solutions prescribed	Limits placed on firm activities and technology solutions
1980's and 1990's	Firm level limits and objectives set. Technology prescriptions ended	<i>Technological flexibility</i>
1980's to 2000's	Economic incentives and tradable credits.	<i>Industry flexibility</i>

New Levels of Flexibility Needed

- As the economic environment changes so to must the regulatory approach
- Globalization - need for *international flexibility*
- New product categories, shorter life cycles and relationships to other policy goals (health) – need for *product* and *volume flexibility*

Regulatory Approach



Case Study – Functional Food/ Nutraceuticals

- Example of the changes in the food sector
- Both scientific knowledge and product offerings are expanding rapidly
- Discernable public health benefits
- Large, growing industries internationally
- Regulations for Natural Health Products (NHPs) but not for Functional Foods

Need for Volume and Product Flexibility

- Natural Health Product Regulations
- Regulations fine – problems with process
- New NHP product registrations in the first year – approximately 1200
- Total applications over five times that
- Potential products – industry estimates that as many as 45,000 may ultimately need registration

Need for International Flexibility

- Many products used around the world
- Canadian regulations differ from major trading partners
- Registered/approved in locations like E.U. and Japan with strong regulatory systems
- Can evidence used in these regions be used in Canada
- Potential for international cross approvals

Functional Food Survey - 2002

How would harmonizing compositional and labeling standards with U.S. standard affect your business?

	Negative	No impact	Positive	Don't know/NA
Global competitiveness	5	17	51	27
Domestic Sales	9	17	56	17
Export Sales	5	17	50	28
Conducting R&D	4	32	39	26

Need for Product Flexibility and a New Approach

- Example of a new class of products
 - Approval of one product opens door for competing products
 - No IP to allow firms to recapture costs of regulatory approval/regulation
- Dilemma – Approval benefits the industry but costs the firm
- Need to new industry wide approach to products, approvals and regulation

Regulation and the Agri-Food Industry of the Future

Science expanding on several fronts

- Better understanding of the relationship between food attributes and health
- New technologies
 - Biotechnology
 - Nanotechnology
 - Bioproducts
 - Natural Health products

More products will be introduced with multiple attributes

Is the Regulatory System Ready?

- Not even close - critical need for
 - Volume flexibility
 - International flexibility
 - Multi-attribute flexibility
- Without these products will languish while others market them internationally
- Companies will develop, produce and market elsewhere

Conclusions/Recommendations

- Regulatory reform should focus on the future needs of the industry
- Address challenge of protecting public when beneficial products are delayed
- Identify and add missing flexibilities
 - International flexibility
 - Product flexibility
 - Volume flexibility
- Explore new industry approval strategies

Action Items

- Process – Bill C212 sets the stage for performance
 - Create a plan for clearing backlogs
 - Tie administrator rewards to achieving targets
- Harmonize food regulations across Canada
- International flexibility
 - Create a separate approval stream for products approved in other G7 jurisdictions – 2-3 get automatic approval in 6 months unless a good reason not to is provided
 - Initiate discussions with the objective of creating a North American Approval Process