

Summary of the Preliminary Regulatory Impact Analysis of the Proposed Food Traceability Rule

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Outline

- Coverage
- Benefits
- Costs
- Impact on Small Businesses
- International Effects



Co-Proposal for Small RFEs

- Option 1:
Full exemption for retail food establishments (RFEs) with 10 or fewer full-time equivalent employees.

- Option 2:
Exempt RFEs with 10 or fewer full-time equivalent employees only from the requirement to provide FDA, under certain circumstances, with an electronic sortable spreadsheet containing requested tracing information.



Number of Affected Entities by Industry Sector

Type	Number of Firms	Number of Establishments
Farms /Aquaculture/Growers	22,912	22,947
Manufacturers/Processors/ Packers	10,623	11,557
Wholesalers/Distributors	18,686	24,224
Warehouse and Storage	3,519	6,880
Retail Food Establishments		
- Option 1	132,551	266,246
- Option 2	366,404	500,841
Total Option 1	188,291	331,853
Total Option 2	422,144	566,448

- Covered entities are those that manufacture, process, pack, or hold foods that FDA has placed on the Food Traceability List and that are not subject to an exemption.



Economic Impact Summary

Measure	Option 1	Option 2	Difference (Option 1 - Option 2)
Covered Establishments	331,853	566,448	(234,595)
- Covered Retail Food Establishments Only	266,246	500,841	(234,595)
Costs¹			
- Costs to Domestic Entities	\$411	\$535	(\$124)
- Costs to Foreign Entities, a Portion of Which Could be Passed Through to US Entities and Consumers	up to \$295	up to \$295	\$0
Benefits¹			
- Public Health Benefits ²	\$567	\$626	(\$59)
- Non-health Benefits from Avoiding Overly Broad Recalls	\$1,658- \$5,634	\$1,658- \$5,634	\$0

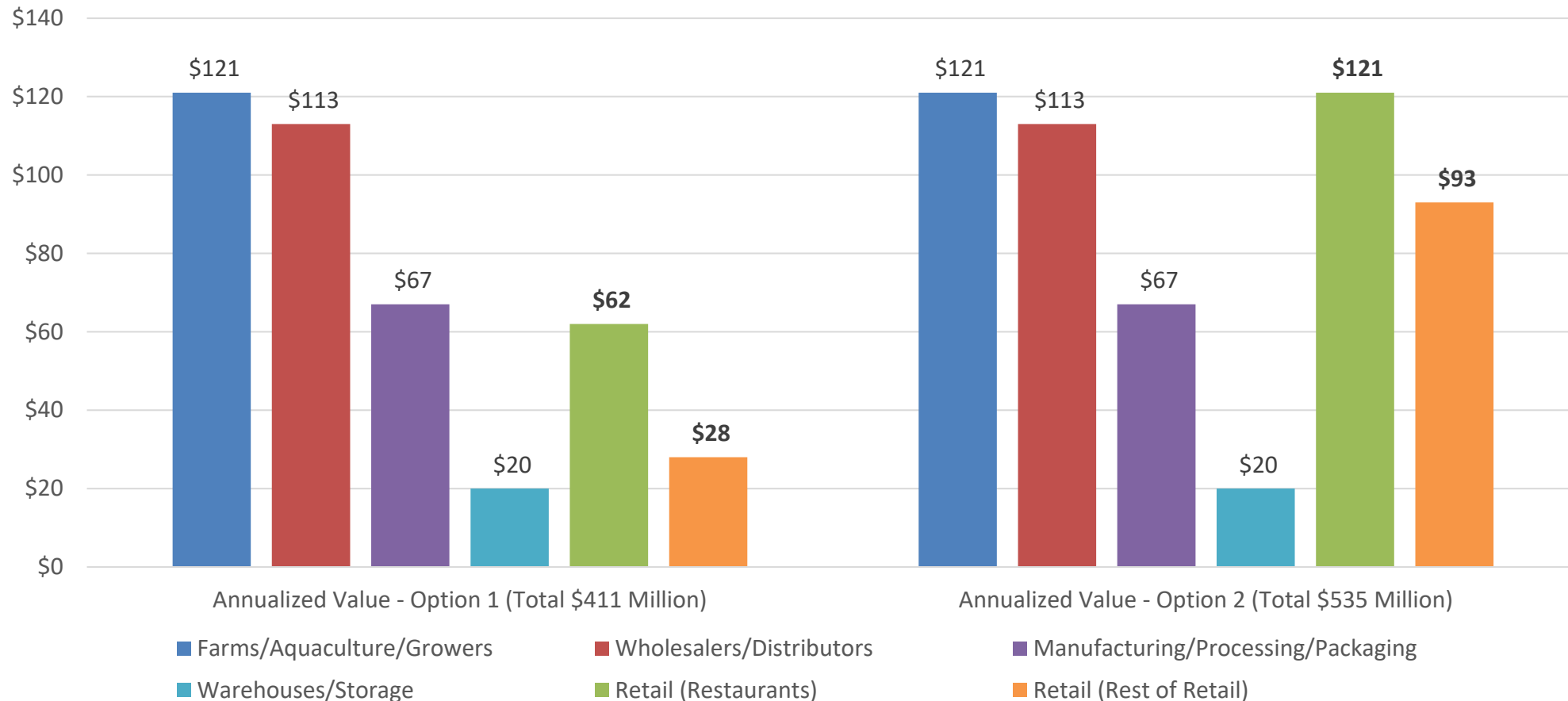
¹ Annualized over 10 years at 7% discount rate, millions \$2018

² Primary benefits are reported for an estimated 84% reduction in traceback time and are based on a sample of four pathogens.



Annualized Costs by Option and Sector

(over 10 years, 7 percent discount rate, millions \$2018)





Benefits

- Public health benefits
 - The value of averted foodborne illnesses
 - records required by the proposed rule are likely to reduce the time that a violative or contaminated food product is distributed in the market.
- Other benefits (see next slide)



Other (Non-Health) Benefits

- Avoiding overly broad market withdrawals and advisories
- Improvements in supply chain management and inventory control
- More expedient initiation and completion of recalls
- Avoiding costs due to unnecessary preventive actions by consumers
- Other supply system efficiencies due to standardized approach to traceability
 - increase in transparency and trust among food supply system participants
 - potential deterrence of fraud



Public Health Benefits

- Model provided in the pilot report
- 15 case studies (CDC and FDA outbreak data)
- Four pathogens
 - Cyclospora
 - E. coli (STEC)
 - Listeria monocytogenes
 - non-typhoidal Salmonella
- Estimated 84% product tracing time improvement (6 days vs. 37 days)
- FDA Cost of Foodborne Illness Model



Public Health Benefits

(over 10 years, 7 percent discount rate, millions \$2018)

Option	Value	Primary	Low	High
Option 1	Net Present Value	\$3,982	\$229	\$9,518
Option 1	Annualized Benefits	\$567	\$33	\$1,355
Option 2	Net Present Value	\$4,400	\$253	\$10,517
Option 2	Annualized Benefits	\$626	\$36	\$1,497



Benefits from Avoiding Broad Recalls of Selected Listed Foods

Category	Total costs of a broad recall Low*	Total costs of a broad recall High**	Total cost of narrower recall Low*	Total cost of narrower recall High**	Social benefit of a targeted recall Low*	Social benefit of a targeted recall High**
Pre-cut Fresh Salad Mix	\$1,049	\$3,442	\$1	\$2	\$1,048	\$3,440
Fresh Lettuce-Romaine	\$204	\$669	\$1	\$3	\$203	\$666
Fresh Tomatoes	\$331	\$1,196	\$0	\$1	\$331	\$1,196
Serrano Peppers	\$331	\$1,198	\$0	\$0	\$331	\$1,198
Sum	\$1,914	\$6,504	\$1	\$5	\$1,913	\$6,499

** High estimate is based on 13-week sales ending 09-27-2014, millions \$2018



Types of Costs to Industry

- Firms that manufacture, process, pack or hold foods on the FTL would need to:
 - Read and understand the rule (one-time cost)
 - Invest in capital (one-time cost)
 - Train personnel (one-time cost)
 - Establish and maintain the required records (recurring costs)



Costs of the Proposed Rule

(over 10 years, 7 percent discount rate, millions \$2018)

Option	Value	Primary	Low	High
Option 1	Net Present Value	\$2,888	\$238	\$17,034
Option 1	Annualized Costs	\$411	\$34	\$2,425
Option 2	Net Present Value	\$3,756	\$301	\$22,548
Option 2	Annualized Costs	\$535	\$43	\$3,210



Costs of the Proposed Rule



(over 10 years, 7 percent discount rate, millions \$2018)

	Option 2	Option 1	Difference (Option 2-Option 1)
One-time Costs (undiscounted, millions \$2018)			
Reading and Understanding the Rule	\$52	\$23	\$29
Capital Investment	\$725	\$356	\$369
Training	\$174	\$85	\$14
1315 – General Recordkeeping	\$163	\$101	\$62
Total One-time Costs	\$1,113	\$565	\$549
Annual Recurring Costs (undiscounted, millions \$2018)			
1315 – General Recordkeeping	\$20	\$13	\$8
1325 – Growing	\$12	\$12	\$0
1330 – Receiving (first receiver)	\$16	\$15	\$1
1335 – Receiving	\$98	\$56	\$42
1340 – Transforming	\$7	\$7	\$0
1345 – Creating	\$0.3	\$0.3	\$0
1350 – Shipping	\$234	\$234	\$0
Total Recurring Costs	\$387	\$336	\$51



Annualized Costs per Small Entity

(over 10 years, 7 percent discount rate)

	Option 1 Lower Bound	Option 1 Upper Bound	Option 2 Lower Bound	Option 2 Upper Bound
Farms / Aquaculture / Growers	\$414	\$5,283	\$416	\$5,286
Manufacturers / Processors / Packers	\$519	\$6,335	\$520	\$6,339
Wholesalers / Distributors	\$521	\$6,054	\$522	\$6,057
Warehouse and Storage	\$470	\$5,615	\$472	\$5,618
Retail Food Establishments	\$57	\$679	\$45	\$582



International Effects

(millions \$2018)

Measure	Option 1 or Option 2
Affected Foreign Establishments	212,404
One-time Costs	\$461
Recurring Costs	\$198
Annualized Total Costs (7% discount rate, 10 years)	\$259



Areas Where We Are Seeking Comment

- Number of entities that manufacture, process, pack, or hold listed foods
- Degree to which entities already satisfy the requirements
- Percentage of remaining traceability investment needed by each industry
- The expected benefits due to complexity of predicting the health benefits of averting shorter foodborne disease outbreaks
- The current number of foodborne illnesses caused by listed foods
- Our estimates of costs and benefits and the extent to which costs may already be internalized by covered entities