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**LOGISTICS ANALYSIS OF THE PATHOGEN  
CONTROL PROVISIONS OF THE ALMOND MARKETING ORDER**

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### ABSTRACT

Following an amendment to the Marketing Order for California almonds in 2007 aimed at enhancing food safety, around 400-500 million pounds of almonds undergo an added step in processing to reduce risk of salmonella contamination. This paper reports on the logistics necessary for implementing the almond food safety program. We use a linear programming model and assess the uncertain costs of transportation and the risks related to regulatory approval of certain pasteurization technologies. The total cost of treatment and the associated logistics is approximately \$28 million per year. Capacity for treatment is adequate, with only modest capacity constraints identified for the southern part of the growing region. The pricing of out-sourced treatment services is the main driver in the cost estimates. The findings highlight the need for a greater understanding of the market for pathogen reduction services and the associated scientific expertise needed to enhance food control.

### ACKNOWLEDGEMENTS

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### INTRODUCTION AND BACKGROUND

Production and exports of almonds increased over the last decade, aided in part by the successful positioning of almonds as healthful and nutritious alternatives for snacking and in recipes. The industry's promotion efforts were threatened by two incidents, in 2003 and 2005, when salmonella contamination was discovered. In response to the contamination and the associated outbreaks of illness, the Almond Board of California sought an amendment to its Marketing Order, which required handlers to assure treatment for pathogen control.<sup>1</sup> The salmonella control Action Plan, referred to as "pasteurization," went into effect in September 2007.<sup>2</sup>

Pathogen control for almonds involves the introduction of a new processing step into the value chain. Almonds are hulled in the field, and then the in-shell nuts are transported to intermediate processors. Subsequent to shelling, handling companies will typically process or package in some way. Value-added processing at the handler level can include blanching, oil or dry roasting, flavoring, slicing and dicing, and more.

There are several alternative ways in which pathogen control activities are integrated into the logistics of handling. Some handlers conduct the pathogen-reduction treatment in-house, then establish separate inventories of treated and untreated products. Other handlers use off-site treatment, which requires that inventory be separated in addition to the loading and transportation of untreated product to the treatment facility. The treatment can be undertaken on bulk bins of product or on pallets of case-packed product, depending on the technology of the treatment operation. Fumigation, for example, is typically on bulk bins. Steam application is either applied to loose product on conveyors or to plastic-wrapped pallets, depending on the technology. After treatment at an off-site facility, the almonds may be shipped directly to customers or returned to the handler for storage until an order is received.

Some value-added processing steps that are standard practice for almonds effectively pasteurize, therefore little change in the logistics is required. Blanching and oil roasting are examples of processes that can achieve pathogen control standards with modest modifications to the time or temperatures used. For these product forms, relatively modest changes in the system are needed.

<sup>1</sup> *Federal Register*. Vol. 72, No. 61 / Friday, March 30, 2007. 7 CFR Part 981, p. 15021.[Docket No. FV06-981-1 FR]. Almonds Grown in California; Outgoing Quality Control Requirements, Final Rule.

<sup>2</sup> Pasteurization has a specific definition to food scientists and FDA regulators in terms of percentage pathogen reduction. In this paper, the term pasteurization is used more generally as a synonym for the terms treatment and pathogen control.

Exported goods experienced the least change in the value chain after the Action Plan. The regulation does not cover almonds exported outside North America. Several handlers export their entire production and need no treatment process.

In the almond industry, where the demand for pathogen control is established by the Action Plan, the decision to “make or buy” treatment services is a key influencer of strategic positioning over the long term. The theory of the firm predicts that a strategy of outsourcing those activities that are not within the core competency of the firm is economically efficient. The choice of which activities to outsource or to keep within the boundaries of the firm is of considerable interest to business managers.

## **PATHOGEN CONTROL AND THE MARKET FOR TREATMENT SERVICES**

The Almond Board of California (ABC) implemented its pathogen control program in collaboration with FDA and various private sector experts so that treatments provide the necessary reduction in salmonella (4-log reduction). Moreover, ABC’s rules and procedures provide oversight that the companies in the industry are in compliance. These rules effectively establish a demand for food safety expertise that did not exist prior to the change in the Marketing Order. The different roles of agents in establishing a credible system can be understood with the following brief description of the pathogen control program.

### **Process Approval**

A treatment process needs to be validated in terms of its technology to accomplish a 4-log reduction in salmonella. The validation of technology requires an investment in time, expertise, testing, and the management of the approval process with FDA. Approved technologies include oil roasting, dry roasting, blanching, steam processing and propylene oxide (PPO) fumigation. The Almond Board of California assists in obtaining approvals and assembles an expert review panel to aid in development of additional acceptable treatment technologies.

Apart from salmonella control, a series of quality issues relating to hardness, flavor, effects on brown skins or color of blanched product, and more have been studied in an effort to broaden the choices of pasteurization processes that are acceptable from the point of view of safety and food quality.

### **Technology Validation**

For either a new treatment facility or an existing process, operators must demonstrate scientifically the ability of the equipment in operation to satisfy requirements of the Action Plan. Third party experts are usually hired to do this and the documentation of the validated technology is provided to ABC.

## **Auditing the Pathogen Control Plan**

Handling companies develop a plan annually for treatment of the crop and are subject to audits to verify that the activities are taking place. The auditing services are procured from the certification agency DFA of California.<sup>3</sup>

## **SUPPLY, DEMAND, AND PRICING OF ALMONDS**

Almonds are a high-value food and a large proportion of the crop is exported to markets where consumers are quality-conscious. More than half of California almond production is exported each year; the leading destinations by volume are Spain, Germany, and China.

Since the adoption of the salmonella control Action Plan in 2007, almond production rose by 14%, to 1.6 billion pounds in the 2008/2009 crop year (ending July 2009) (Almond Board of California). North American shipments, those subject to the Action Plan regulation, increased by 4%, to 451 million pounds in the 2008/2009 crop year. The remaining amount, approximately one billion pounds, is exported outside North America and is exempt from the treatment requirement.

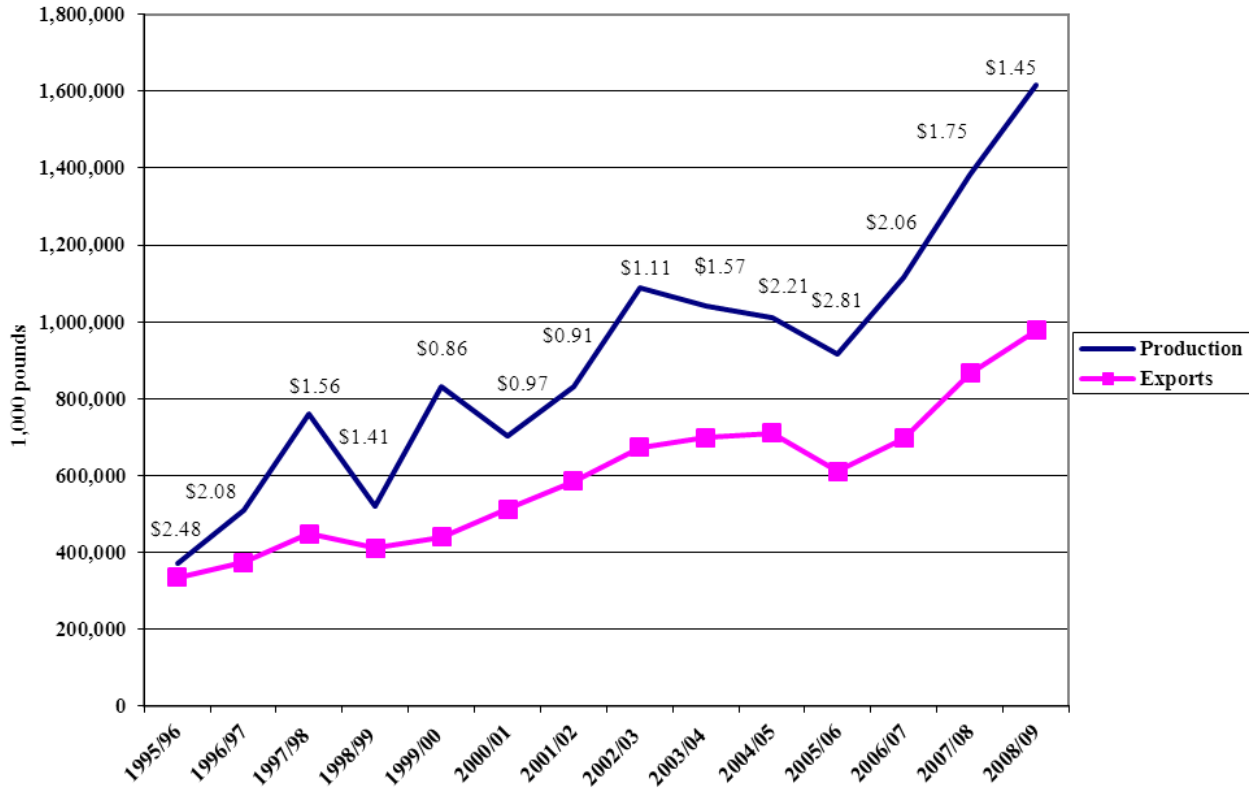
Farm prices of almonds fell consistently since 2005 along with the rapid increase in production. The grower price was less than \$1.50 per pound in crop year 2008/2009, down by 50% from the peak in 2005/06.

The downturn in prices affects the economic impact of the pasteurization rules, according to some business metrics. As an example, assume that the total cost of treatment and the associated handling/management is approximately 10 cents per pound. In a year in which prices of almonds are high, say \$2.50 per pound as they were in 2005/2006, the price-cost margin associated with the program is 4%. When market prices are down to \$1.50, the burden of the pathogen treatment in terms of per-pound value is significantly higher, 6.7%.

Almond exports rose consistently during the last several years (figure 1). In some years, exports grew significantly faster than domestic shipments. The growth trend in exports has served as a relief valve on the total costs of the Action Plan because most exports are exempt. Therefore, expansion in the almond crop has not led to significant bottlenecks in treatment or cost increases.

<sup>3</sup> DFA of California is also known as the American Council for Food Safety and Quality.

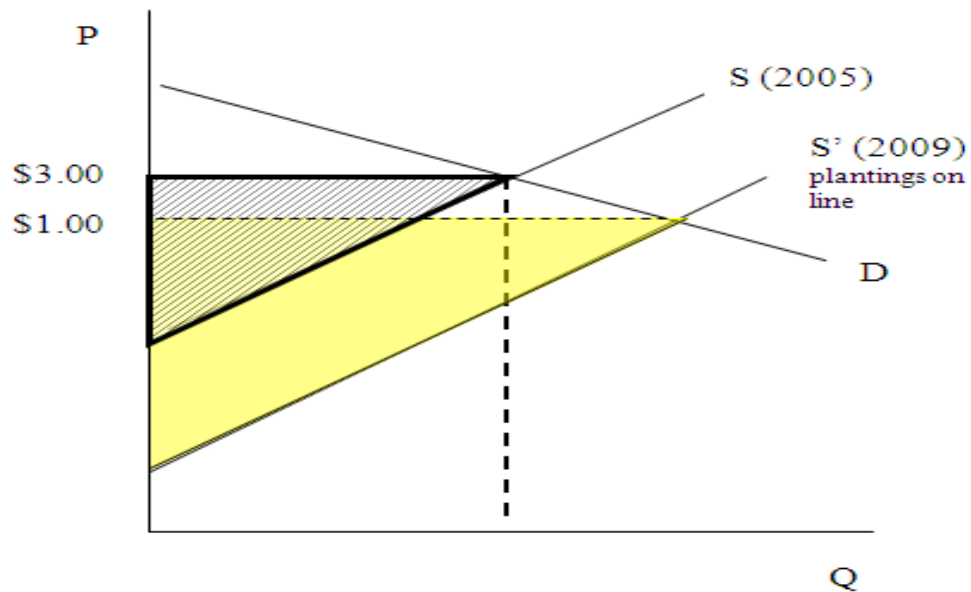
**Figure 1: Growth in almond production, exports and grower prices, 1995-2008.**



Source: NASS. 2008/09 is forecast.

Note: Dollar values are the season average grower price received in the year.

**Figure 2: Producers' surplus and decreasing grower price of almonds.**





**Table 1: Growers' Selected Financial Data.**

Firm	Sales (\$ million)	Income (\$ million)	Employees	Members
Blue Diamond Growers	709	458	1,100	~3,000 Cooperative
Paramount Farms (data are for parent co. Roll Intl. Corp)	2,010	n.a.	3,765	
Stewart & Jasper Orchards	75	n.a.	175	
John B. SanFilippo & Son, Inc.	553	6.9	1,350	

Source: Hoovers.com

Almonds are prepared in a variety of ways to meet differentiated demands among final consumers worldwide. The bakery and confectionary industries purchase almonds in whole or blanched forms and further process them into sweet baked goods, candies, breakfast cereals and snack bars and mixes. Some handlers, typically larger operations, conduct a full range of processing within their businesses and deliver consumer-packaged-goods to retailers or distributors. Some consumers demand organic or raw foods and several handlers are specialized in serving organic product niches. Other handlers provide both organically-grown and conventionally-grown nuts. Financial data for the largest public companies in the handling sector are in table 1.

Given the various preferences and requirements of the highly differentiated consumer markets, specifications for production and, now, pathogen reduction treatments, must be established to meet a wide range of dimensions in terms of quality. For example, quality to certain customers means timely fulfillment of a large order of consistent size product, to be used for further processing. To another customer, quality is intact brown skins for goods that are meant to be sold whole, in a natural or organic product line. Treatment of almonds with heating processes has been perceived as an impediment to meeting quality specifications. There is a risk that skin flaking is related to heat or steam. For a very small niche of consumers who select almonds as a raw food item, any form of heat treatment is not acceptable.

A further dimension of quality is accuracy in terms of records regarding the processes that the goods have undergone. Subsequent to the Action Plan, domestically shipped almonds must be certified as treated. Or if they have not been treated, they must be labeled “unpasteurized” and shipped outside North America or to a customer that has been approved to conduct pasteurization in its processes.

The availability of approved, validated treatment facilities was disrupted when a particular vendor's technology that seemed promising in 2006 failed to achieve the 4-log pathogen reduction required by FDA. The inability of the Ventilex technology to be approved was a major blow to investors and to the nearby handlers that had planned to use Ventilex as their out-source treatment facility.

### **LEAST – COST TREATMENT LOGISTICS PLAN**

An economic model of logistics costs, including shipping, handling, and treatment, is used to develop the least-cost plan from an industry-wide perspective (Bazaraa, Jarvis, and Sherali). The main goals of the model are to identify capacity constraints, if any, and to analyze the effects of possible changes in energy costs on the future implementation of the almond industry Action Plan.

The availability of treatment capacity is a critical issue that affects the costs of implementing the almond industry's food safety Action Plan. To avoid the possibility of bottlenecks in accessing treatment services, some of the largest handlers invested in on-site treatment facilities. A large number of handlers, many of them smaller businesses, depend on outsourcing arrangements for the required pathogen-reduction treatment.

Scenarios that may affect strategic planning are examined, including changes in fuel prices, potential production growth in the industry, and technologies failing to provide adequate pathogen control.

A linear programming (LP) model is used to represent the geographic patterns of production and treatment and identify the routes that minimize total transportation costs from handlers to treatment facilities and then from treatment facilities to shipping points. The constraints reflect product flows as of the 2006/2007 crop year. The 100 handling companies were aggregated into supply points of origin according to ZIP codes. The largest handlers (those shipping more than 5 million pounds per year) were the starting point for creating supply regions. Some of those large handlers share a ZIP code with another handler and were combined into the same supply location (leaving 20 source points in the model). The distances combined within a source region are typically 20-35 miles.

The location of 16 treatment facilities is based on data provided by the Almond Board of California (ABC); capacity is estimated from discussions with industry sources, including vendors of technologies. Final destination points are represented as East Coast USA, two California locations, Canada, and Mexico.

The linear programming model structure is:

Indices:

- $i$  handlers ( $i = 1, 2, \dots, 20$ )
- $j$  treatment facilities ( $j = 1, 2, \dots, 16$ )
- $k$  shipment destinations ( $k = 1, 2, \dots, 5$ )

Variables:

$X_{ij}$  quantity of almonds transported from handler  $i$  to treatment facility  $j$   
 $X_{jk}$  quantity of almonds transported from treatment facility  $j$  to shipment destination  $k$

Other Variables:

$A_j$  maximum capacity at treatment facility  $j$   
 $D$  quantity demanded from almond consumers  
 $S_i$  quantity supplied from handler  $i$   
 $S_j$  quantity supplied from treatment facility  $j$

Coefficients:

$C_{ij}$  transportation cost from handler  $i$  to treatment facility  $j$   
 $C_{jk}$  transportation cost from treatment facility  $j$  to shipment destination  $k$   
 $V_j$  variable costs of treatment facility  $j$

The objective function is:

$$\text{Minimize Cost} = \sum_i \sum_j C_{ij} X_{ij} + \sum_j \sum_k C_{jk} X_{jk} + \sum_i V_j X_{ij} \quad (1)$$

where  $i = 1, 2, \dots, 20$  handlers  
 $j = 1, 2, \dots, 16$  treatment facilities  
 $k = 1, 2, \dots, 5$  shipment destinations, shipping to New York (for East Coast USA & Europe), San Francisco (for West Coast USA & Asia), Long Beach (for West Coast USA & Asia), Mexico, and Canada

The constraints are:

$$\sum_j X_{ij} \leq S_i \quad \forall_{i,j} \quad (2)$$

The total quantity of almonds transported from handler  $i$  to all treatment facilities must be less than or equal to the supply of almonds from handler  $i$  for all handlers.

$$\sum_i X_{ij} = T_j \quad \forall_{i,j} \quad (3)$$

The quantity of almonds transported from all handlers to treatment facility  $j$  must equal the supply of almonds at treatment facility  $j$  (16 constraints, one for each treatment facility).

$$\sum_k X_{jk} \leq T_j \quad \forall_{j,k} \quad (4)$$

The quantity of almonds transported from treatment facility  $j$  to each shipment destination point must be less than or equal to the supply of almonds from treatment facility  $j$  for all treatment facilities.

$$\sum_{ij} X_{ij} = \sum_{jk} X_{jk} \quad (5)$$

The quantity of almonds transported from all handlers to all treatment facilities must equal the quantity of almonds transported from all treatment facilities to all shipment destination points.

$$\sum_j X_{jk} \geq D \quad (6)$$

The quantity of almonds being transported from all treatment facilities to all shipment destination points must be greater than or equal to the quantity demanded by almond consumers.

$$\sum_i X_{ij} \leq A_j \quad \forall_{i,j} \quad (7)$$

The quantity of almonds from all handlers that are transported to treatment facility  $j$  must be less than or equal to the maximum capacity of treatment facility  $j$  for all treatment facilities.

The non-negativity constraints are:

$$X_{ij} \geq 0 \quad \forall_{i,j} \quad (8)$$

$$X_{jk} \geq 0 \quad \forall_{j,k} \quad (9)$$

Solutions were obtained using GAMS (General Algebraic Modeling System) MINOS solver. Modeling frameworks such as this one have several embedded assumptions and limitations. One important limitation is that logistics choices are assumed to be made with the goal of cost-minimization alone. To that extent, other non-monetary factors that affect the decision to select a treatment location are overlooked. For example, with this model, one cannot analyze the possibility that customers choose a treatment location for reasons related to the type of technology, service levels, or proprietary decisions.

The assurance processes that lead to high quality products generate transactions costs that are difficult to price in a market exchange. Unobserved costs include the “hassle factor,” the time and energy of staff in arranging for the approvals or audits, or the unwillingness of customers to make a transaction because of concerns about reputation or quality. These are not included in the model.

Another important assumption is the absence of economies of scale. That is, costs are assumed to be accurately modeled on the basis of a charge per-mile or per-pound and there are not significant overheads or sunk costs. This assumption is standard in transportation analysis and is supported by industry sources as applicable for this study.

The cost of shipment from treatment providers to destination points is excluded from the total costs reported in this study, because even in the absence of the Action Plan, almonds would have been shipped to those destinations. Transportation from the handler to the treatment location and variable charges of treatment services are included in the total cost estimate.

Treatment facilities included in this model use either fumigation technology (PPO), blanching, oil roasting, steam, and moist heat treatments. The cost of treatment used is an average of the expected charges; there is no differentiation in pricing for different types of technology or for individual businesses' policies.

### **Data and Baseline Parameters**

The baseline volume of 502.5 million pounds was determined from the 2006/2007 crop year shipment records and includes the almonds that were destined for North American customers in that year (table 2). Almonds exported outside of North America (821 million pounds) are not subject to the treatment requirement, hence are not included in the estimate of logistics costs.

A portion of the almond crop is shipped domestically without treatment because the almonds are delivered to a user under the Direct Verifiable (DV) program. As of late 2008, 24 food processing companies (40 different premises) were approved to receive untreated almonds on the basis that their production processes provide pathogen control. The actual levels of DV shipments are proprietary information. We assume in the baseline model that a relatively small share of the crop is shipped under the DV program (110,000 pounds). This assumption, if incorrect, will tend to overestimate the costs of the Action Plan. The rationale for a conservative size of the DV program is that there are no published sources on the volume shipped under the program and industry sources were not available to provide defensible estimates.

Baseline cost parameters are \$2.70 per gallon of diesel fuel, \$13.50 for truckers hourly wages, and maintenance expenses of 9 cents per mile. The fuel economy is fixed at 7 miles per gallon. Treatment charges are set at 5.5 cents per pound of almonds for all technology types and locations.

**Table 2: Shipments of California almonds, by final destination, 2007 / 08 crop year.**

	<u>Pounds</u>
Total	1,323,850,551
Shipments to USA customers	454,474,255 <sup>a</sup>
Exports	869,376,296
Of which:	
To Mexico	9,103,173 <sup>a</sup>
To Canada	39,038,456 <sup>a</sup>
Direct Verifiable program (estimate)	110,000 <sup>b</sup>

<sup>a</sup> Treatment required under the Action Plan.

<sup>b</sup> Authors' estimate of a limited Direct Verifiable program.

This assumption is re-examined in further analysis.

Source: Sue Olson, ABC, via email Oct. 2008 for shipment destination.

## RESULTS OF LOGISTICS ANALYSIS

The total logistics cost associated with the food safety Action Plan is an estimated \$28 million per year. Cost efficiencies are obtained because the largest handlers have access to treatment facilities on their own premises, or nearby. Low-cost transportation is a competitive advantage to those almond handling firms that have invested in on-site treatment. Investments in treatment facilities that several handlers have made contribute to systemwide efficiency in terms of transportation costs. Other handler firms that have not invested in on-site treatment, but are located near a service provider, also benefit from low-cost transportation.

The findings indicate that:

- Capacity of treatment is not a limiting factor.
- Charges for outsourced treatment are the largest contributor to total cost of the Action Plan.
- Diesel fuel costs rising to historically high levels add less than 1% to the total cost (\$290,000).

Capacity for pathogen-reducing treatment of almonds is more than adequate for the industry's needs. Even excluding the Ventilex systems from total capacity, there is sufficient treatment access in terms of industry-wide needs. More than 320 million pounds of capacity goes un-used. Four of the fourteen different treatment locations have excess capacity. These results are strong indications that treatment is adequately distributed.

The North (Chico area) and Central regions (Modesto area) are not capacity constrained, even under the assumption that Ventilex is shut down and not replaced. However, in the Sacramento region, total capacity is insufficient to meet the demand. The optimized logistics model indicates that treatment facilities in the regions north and south of Sacramento are used, each route exceeding 100 miles.

The marginal benefits of additional capacity at two treatment locations (Wasco and Lost Hills) are among the highest. That is to say, there is an incremental benefit from locating capacity in these regions. Part of the reason is the large number of almonds that are supplied by handlers originating in the regions. If there were more capacity in those regions, modest savings in transportation costs would be expected. At the margin, a one-pound increase in capacity in these locations leads to transportation cost savings of 60 cents.

## **Impact of Regulatory Approvals on Capacity Constraints**

When the Action Plan went into effect, several treatment facilities were operating under temporary approvals, as appropriate for the implementation phase of the regulation. During 2008, three of the treatment facilities using Ventilex steam technology failed to meet final approval for satisfactory pathogen-reduction performance.

The baseline results reported in this study do not include the Ventilex facilities. As a test of the impact of removing that capacity from the system, a model was developed in which Ventilex facilities are included, which was actually the case in the 2007 crop year. Treatment capacity increases by 162 million tons with the inclusion of these facilities, and the impact on total cost is minimal. Total cost falls by \$40,000, or by less than one percent (0.14%). The cost per pound treated was held constant in both versions of the model; therefore, changes in location alone explain the estimated modest change. With Ventilex facilities in place, a route of more than 150 miles from region 4 to region 3 is no longer necessary and the shadow price of capacity limits at the two facilities in region 4 are reduced.

It should be noted that the logistics model does not represent the firm-level impact of the lack of access to Ventilex technology. There are adjustment costs in finding an alternative arrangement for treatment, particularly if their customers' requirements did not allow them to utilize another form of treatment technology nearby.

## **Charges for Treatment Services**

The total cost of the Action Plan logistics is highly sensitive to the charges for treatment that are assumed. Lacking detailed data on charges for treatment, we use a constant cost per pound treated for each treatment facility, regardless of technology and location. This assumption is consistent with a competitive market for treatment services. Each additional penny in average per-pound for treatment generates \$5 million more in total logistics costs (table 3).

## **Fuel Prices**

As a starting point, the baseline model has diesel fuel price at \$2.70 per gallon. This was the average price in California during 2003-2009, according to the U.S. Department of Energy. Diesel prices ranged from \$1.10 per gallon in Feb. 1999 to \$4.97 per gallon in July 2008, then fell to \$2.30 per gallon in early 2009 (table 4). The sensitivity of the logistics costs to diesel fuel prices is relatively low. If diesel fuel is included at \$4.97 per gallon (the July 2008 peak), total costs rise by \$290,000.

**Table 3: Effect on total cost of increasing charge for treatment.**

<i>Charges for treatment</i> in cents per pound	<i>Total logistics cost</i> in million dollars
3.5	17.98
4.5	23.00
5.5	28.03
6.5	33.06
7.5	38.08
8.5	43.11
9.5	48.13
10.5	53.16

**Table 4: Statistics on diesel prices, in dollars per gallon.**

	<i>2003-2009</i>	<i>1995-2009</i>
Average	2.71 <sup>a</sup>	2.00
Standard deviation	0.82	0.85
Minimum	1.54	1.10
Maximum	4.97	4.97
Median	2.68	1.61

<sup>a</sup> Price used in baseline model.

Note: Prices for diesel on highway, ultra-low sulfur, California.

Source: Energy Information Administration, U.S. Department of Energy.

## CONCLUSIONS

An economic model of an efficient logistics system for treatment of almonds indicates that total capacity is adequate to treat all the almonds shipped to North American customers. Costs of the treatment and related logistics are estimated at approximately \$28 million per year.

Energy costs have a relatively small effect on the total cost. If diesel prices return to the high levels of the summer of 2008, the increase in the total cost of transportation is expected to be less than \$300,000. Given the modest impact of diesel fuel, attention should be focused on the charges for pathogen-reduction treatment as the driver in total cost of the Action Plan. The majority of handlers depend on outsourcing to custom providers to treat their products. The most efficient locations for treatment are the largest handlers' operations, and they may not be offering services on a for-hire basis in ways that meet the needs of the smaller handlers.

Clearly, an economically efficient treatment industry is an important goal. Treatment services are not "one size fits all," and as in most differentiated markets, pricing issues are complex. Is



monitoring the competitiveness of the market for treatment services a role for industry, for USDA, or for FDA?

Food contamination incidents since the adoption of the Action Plan have reinforced the value of a proactive system to reduce contamination risks industry-wide. Peanuts, and now pistachios, have been implicated in salmonella outbreaks. According to the Almond Board of California,

“Product recontamination was a contributing factor in a number of product recalls of other nuts in 2009. ABC acted quickly to develop the Plant Environmental Monitoring Program (PEM), which is an important tool that hullers/shellers, handlers, DV users, and manufacturers can use to help control product recontamination. A well-thought-out PEM will help to significantly reduce the risk of product recontamination in a processing operation.” (ABC, Almanac 2009: 18).

The experience of the almond industry demonstrates that regulatory risk is a factor in the efficient deployment of safety-enhancing technology and services. Industry is investing in technologies under the expectation that the systems will satisfy technical standards, and there are real possibilities that the systems in place may not perform as expected. While the impact of the approval problems in this industry-wide model was modest in terms of capacity constraints, the disruption to the particular firms involved is notable.

Further complications, in terms of the technology that is deployed for food safety, relates to the differentiation of consumer demands in the market. The fact that some processes are not acceptable to certain customers, even if they accomplish pathogen control, means that the market for treatment services must be differentiated. A custom provider that can offer pathogen reduction without fumigation, for example, can meet the requirements of organic foods producers and consumers. There will be some potential for differentiation and possibly profit-making as treatment service providers find ways to attract specialized customers who will pay for premium-priced services in association with the premium-priced final goods.

In assessing the developing market for safety-enhancing services, economists have much to offer. It can easily be established that some mark-ups in the pricing of treatment services are simply cost recovery; justified by the complexity of bringing in small lots from many different handlers. Another valid reason for differentials in charges across types of treatment is that some markets with high willingness to pay for quality will be able to sustain higher charges for the form of treatment that is acceptable to those customers, leading to a premium price at the treatment facility.

As the market for pathogen control services matures, one could expect that competitive forces would affect the supply and demand for treatment services. Handlers requiring custom treatment would be able to choose between alternative providers on the basis of location, service provided, and timeliness. And, if the competition were vigorous, one would expect an equilibrium at which treatment suppliers price their custom services to cover their cost, not to be a profit center. Such a competitive market will develop more quickly if there are few constraints on the scientific expertise needed to assure the qualifications of service providers.

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