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New Pathogen Testing Technologies and the Market for Food Safety Information

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New rapid and sensitive testing technologies, based on the biotechnology tools underlying modern medical diagnostics, have been developed for the food industry. The growing demand for food safety in the marketplace, combined with increased availability of new testing technologies, has led to shifts in both the demand and supply of food safety information. As a result, more food safety information is being generated, and this information is being used in firm management and food buyer decisions. These biotechnology-based testing methods are leading to better food safety performance in the marketplace.

Key words: economics of information, food safety, rapid diagnostic tests

The impact of modern biotechnology on productivity in agricultural production is widely appreciated. Less attention has been paid to other ways in which modern biotechnology is changing the food system. Relatively recent advances in pathogen testing technology, based on the biotechnology tools underlying modern medical diagnostics, are changing the ability of food producers to measure food safety. Although real-time results for specific pathogens are still in the future, these new tests provide better information at lower cost and in a shorter time. New tests allow food buyers to more easily specify desired food safety levels and food sellers to more easily certify their products' safety.

This paper investigates how the availability of new testing methods influences private incentives to generate and use food safety information. We use an economic framework that describes the supply of information and the demand for information. The impact of shifts in supply and demand for information on food markets is discussed, based on published case studies and interviews with firms that make test kits, carry out food safety audits, or provide third-party certification. We conclude with the implications of these testing technologies for market performance in delivering improved food safety.

New Testing Methods Rely on Modern Biotechnology and Bioinformatics

Several advances in modern biotechnology and in information technology have hastened the development of faster, more sensitive, and even less expensive analytical tests. One biotechnological advance that has aided rapid method development is automated sequencing equipment. Thirty years ago, sequencing a protein was research—now it is a simple analysis. Similarly, twenty years ago, sequencing a microbial genome was doctoral dissertation material. Now, sequencing nucleic acid genomes is routine work. A recent Google search (*+sequencing +PCR +primer*) produced more than 500,000 results. Many on the first page were companies—not universities—soliciting business.

Knowing the sequence of a pathogen's nucleic acid enables scientists to construct *PCR primers* to detect that pathogen. These PCR primers are at the heart of many of the highly specific analytical tests now on the market. Sequencing the DNA (or the short-lived RNA for live or recently alive microorganisms) nucleic acid of pathogens also enables scientists to identify the pathogens' virulence factors. Knowing the sequence of a virulence factor then enables scientists to construct specific PCR primers to detect the microbe that carries that virulence factor. Now and in the near future, the focus may be less on the genus, species, or serotype of a bacterial pathogen and more on whether it is carrying the virulence factor or the combination of factors that make the microorganism a public health threat.

Other automated equipment has facilitated development of nucleic acid sequencing equipment as well as other analytical tests. Rather than a technician slipping cuvettes one by one into a spectrophotometer, modern scanners can read the optical density of 64 wells in a plate in the same time. There are automated devices that inoculate wells containing different enrichment media, incubate the wells, scan their optical density to monitor any growth overnight, and have the data ready in the morning. This automation facilitates gathering the reams of data needed to show correlation for research or simply lowers labor costs for routine tests.

Simple technical innovations have also contributed to the advance in faster, cheaper, and more sensitive

analytical methods. One is better membrane filters and filtering techniques, which facilitate separation of pathogens from food products. Another innovation is antibody-labeled magnets to pull the pathogen of choice out a food matrix for enrichment and concentration; these have also enabled higher sensitivity and sped up analyses. Better chemistry, such as the colloidal gold flag for ELISA assays, made so-called "dipstick" tests much more user friendly. These and other innovations continue to contribute to the rapid expansion of biological knowledge about pathogens.

However, few of these developments and innovations would be possible or even useful without the computer. The computer microchip and programming software have enabled both the development and control of these automated analytical devices. They have also facilitated the analysis of the reams of data that these analytical devices produce. With the aid of such analysis, test results can inform risk assessment and better design of food safety controls.

Economic Framework—Shifts in Supply and Demand for Food Safety Information

Food safety information can be viewed as an input into the production of food. As such, it can be analyzed according to a model of input supply and demand (Figure 1). The supply curve for information reflects its marginal cost, which rises as more information is generated. For example, more resources are needed to carry out more tests for microbial pathogens, for different pathogens, or to utilize information within a management system. These costs are determined by the costs and availability of testing methods that generate information. The demand for information is a derived demand, which depends on market demand for the food product and for safety in that product's market. Incentives for safety provisions will be determined by market forces and regulatory initiatives. This derived demand curve slopes downward, because there is diminishing marginal utility to additional information. Initial accurate information has very high value, but this value declines as more information is obtained.[1] Thus, firms will generate the amount of information determined by the intersection of the supply and demand curves. When information is very costly or nearly impossible to obtain, and simultaneously its value is not obvious to firms, little or no information may be generated, as the intersection of supply and demand may lie to the left of the y axis. Next, we consider how the development of new testing technologies has shifted the supply curve for information and the simultaneous shifts in demand for information.

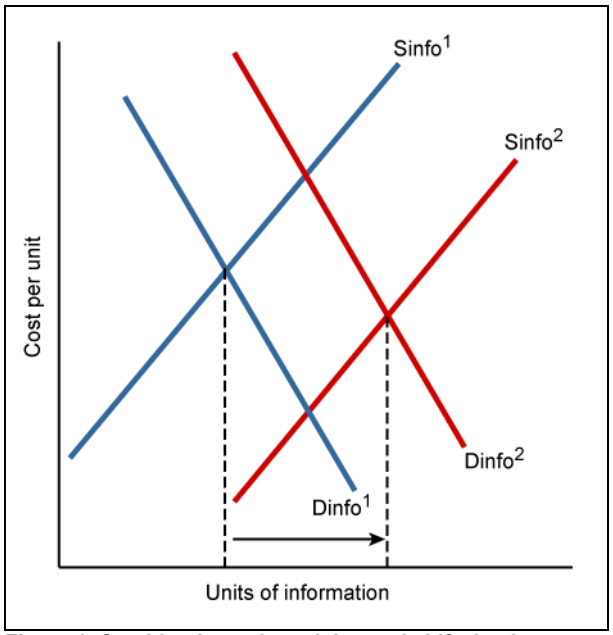

Figure 1. Combined supply and demand shifts lead to more information use. When both S and D shift, there is high adoption and a big increase in information generated.
Adapted from Bullock, Lowenberg-Deboer, & Swinton (2002)

Shift in the Supply of Information

Medical advances, the development of epidemiologic methods, and new pathogen tests have all played a part in linking foodborne pathogens to many known acute and chronic human illnesses that previously did not have an identified cause (Council for Agricultural Science and Technology, 1994). Early in the 20th century, pathogen testing relied on growing cultures of the pathogen in broth or on plates filled with growth media. Once the colonies of the pathogens grew into the millions, they were visible to the naked eye and confirmed by microscopic examination. This is called the *standard culture test* and took several days or even weeks (depending on the pathogen) to get test results. Sometimes there are problems with definitive pathogen identification or spoilage bacteria in the sample that grow rampantly and cover up the pathogen. These problems led to the development of selective growth media that

1. *It is possible that the demand curve for microbial pathogen tests is kinked at the upper portion due to the need for a minimum number of tests to provide accurate information.*

permit only the target pathogen (or closely related bacteria) to grow and inhibit the growth of other bacteria.

In the 1960s, *enzyme linked immunosorbent assay* (ELISA) tests became available to the food industry. ELISAs use a specific antigen or antibody to detect the presence of a specific pathogen, toxin, antibiotics, or drug/pesticide residues. The novelty of ELISA was the use of an enzyme "flag" on the antibody to show the presence of the antigen. More recently, highly specific antibodies were developed, along with monoclonal antibody production methods. These tests are widely used today because they are inexpensive, and preliminary results can be obtained in only 24–48 hours. "The convenience of the portable, self-contained 'dipstick' sampling systems have proved beneficial to plant operations; these devices have gone a long way toward the... ideal of on-line or at-line monitoring. The highly automated and sensitive laboratory bench-top instruments based on immunoassay have decreased time to result substantially over the last few years, as well" (Vasavada, 2001, p. 32).

In the 1980s and 1990s, the *polymerase chain reaction* (PCR) test became widely used as a method to detect foodborne pathogens in both humans and in food products (Chen, 2003). The PCR test was invented in 1971 and is based on identifying DNA fragments that are unique to the pathogen. PCR is very fast, producing results within 24–48 hours. It can be engineered to detect very low levels of a pathogen in food. If messenger RNA is used (called a RT-PCR test), the test gives a very low rate of false positives—a useful trait for food processing plants. The speed and accuracy of RT-PCR allow plants to test a product and hold it until the pathogen test results are available.

Pathogens in foods are usually found at lower levels than in samples taken from people who are ill (Chen, 2003). Thus, tests for pathogens in food must be more sensitive than clinical tests. To increase the probability of detecting foodborne pathogens present at low levels, microbiologists have developed ways to link the PCR test method with other new techniques, including immunomagnetic separation (IMS), ELISA, and nested or seminested primers. It is important to test for low pathogen levels, because recent outbreaks have shown that low numbers of pathogens can cause illness depending on the virulence of the pathogen, vulnerability of the human, and the fat content of the food.

New test methods are linked to computer reporting systems that make the interpretation of results easier and faster. Some of the newest test methods permit testing for detection of several pathogens at once with one sample and almost instantaneous quantification of the total bacterial load on the food sample. In the future, instantaneous results for pathogens may be possible, and are certainly a goal of test innovators.

In summary, advances in pathogen testing have resulted in more pathogen tests, faster results (down to 1–2 days now for some common foodborne pathogens instead of 3–5 days or weeks), low-level pathogen detection, identification of specific strains of a pathogen, amazing accuracy (fewer false positives and false negatives), and integration into computerized data reporting systems. A comprehensive review of rapid methods is found in Fung (2002).

The development of new rapid test methods increased the ability to identify new human pathogens and their importance. In 1972, for the first time, a virus was identified as causing human foodborne illness. However, it took two decades "to cultivate the virus, develop an animal model, or prepare simple, sensitive, diagnostic tests that could be widely used to study the extent of the disease" (Glass et al., 2000, p. S255). Today Norwalk virus and its close relatives are the most common known cause of acute gastroenteritis (diarrhea and vomiting) in the United States. The new tests improve the ability to identify the foods and pathogens causing illness outbreaks.

In addition to identifying new pathogens, the pace of test development has quickened, as demonstrated by the AIDS and SARS tests (Gerberding, 2003). AIDS emerged as a public health threat in 1981, but it took until 1985 to develop a diagnostic test. In contrast, the World Health Organization alerted the world to the threat of SARS on March 12, 2003, and a diagnostic test was developed by April 29, 2003. Scientists worked for 20 years to develop the Norwalk virus test, four years to develop the AIDS test, and only six weeks to develop the SARS test.

The rapid advances in the accuracy, sensitivity, speed, and lower cost of pathogen tests have done much to make foodborne contamination more transparent. Used in conjunction with process controls, these tests permit firms to analyze their production processes and redesign protocols to reduce risk on a consistent basis. Thus, the availability of new testing methods reduces the cost of generating food safety information in the production process. Next, we look at how private incentives to generate and use food safety information are increasing.

Shifts in the Demand for Information

Food safety information has several different kinds of economic value to food producers, including avoidance of loss, capturing price premiums, increasing sales, or reduced production costs. Identifying a bad product before it is sold can prevent a costly recall or other types of costs associated with product rejection, including liability for foodborne illness outbreaks.

A simple model of the demand for information to avoid product loss is given below (adapted from Frank, 2003, p. 88). Expected utility, *EU*, is derived from product sales and losses. These are the sum of the probability of having a bad product times the losses from such products plus the probability of a good product times utility from sales of those products (Equation 1). The introduction of a test to determine whether a product is good or bad adds cost *T* to the expected utility function, which must be subtracted from the sales value and further reduces the negative losses (Equation 2).

$$EU = p_L U[LOSS] + p_S U[SALE] \quad (1)$$

$$EU = p_L U[LOSS - T] + p_S U[SALE - T] \quad (2)$$

Solving the *EU* function for *T* gives the maximum value of the test's information to the firm. That is, it shows the value of knowing about bad products and avoiding their associated losses. This simple model predicts that the value of knowing about a potential bad outcome (unsafe product) is a function of the probability of the outcome and its cost. The form of the utility function reflects the firms' degree of risk aversion. The value of information to the firm is higher when (a) the probability of the outcome is higher, (b) the cost of the bad outcome is higher, or (c) the firm is more risk averse.

In addition to avoiding losses from allowing a bad product to enter the market, food safety information can also help firms to demonstrate compliance with regulation or to avoid regulatory actions that result in lost production or sales. Returns from product sales can be enhanced by certifying safe (and consistently safe) products, which can ensure market access to a particular buyer and may result in higher prices or less variation in prices obtained over time. Finally, more specific food safety information can help firms to alter their production processes so as to more cost effectively supply food safety. As food safety in the final product is the result of many different actions in food processing, better understanding of how food safety results from these interlinked actions can lead to better management of food production processes.

The value of food safety information may be increasing during the past decade at the same time that the cost of information is falling. Increasing value arises from greater market and regulatory attention to food safety, both of which increase the cost of food safety incidents. The United States Department of Agriculture Food Safety and Inspection Service's (FSIS) pathogen performance requirements for raw ground beef started in the 1990s with a testing program for *Escherichia coli* O157:H7 in raw ground beef as a response to the 1993 Jack in the Box outbreak. The 1996 Hazard Analysis Critical Control Point (HACCP) regulations required plants to test for generic *Escherichia coli* while the FSIS took *Salmonella* samples. *Listeria* testing is required since 2003 for ready-to-eat meat and poultry products. These new regulations have increased compliance incentives in industry. The increased rigor in the FSIS's verification of HACCP and Sanitation Standard Operating Procedure (SSOP) implementation also increases the demand by plants to use pathogen testing defensively (Murano, 2002).

Market attention to food safety has increased among food service buyers who are more easily identified with any illness outbreak and therefore seek greater assurances of safety from suppliers. That is, as buyers, they seek to reduce the probability of loss in the simple model above and therefore are more willing to pay for testing and certification. Fast food companies, large retailers, and importers are also imposing pathogen testing requirements to protect themselves from outbreaks and legal liability suits (Golan, Roberts, & Ollinger, 2004). These buyers are acting as channel captains and are policing the actions of firms up and down the food supply chain with tests and food safety audits. When food suppliers sell to these customers, an increase in demand for pathogen testing is likely in the private marketplace. International trade in meat and poultry products has expanded, bringing increased attention to ensuring safety and shelf life over longer distances and greater elapsed time (Dyck & Nelson, 2003). At the same time, the reduced cost of generating information increases the probability of detection and traceback to specific firms. This further reinforces the higher value of food safety information within the firm.

A New Equilibrium

These shifts in supply and demand together result in greater adoption of new tests and the generation of more information than an isolated shift in either supply or demand (Figure 1). The shift in supply of new tests

began over two decades ago with the advent of immunoassay technology. However, this technology was commercialized for food products (in particular for meats) in response to the shift in demand for food safety information. The availability of means to generate information more quickly and easily in turn reinforced the outward shift in demand. These mutually reinforcing changes have resulted in greater use of rapid methods to detect specific microbial pathogens and integration of this new information into food production and marketing, as we will discuss below.

Evidence of the Impact of New Tests in Food Markets

The impact of new testing technologies on food production and marketing can be seen in several different ways. We examine cases demonstrating their impact from meat producing firms, laboratory services, certification services, and regulatory agencies.

First, meat and poultry firms have increased their use of microbial pathogen tests since the 1996 Pathogen Reduction regulation. A survey of 861 meat and poultry slaughter and processing plants was carried out by the USDA Economic Research Service (ERS) in January 2001. Over half of all plants surveyed carry out tests for *Salmonella* and for *Escherichia coli* O157:H7 or *Listeria* (USDA ERS, 2003). About two thirds of plants either started testing or increased testing since 1996 for these pathogens, and about one fifth have doubled the amount of testing since 1996. These survey data reveal the increased demand for information.

Second, new testing technologies are being used to improve food safety and to certify food safety for buyers. An example is the use of frequent PCR-based tests for ground beef supplies sold to Jack in the Box (Golan, Roberts, and Ollinger, 2004). After a 1993 *Escherichia coli* O157:H7 illness outbreak linked to hamburgers from Jack in the Box, the company sought greater assurances of food safety from suppliers. Collaborative efforts between one of their suppliers and a test kit vendor led to the adaptation of PCR-based tests for use in evaluating ground beef samples. A process of trial and error resulted in the development of standards for the presence of *Escherichia coli* O157:H7 that met the buyer's need to assure minimal risk of foodborne disease.

This case involved collaborative effort to develop and verify new testing methods. PCR-based technologies were adapted for use in ground beef products through cooperation between the ground beef grinding plant and the test kit vendor. The plant initiated a multilab research project with both private sector and FSIS labs. The labs tested samples, using both ELISA and PCR tests, to determine the likely entry points of the pathogen in processing. PCR detected the largest number of culture-confirmed positive *Escherichia coli* O157:H7. The study concluded that aggressive sampling plans and PCR tests can detect low levels of *Escherichia coli* O157:H7 in ground beef products (Pruett et al., 2002). This collaborative effort among a food service buyer, a product vendor, a test kit vendor, a regulatory agency, and a laboratory service provides an interesting model of how testing methods might be adapted and adopted in the future.

Third, tests are playing a role in addressing the growing need for food safety verification in international trade. With growth in imports and changes in import sources, microbial pathogen contamination in fresh produce is an issue of increasing concern in the United States. Guatemalan producers of raspberries implemented on-farm controls with third-party verification following the linkage of their product with a *Cyclospora* outbreak in the United States (Calvin et al., 2001). The controls include tests of soil, water, and farm personnel to ensure that the pathogen is not endemic in the farm environment. Process and sanitation controls are also used to ensure that the pathogen is not introduced into the product. Thus, both tests and process controls are part of the system of product verification for international trade of a perishable product.

A fourth impact of new testing technologies is seen in the changing role of laboratory services in the food industry (C.J. Reynolds, personal communication, March 4, 2002). One major laboratory service vendor provides testing services to many different kinds of food processors. This company has seen the demand for tests increase during the past decade, and the availability of new testing technologies has changed the nature of the service provided. This laboratory service company purchases test kits for use in an integrated package of information services to food processors. New and more rapid tests have continually been adopted by this service company during the last five years. In the process, the service reports a shift in their resource use, from utilizing laboratory technicians to carry out time-intensive traditional tests to using these same technicians to analyze and interpret more rapid and automated test results.

Food processors chose to use a service rather than carry out their own tests for several reasons (C.J. Reynolds, personal communication, March 4, 2002). The laboratory service is better positioned to evaluate which

tests to use and can better keep abreast of new testing developments than individual food processors. Some tests require laboratory equipment and have economies of scale through volume discounts for individual tests that might not be captured by an individual plant. Finally, the laboratory service can provide an automated data base and data analysis to help food processors use and understand their test results. Thus, the availability of more specific and timely information from new testing technologies has altered the nature of laboratory services and their use by food processors.

The fifth impact of new testing technologies is in US regulatory agencies. New technologies improve the ability of regulators to monitor food safety performance in plants, although the extent to which such monitoring can provide a basis for regulation is still controversial. The FSIS has made recent changes in its test procedures that increase the probability of detecting pathogens. Selection of testing technology is one important component of such changes. The FSIS has switched to the very sensitive and selective RT-PCR BAX test for *Salmonella* and *Listeria* and is investigating use of the BAX test for *Escherichia coli* O157:H7. Increased attention to testing methods and accuracy is a response to legal challenges to the performance standards set in the 1996 Pathogen Reduction regulation (Unnevehr, 2003).

Conclusions

New testing technologies, based on the biotechnology tools underlying modern medical diagnostics, have been adapted and adopted in the food industry. The growing demand for food safety in the marketplace, combined with increased availability of new testing technologies, has led to shifts in both the demand and supply of food safety information. Regulatory and buyer scrutiny leads firms to demand more information about pathogens in their products. Test developers and service providers have responded by providing new kinds of information and analysis. The availability of such information, in turn, has led to greater specificity in buyer demands and in the application of regulatory standards. Thus, the shifts in supply and demand of information are reinforcing. The shifts in both supply and demand of information mean that more testing is being done and more information is being generated; this information is being used in firm management, regulatory, and food buyer decisions. Thus, the diagnostic tools provided by modern biotechnology are leading to better food safety performance in the marketplace.

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