BEEF “MEGA REG”

AND THE

PRODUCE VOLUNTARY PROGRAM

by

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FOOD REGULATION IN THE UNITED STATES
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Foodborne illness (FBI) has been plaguing mankind mostly likely since the “invention” of food. In modern times, prevention and tracking of FBI has become important not only for the health and safety of people, but also for the economic impact on society. A foodborne illness outbreak is typically defined as two or more persons having a similar illness resulting from the ingestion of the same food and in the case of botulism or chemical poisoning one or more persons.

In recent years, two groups of foods have been most implicated in foodborne illness outbreaks, *E. coli* in ground beef and *E. coli* and *Salmonella ssp.* in certain produce varieties, mainly leafy greens, tomatoes, and peppers. The ground beef outbreaks resulted in tighter regulation and inspection of the beef industry to minimize these occurrences. Could similar regulation be on the way for produce and could it work?

In this paper, I will examine the beef regulations commonly referred to as the “Mega Reg” and how it came to be. Recent outbreaks in the produce industry and their impact on society will be reviewed in light of the current voluntary produce program with regard to the program’s effectiveness. The beef regulations and produce program will be compared and contrasted and finally a look into whether a produce “Mega Reg” could
work and what hurdles it could face within industry, consumers, and its possible effectiveness.

The 1996 Pathogen Reduction; HACCP Systems; Final Rule, also know as the PR/HACCP rule or commonly as the “Mega Reg” was passed to reduce the risk of foodborne illness with *Salmonella* being the targeted bacteria of concern. This was to be accomplished by improving and simplifying the scientific and organoleptic based methods of inspection along with putting greater responsibility on slaughter establishments in regards to their sanitation and safety processes.¹

With any new regulation, there are costs associated with their implementation. The United States Department of Agriculture’s Food Safety and Inspection Service (USDA FSIS) conducted a Regulatory Impact Assessment (RIA) to determine the cost to industry for the “Mega Reg.” FSIS reported that the cost to industry would be about $100 million while the benefits could range from $.99 billion to $3.69 billion dollars.² Another report from the Office of Budget Management (OMB) estimates cost at $.97 to $1.16 billion with the benefits at $.71 to $26.59 billion with the present value in each case discounted over 20 years.³

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In a study cost/benefits study, John M. Antle concluded that the cost to industry could range from $500 million to $5 billion dollars without adding on the FSIS cost estimates.\(^4\) Thus the cost to industry of the “Mega Reg” could exceed the benefits.

With the program now in place for a number of years, has it been effective? In recent years, there have been several high profile recalls of beef products with some resulting in illness and one leading to the bankruptcy of the firm.

1997, Hudson Foods recalled 35 million pounds of ground beef for *E. coli*. a mere 0.3% of its production.\(^5\) July 2002, the FSIS issued what was then the second largest beef recall in history, 19 million pounds produced by ConAgra Beef Company for *E. coli* 0157:H7.\(^6\) October 2007, Topps Meat Company closes its door after recalling nearly 22 million pounds of ground beef for *E. coli*.\(^7\) February 2008, Westland/Hallmark Meat Company issued the largest recall on record thus far, 143 million pounds of beef due to the use of meat from “Downer” animals, cattle that are sick and/or unable to walk.\(^8\)

Tainted meat is just one source of foodborne illness. Many illnesses result at the retail level as well as other food sources. The Centers for Disease Control and Prevention (CDC) estimates that each year there are 76 million cases of foodborne illness resulting in


325,000 hospitalizations and 5,000 deaths in the U.S. *Salmonella, Listeria,* and *Toxoplasma* are implicated in 1,500 deaths each year.\(^9\)

To consumers, monetary losses due to foodborne illness are staggering. Costs include lost wages, loss in production, and health related expenses. Plus, how does one put a price tag on life itself.

For industry, loss of profits, product, and increased cost begin to add up not to mention litigation and judicial awards due to foodborne illness. And in the case of Topps Meat Company, a foodborne illness caused the loss of the business and jobs.

How effective has the “Mega Reg” been for the meat industry? Has it been able to reach it goals for the reduction of pathogens at the manufacturing level? According to a study by H.L. Goodwin, Jr. from the Department of Agricultural Economics and Agribusiness, University of Arkansas and Rimma Shiptsova from the Department of Economics, Utah State University, losses in the poultry industry were estimated at $35 million and for consumers near $197 million dollars. Losses to consumers, retailers and manufacturers for the first three years of the “Mega Reg” were estimated at $2 billion per year.\(^10\) The research goes on to state there were no significant changes in the incidences of foodborne illnesses during the first three years.

What about the produce industry? Fresh produce has been implicated as the most common cause of foodborne illness in the U.S.\(^11\)

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Recent foodborne illness outbreaks have been traced to produce. Having lived in an area where produce is grown and harvested, I witnessed first hand the process. The majority of produce is grown in an open field that is exposed to many different hazards. The hazards can be natural such as animals walking through the crops, to unnatural such as run off from livestock operations into irrigation water, and even human contamination. Growing field sanitation has improved in recent years to provide laborers sanitary facilities equipped with hand washing facilities to minimize human fecal contamination on produce.

Yet with all the precautions taken, produce related outbreaks are still occurring. We must keep in mind that in order to satisfy the U.S. market, much of our produce is imported from around the world. It is thus impossible to expect sanitation standards to be up to U.S. standards. It is also important to remember that many crops are harvested and packed in the field for shipment; from field to refrigerated truck.

Recently there have been several high profile outbreaks associated with fresh produce. The source of contamination originated in Mexico and blamed on the poor sanitation standards of growers. The only requirement for a grower from Mexico to sell to the U.S. is to register on-line.¹² No testing is done to ensure the safety of the product, although some growers hire outside companies to certify their crops are grown in sanitary conditions to be able to sell to prominent U.S. Grocers.¹²

The most recent outbreak, *Salmonella saintpauli*, involved what was finally determined to be from Serrano peppers, but was thought to have been red tomatoes. This

outbreak affected over 1400 people in 43 states, the District of Columbia and Canada.\textsuperscript{13} In our company alone, H-E-B disposed of large amounts of not only fresh produce, but many in house products made with the implicated produce.

Prior to this outbreak, in September 2006 fresh bagged spinach was implicated in an outbreak of \textit{E. coli O157H7} where 183 cases were reported with at least one fatality directly linked to the outbreak.\textsuperscript{14} By October, 199 persons were infected with all three fatalities attributed to the outbreak.\textsuperscript{15}

Here again, our company disposed of a large amount of not only the bagged spinach, but a vast variety of other foods that used the fresh spinach from salads, spinach stuffed beef, pork, and chicken, and sausages.

The impact on consumers and industry is not only financial, but health related. As mentioned in the fresh spinach incident, three fatalities were tied to the outbreak with 199 cases. Two fatalities were elderly women and the third a two year old child. Yes one can safely assume that lost time at work plus medical costs were a direct result of the illness, but again one can not put a price on the life of a loved one.

As far as industry, the loss of consumer confidence was a great casualty of the spinach outbreak. In Texas alone, the industry lost at least 20\% of income from $55 million to $44 million, a loss of $11 million dollars.\textsuperscript{16} Nationwide, sales of packaged

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spinach were down 37%, or just over $570,000 three months after the outbreak. Sales of packaged salads that contained spinach were down 28% or a loss of half a million dollars and sales of packaged salad without spinach were down 7.9% or a loss of nearly $2.7 million.\textsuperscript{17}

What inspection programs are in place? The produce products we eat every day are not under a mandatory inspection program. This program is voluntary following a set of guidelines put forth by the FDA, USDA, and CDC. These guidelines set standards to follow with produce in all areas from water sources, cooling and ice, manure as a fertilizer, wildlife pests, worker field sanitation, packing sheds, pest control, transportation and traceback.\textsuperscript{18} Growers/packers can voluntarily submit to unannounced audits conducted in accordance to the USDA Guide. They are then listed by the USDA Agricultural Marketing Service (AMS) if they successfully pass these audits.\textsuperscript{19}

AMS also offers a “Quality Through Verification” (QTV) program. This voluntary program teams a technical specialist with a production facility to develop a HACCP plan. Again unannounced audits verify compliance by the facility allowing it to use the “QTV” label on its product.\textsuperscript{20} As of May 2007, there were 317 farms and


facilities in 32 states and Puerto Rico adhering to the standards set forth in their HACCP plans.  

From the information, one can see the major difference between the beef and produce industry is in the program requirements. The beef industry is under a mandatory HACCP program to help reduce mainly Salmonella while the produce program is a voluntary HACCP program. Yet according to Resources for the Future (RFF), produce has been implicated as the most common cause of foodborne illness for many years. As such, is there a need to move from a voluntary program to a mandatory one?

When the beef “Mega Reg” was implemented, it was phased in over 30 months to allow the smaller plants ample time to comply with the HACCP requirements. The produce program again is a voluntary one. Producers and packers are not required to comply, but one can surmise it would benefit them to do so as they would be able to market their product much better.

and Verification Web site: http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=RequestQualitySystemsVerificationServicesGradingCertificationandVerification&rightNav1=RequestQualitySystemsVerificationServicesGradingCertificationandVerification&topNav=&leftNav=GradingCertificationandVerification&page=ProcessedVerificationorAuditBasedPrograms&resultType=


Some benefits from a mandatory program would be the improvement of quality and safety of agricultural products, compliance with national and international guidelines, standards and regulations, and sustainable products.\(^\text{24}\)

What about challenges to implementing a mandatory program? Just like the beef industry, the produce industry would have similar obstacles to overcome if the program was to be mandatory.

One would have to take into account the great number of countries produce is imported from depending on the season. Importers/packers would have to work even closer with suppliers to verify their agricultural practices in the field and set up an auditing process. The cost industry is substantial due to the number of producers and remoteness of some locations.

Government personnel would be needed to conduct audits of the facilities and fields to ensure compliance with the regulations or certified third party auditors. Then of course there is the Hazard Analysis Critical Control Point (HACCP) plan itself.

HACCP requires monitoring and verification throughout the process. Initial cost to industry would be writing and setting up the HACCP plan for each facility. Because of the differences in operations due to location and product, a generic industry plan would not be feasible. Standards would have to be set similar to the beef industry where the rules were phased in over time to allow for all growers and producers to implement HACCP. Current industry standards could be used as a blueprint for government standards.

Any mandatory program would have to include provisions for traceability of product back to its origin. “Traceback” allows for investigators to determine the source

of an outbreak or other problem much more efficiently. The HACCP program would mandate record keeping for all product to include the source. As one begins to think of all the countries produce is sourced from, one can imagine the nearly insurmountable task of finding the source of an outbreak and the mountains of paperwork that could result.

What about the consumer? A consumer purchases food of any kind with the expectation it is safe and wholesome. The recent recalls in the beef and produce industry does leave one wondering if the meals they eat are really safe. This increased awareness and demand by consumers has led the push for programs discussed earlier.25

In order to stay ahead, the produce industry in response to consumer demands moved forward to establish voluntary programs lead by retailers such as Safeway26 and Albertsons.27 From this it is safe to assume consumers for the most part would support a mandatory program. However, with the industry’s quick action, it appears they staved off any compulsory government action.

So where does this leave us? Is a produce “Mega Reg” a necessity as in the beef industry or is the current voluntary program working? The USDA along with the U.S. government stepped in after an outbreak of foodborne illness caused deaths along with hospitalizations28. They saw a need to bring tighter control to the industry to minimize the occurrence of illness through HACCP by reducing the bacterial load on processed meat products. However, even after implementation, several high profile recalls of beef

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products, most notably the Topps Meat Company nearly 22 million pounds in 2007 have occurred. Could there have been more? Quite possibly so, had it not been for better sanitation standards in the industry. And with the advances in technology, such as irradiation, occurrences of foodborne illness could be diminished even more.

Compare this to the produce industry. As stated by RFF, produce has been implicated as the most common cause of foodborne illness for many years. Why then is the produce industry allowed to operate under a voluntary program? It would seem that their quick actions to get control of the outbreaks showed their understanding of the need for better industry practices. Borrowing from lessons learned in the beef industry, they established a voluntary program that was sound and feasible; i.e. self regulation. Some would argue that the old adage of the “fox guarding the hen house” could apply here. However, in the long run, a business is not in the business of losing money. Profit and sustainability appear to be great motivators to accomplish the task at hand.

Like the beef industry, there have been recent high profile outbreaks involving produce. This shows that no system is perfect and adjustments and improvements must be made as the need arises. In years to come, statistical research can be done to compare and contrast the efficacy of both mandated and voluntary programs. It will not be a case of which is better and which won, but a case of how many outbreaks were prevented. It is the consumer, us, who would hope to reap the benefits.

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