Consumers Union
Nonprofit Publisher of Consumer Reports

June 26, 2014

Tom Vilsack
Secretary, United States Department of Agriculture
1400 Independence Ave SW
Washington, DC 20250

CITIZEN PETITION

Consumer Reports Food Safety and Sustainability Center and the undersigned submit this petition under 5 U.S.C. 553(e)) and 7 CFR 1.28 and 9 CFR 392 to request the Secretary of Agriculture to issue an interpretive rule prohibiting the "natural" label on meat and poultry products.

We believe consumers are being misled by the "natural" label and are providing recent national poll data, conducted by the Consumer Reports National Research Center, that underscores this assertion.

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) both state that meat and poultry shall be "misbranded" if its "labeling is false or misleading in any particular" (21 USC §601(n)(1)) and 21 USC §453(h)(1)).

The current definition of "natural" used by the USDA to approve the "natural" label on meat and poultry addresses only the absence of artificial ingredients in the final product and minimal processing, which we believe to be misleading to consumers and therefore not consistent with the FMIA and PPIA labeling requirements.

We believe that the difference is drastic between the USDA's current definition of "natural" for meat and poultry and what people think the "natural" label should mean.

We have also submitted a citizen petition to the Food and Drug Administration, which regulates the labeling of foods other than meat and poultry products, requesting that the "natural" label be prohibited on those foods as well. The Federal Food, Drug and Cosmetics Act, similar to the

FMIA and PPIA, states that foods are misbranded if their labeling is misleading (21 USC §343(a)(1)). We believe that the use of the "natural" label on any food currently misleads consumers.

As outlined in detail below, nationally representative surveys of U.S. consumers, conducted in 2007, 2008 and April 2014 by the Consumer Reports National Research Center, strongly suggest that a majority of U.S. consumers are misled by the "natural" label on meat and poultry, and have consistently expected the "natural" label on meat and poultry products to mean more than just "minimal processing" and "no artificial ingredients."

Our survey shows that 68% of U.S. consumers think that the "natural" label means that the animal was not given growth hormones, 60% think no antibiotics and other drugs were given to the animals, 64% think that feed did not contain genetically engineered organisms and 60% think the feed contained no artificial ingredients. These numbers suggest that the majority of U.S. consumers are currently misled by the "natural" label on meat and poultry, since the "natural" label does not guarantee these requirements were met.

In our 2007 survey, 83% of consumers expected meat and poultry labeled "natural" to come from an animal that was raised in a natural environment. In 2008, 85% of consumers responded that they think the "naturally raised" claim should mean the animal was raised in a natural environment, and 77% believed that the animal should have access to the outdoors.

When asked what they think the "natural" label *should* mean in our 2014 survey, 89% believe the animal should not be given growth hormones, 85% believe the animals' diet should have no artificial ingredients and no GMOs, 81% believe the animal should not be given antibiotics or other drugs, and 66% believe that the animals should be able to go outdoors.

These survey results suggest that nearly two-thirds of U.S. consumers are misled by the "natural" label on meat and poultry products, and nearly 90% expect it to mean much more than it does. We believe that meat and poultry with misleading "natural" claims are misbranded, as outlined by the FMIA and PPIA.

STATEMENT OF ACTION REQUESTED

We request that the USDA issue an interpretive rule prohibiting the "natural" label on meat and poultry by amending the Food Standards and Labeling Policy Book to specifically prohibit the use of the "natural" label, which is a misleading label.

FSIS regulations do not define the "natural" claim, but the claim is defined in the FSIS "Food Standards and Labeling Policy Book," which provides guidance but is not a formal rule. The USDA states that this Policy Book provides guidance and helps manufacturers prepare labels that "are truthful and not misleading." The Policy Book defines "natural claims" as follows:

The term "natural" may be used on labeling for meat products and poultry products, provided the applicant for such labeling demonstrates that:

(1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed.

The FSIS definition says nothing about how the animal was raised, its living conditions, whether it was physically altered, its feed, and drugs and growth hormones it was administered. We do not agree that this definition helps manufacturers comply with the FMIA and PPIA by ensuring their labels are truthful and misleading.

Given consumer expectation and our survey results, we request that the following section replace the section above:

The term "natural" is misleading to consumers and may not be used on labeling for meat products and poultry products.

We request that the "natural" label on meat and poultry be prohibited.

STATEMENT OF GROUNDS: LEGAL

U.S. citizens have the right to petition the government to add, amend or repeal rules under the First Amendment of the U.S. Constitution and the Administrative Procedure Act (5 U.S.C. 553(e)), and may petition to amend USDA rules under 7 CFR 1.28 and 9 CFR 392.

Under this authority, the petitioners request that the Secretary of Agriculture amend the Food Standards and Labeling Policy Book by prohibiting the use of the "natural" label.

STATEMENT OF GROUNDS: FACTUAL

The FSIS has primary responsibility for the regulation of food labeling for meat and poultry products under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). The FMIA states that a meat or meat food product shall be "misbranded" if its "labeling is false or misleading in any particular" (21 USC §601). The PPIA states that any poultry product shall be deemed "misbranded" if "its labeling is false or misleading in any particular" (21 USC§453(h)(1)).

Currently, the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) regulations, 9 CFR 412.1 and 412.2, require that the "natural" label on meat and poultry be submitted to the FSIS for approval.

The USDA's Food Safety and Inspection Service (FSIS) considers label claims on meat and poultry on a case by case basis, including the "natural" claim. According to the USDA, the claim "natural" may be used for meat and poultry products if the product contains no artificial flavor, color, or chemical preservative, or any other artificial or synthetic ingredient, and the product is minimally processed.

To determine whether consumers are currently misled by "natural" labels, and what consumers expect from the label, the Consumer Reports National Research Center conducted a nationally representative survey of U.S. consumers in April 2014. We conducted a similar consumer survey in 2007, and in 2008 we conducted a survey asking about the "naturally raised" label on meat and poultry. Survey findings support our petition, showing that a majority of consumers are currently misled by the "natural" label, and the vast majority of consumers reasonably expect the "natural" label to cover how the animal was raised, its diet, drugs it was administered, whether artificial growth hormones were used, and outdoor access.

Antibiotics, growth hormones and other drugs

Our survey results show that consumers are misled by the "natural" label as it is currently used on meat and poultry. Sixty-eight percent of consumers think that animals raised for meat and poultry sold as "natural" were not given artificial growth hormones, and 60% believe no antibiotics or other drugs were used. This is not the case, and shows consumers are currently misled.

A number of steroid hormone drugs are approved in beef production. These hormones are implanted in beef cattle to speed up growth, and some of the approved drugs are synthetic versions of natural hormones. Meat from these animals can be sold as "natural." However, consumers reasonably believe that they cannot be since implanting artificial growth hormones to speed up growth is not a "natural" way to raise beef cattle.

Animals raised for "natural" meat and poultry may also be fed sub-therapeutic doses of antibiotics and other drugs daily, regardless of whether they are ill. According to the FDA, more than 13.5 million kilograms (nearly 30 million pounds) of antimicrobial drugs were sold and distributed for use in food-producing animals in 2011.

As expressed by the Centers for Disease Control and Prevention (CDC) in a September 2013 report, feeding antimicrobial drugs, including those that are critical to human medicine such as tetracyclines and penicillins, gives rise to antibiotic-resistant human pathogens and raises serious public health concerns.

In a 2007 Consumer Reports National Research Center poll, nearly 9 out of 10 consumers indicated that meat labeled "natural" should come from animals that were raised on a diet

without drugs and chemicals. In a 2008 poll, 86% of consumers responded that the "naturally raised" label should mean the animal's diet was free of chemicals and drugs.

According to our 2014 survey, 89% of consumers believe that meat sold as "natural" should come from animals that were not given artificial growth hormones, and 81% believe that meat and poultry sold as "natural" should come from animals that were not given antibiotics or other drugs.

Feed

Consumers are also misled about the meaning of the "natural" label and the animals' feed. Currently, feed given to animals whose meat will eventually be sold as "natural" may include genetically engineered corn and soybeans and artificial ingredients. Yet 64% of consumers very reasonably believe that meat and poultry sold as "natural" means the animals were not fed a diet containing genetically engineered organisms, and 60% think that their feed contained no artificial ingredients or colors.

A large portion of livestock feed consists of corn and soybeans, including finishing rations for beef cattle. Not only is a grain-based diet not the natural diet of cattle, which are ruminants that naturally feed on forage and pasture, but the grain in the rations is likely genetically engineered.

Ninety-three percent of soybeans and 85% of corn in the United States are grown from genetically engineered seed. Genetic engineering is different from conventional breeding: it requires intensive genetic overwriting to allow for genetic changes that cannot occur in nature, such as combining genes of bacteria and viruses with genes of plants, or combining genes from different species of animals. We do not believe that genetically engineered crops used in animal feed qualifies as "natural."

The FDA also allows a long list of artificial ingredients in animal feed. By definition, these artificial ingredients are not "natural." It is also worth noting that many of the artificial substances in the feed can be transferred to the meat, and end up in the final product that the consumer buys. Artificial ingredients allowed in animal feed include formaldehyde, which can be a component of beef and non-lactating dairy cow feed, propylene glycol, butane, ammonium hydroxide, propylparaben, sulfur dioxide and many others.

Artificial ingredients are even allowed as energy sources for the animals, such as 1,3-butylene glycol, which is allowed as an energy source in pig feed, or protein sources, such as synthetic methionine in poultry feed. Even polyethylene plastic pellets that replace natural sources of fiber and roughage in the diet, are used in cattle feed.

As noted above, in our 2007 survey results, nearly 9 out of 10 consumers indicated that meat labeled "natural" should come from animals that were raised on a diet without chemicals and

artificial ingredients. In 2008, 85% of consumers believed that the "naturally raised" label should mean the animal ate a natural diet.

According to our 2014 survey, 85% of consumers believe that the "natural" label on meat and poultry should mean that the animals were given a diet that contained no genetically engineered organisms and no artificial ingredients or colors.

Living conditions

Our 2014 survey results show that nearly half of consumers are misled about the meaning of the "natural" label as it pertains to outdoor access: 48% think that animals raised for "natural" meat and poultry went outdoors.

Chickens and pigs labeled as "natural" may be raised in crowded barns without outdoor access. This means that the animals were not able to engage in natural behaviors. Animals are routinely physically altered to compensate for destructive behavior that results from unnatural, stressful and crowded living conditions. This includes beak trimming of laying hens, dehorning or disbudding of beef cattle, and tail docking and teeth filing of pigs.

For chickens, foraging and pecking are natural behaviors, and outdoor runs have a much higher number and diversity of stimuli that allow for these natural behaviors than any indoor environment can provide. Outdoor runs also allow the animals to exercise, which benefits their health, and gives the animals access to fresh air and sunshine that are not available in indoor confinement.

When given the opportunity, domestic pigs will spend several hours per day rooting and foraging, feeding on grass, roots, tubers, acorns, nuts, berries and small animals. When confined indoors, the animals are not able to engage in these natural behaviors. Tail docking and teeth filing are common management practices to prevent tail biting, which likely results from frustration due to living in a stressful environment and the inability to engage in natural behaviors.

In our 2007 survey, 83% of consumers expected meat and poultry labeled "natural" to come from an animal that was raised in a natural environment. In 2008, 85% of consumers responded that they think the "naturally raised" claim should mean the animal was raised in a natural environment, and 77% believed that the animal should have access to the outdoors.

According to our 2014 survey, two-thirds of consumers believe that meat and poultry labeled "natural" should come from an animal that was able to go outdoors.

CONCLUSION

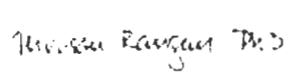
The FMIA and PPIA state that labels on meat and poultry must not be false and misleading, and our survey results show that consumers are currently widely misled by the "natural" label.

A majority of U.S. consumers currently believe that the "natural" label on meat and poultry means certain requirements were met, such as no artificial growth hormones and no antibiotics and other drugs were administered to the animals, their feed contains no artificial ingredients and GMOs. Nearly half of U.S. consumers think the animals were able to go outdoors. A majority of consumers believe that the "natural" label *should* mean no artificial growth hormones, antibiotics or other drugs, no artificial ingredients or GMOs in the feed, and the animals were able to go outdoors.

As our surveys show, consumers have over the years consistently expected more from the "natural" label on foods derived from animals. Since we first asked consumers about their expectations for "natural" claims on meat and poultry in 2007, the vast majority have responded that they expect the "natural" claim to go beyond the absence of artificial ingredients and minimal processing, and to include how the animal was raised. We believe it is time for the USDA to address the misleading nature of the "natural" claim and ensure that it comports with the expectations that consumers have had for years.

Given the widespread confusion among consumers about the label, we urge the USDA to issue an interpretive rule to prohibit the use of the "natural" label on meat and poultry, to ensure the products are not misleading to consumers.[1]

Respectfully Submitted,



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[1] Regardless of whether the USDA grants this petition, we believe that the use of the "natural" label on any food misleads consumers and may therefore be actionable under state and federal laws prohibiting misleading labeling and marketing. By filing this petition, we do not give up our right to pursue any remedies available to us under state or federal law.

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CONSUMER REPORTS® NATIONAL RESEARCH CENTER

Survey Research Report

Food Labels Survey

2014 Nationally-Representative Phone Survey

Introduction

The consumer demand for more natural, environmentally friendly and socially-responsible food has proliferated. More than ever, consumers want to know exactly what is in their food; they are turning to food labels to provide this information. But can these labels be trusted? Questions remain about exactly what consumers know about food labeling, and the standards consumers want for food labeling.

In April, 2014, the Consumer Reports® National Research Center conducted a nationally representative phone survey to assess consumer opinion regarding the labeling of food (tables for all questions are included in the appendix). Opinion Research Corporation (ORC) of Princeton, New Jersey administered the survey to a nationally representative sample of 1,004 adult US residents (half of the respondents were women) through its CARAVAN Omnibus Survey. Respondents were selected by means of random-digit dialing and were interviewed via phone. The data were statistically weighted so that respondents in the survey were demographically and geographically representative of the US population. This report summarizes the findings from this survey.

Highlights

Consumers Are Looking for Natural and Locally Produced Food

- When shopping for food, two-thirds of Americans are checking to see if their food is locally produced; the majority of consumers (59%) are also checking to see if their food is natural.

Environmentally Conscious and Socially Responsible Food a Priority for Most Americans

- A range of environmental, safety and social concerns are imperative to most US consumers when purchasing food; the vast majority of consumers prioritize supporting local farmers, protecting the environment from chemicals, fair conditions for workers, reducing exposure to pesticides, good living conditions for animals, and reducing antibiotic use in food.

Consumer Mandate for Fair Wage and Working Conditions for Farm Workers

- Making sure that the workers that produced their food are treated fairly is important to US consumers and most are willing to put their money where their mouth is!

Consumers Want More Stringent Standards for Natural and Organic Labeling on Meat and Poultry

- The majority of consumers think that the natural or organic label on meat and poultry *currently* means that no artificial ingredients, growth hormones, genetically modified ingredients, or antibiotics were used; an even greater amount of consumers feel that this labeling *should* indicate this.

Consumers Demand More Standards for Natural and Organic Labels on Packaged and Processed Foods

- The majority of consumers think that the natural or organic label on packaged and processed foods *currently* means that no pesticides, artificial ingredients or chemicals, or genetically modified ingredients were used; an even greater amount of consumers feel that this labeling *should* indicate this.

Consumers Have High Expectations for Humanely Raised Claims on Eggs, Dairy and Meat

- While only half of consumers think a humanely raised claim *currently* means that the animals were raised without cages, a clear majority of consumers (75%) think these claims *should* mean this.

Consumers Demand Information about Food Origin

- The overwhelming majority of consumers want food labels to reflect country of origin (92% of consumers) and state of origin (82%). In addition, an outstanding percentage of consumers (90%) want to know if their meat is from outside the US.

Consumers Demand Labeling of Meat Raised with Antibiotics

- If an animal was routinely given antibiotics, the vast majority of consumers (83%) demand that the government require that this meat be labeled as "raised with antibiotics."

Consumer Mandate for Labeling and Strong Federal Safety Standards for Genetically Engineered Food

- An overwhelming majority of US consumers think that before genetically engineered food can be sold it must be labeled as such and meet government safety standards. Moreover, an outstanding percentage of Americans (92%) demand that the government require that genetically engineered salmon be labeled as such.

Consumers Skeptical about Labels on Seafood

- Most consumers who buy seafood (83%) have some doubt about the accuracy of labels on seafood at the fish counter.

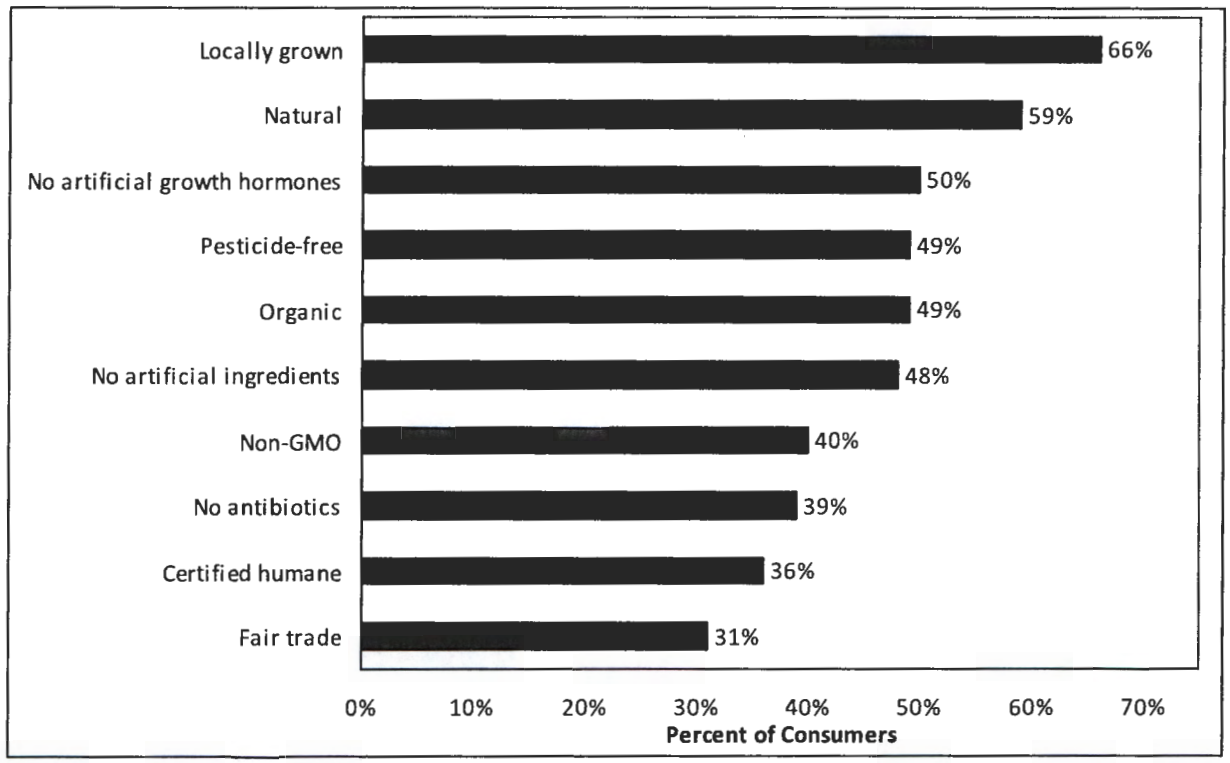
Consumers Think Most Shrimp in US Farm Raised, Imported and Not Fresh

- The majority of consumers think that most of the shrimp in the US is farm raised and imported. In addition, most consumers believe that unfrozen shrimp at the store was originally frozen and then thawed.

Consumers Are Looking for Natural and Locally Produced Food
When shopping for food, two-thirds of Americans are checking to see if their food is locally produced; the majority of consumers (59%) are also checking to see if their food is natural.

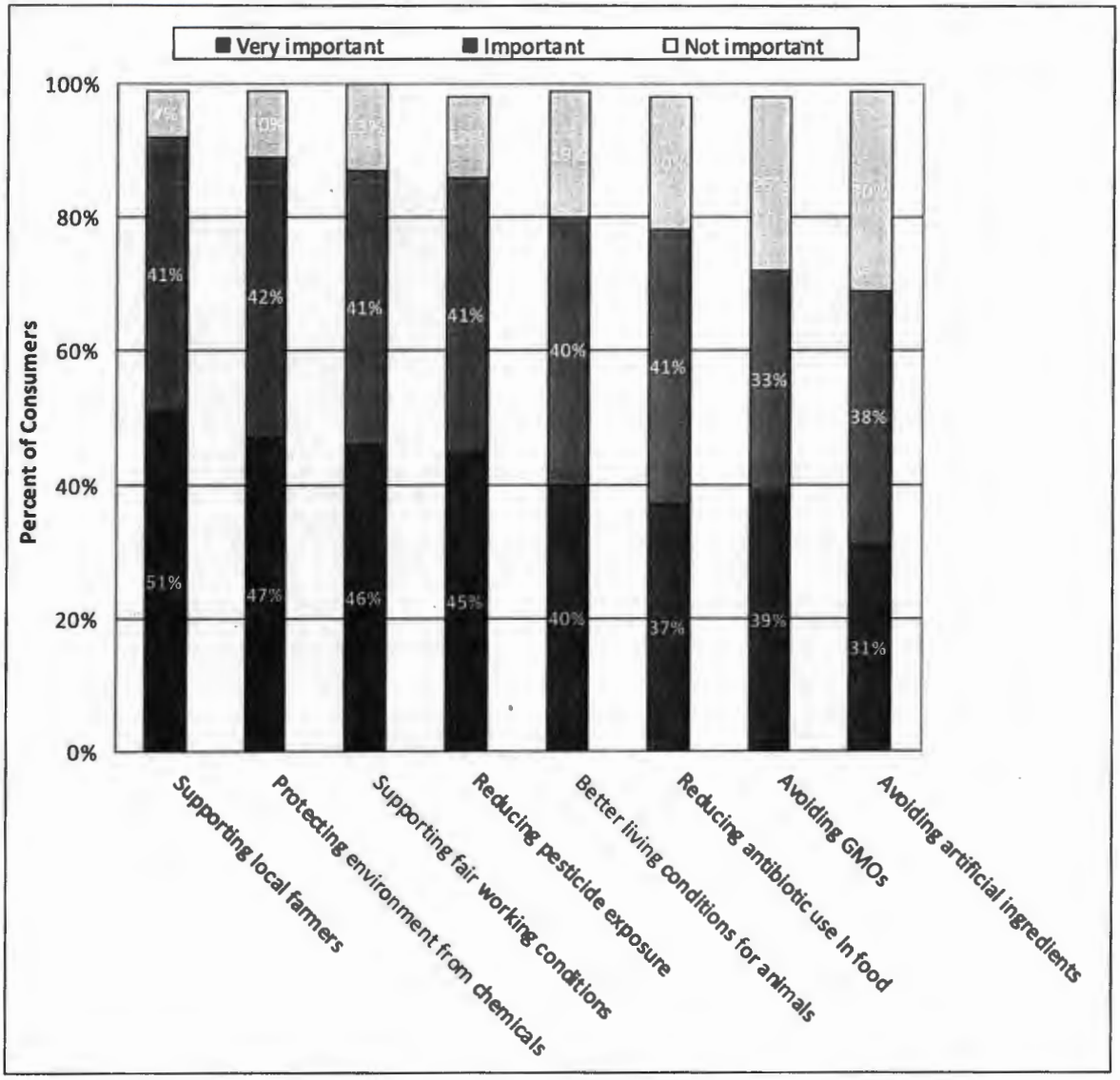
Consumers are less likely to look for fair trade (31% of consumers), animal welfare (36%), antibiotic (39%) and non-GMO (40%) claims.

Claims Consumers Look for on Food Labels

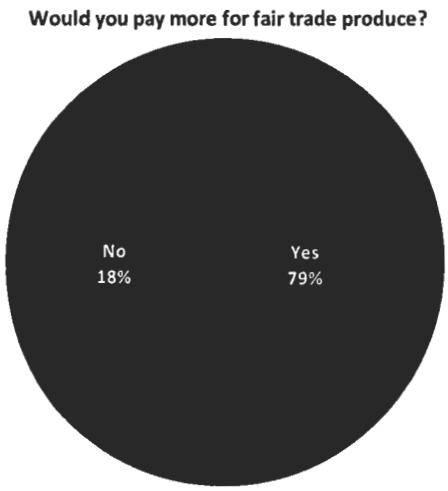


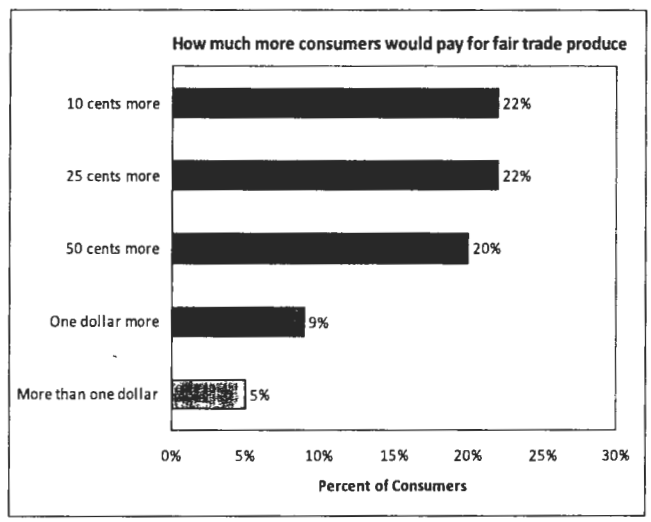
Environmentally Conscious and Socially Responsible Food a Priority for Most Americans
A range of environmental, safety and social concerns are imperative to most US consumers when purchasing food. For the overwhelming majority of consumers crucial (*very important* or *important*) objectives include supporting local farmers (92% of consumers), protecting the environment from chemicals (89%), fair conditions for workers (86%), reducing exposure to pesticides (87%), good living conditions for animals (80%), and reducing antibiotic use in food (78%). Avoiding GMOs (72% of consumers) and artificial ingredients (69%) are also crucial objectives for many consumers.

Importance of Objectives to Consumers



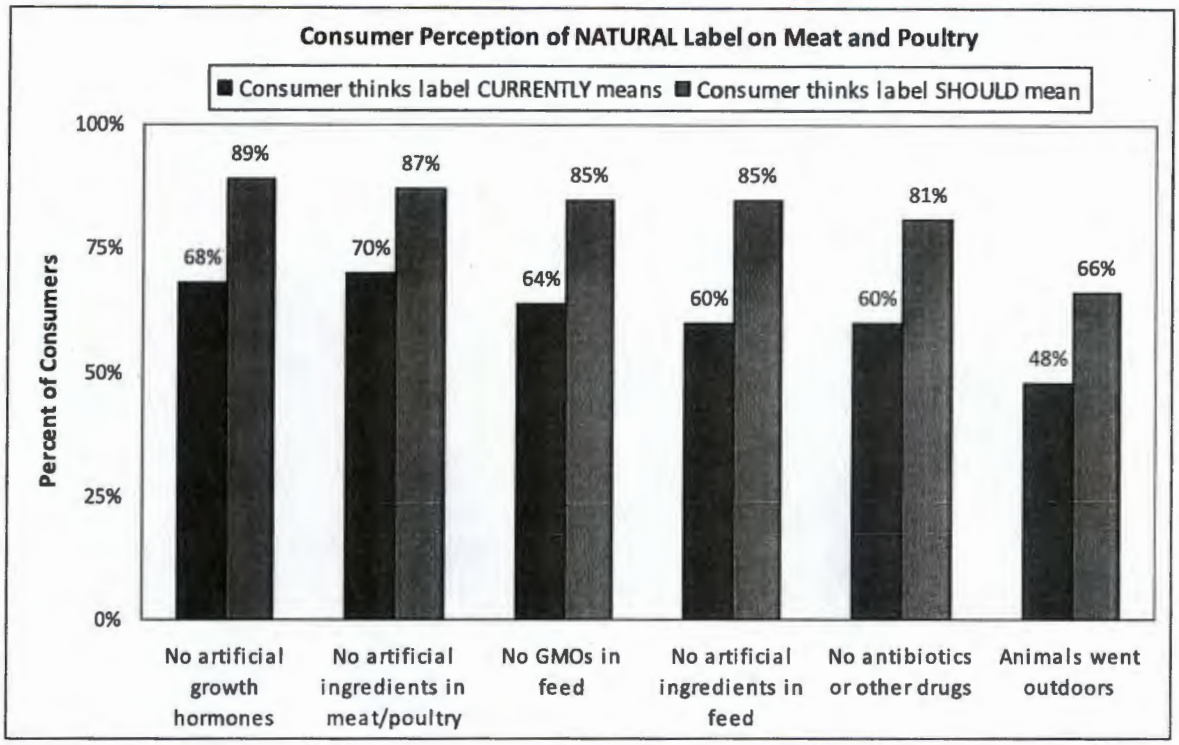
Consumer Mandate for Fair Wage and Working Conditions for Farm Workers
Making sure that the workers that produced their food are treated fairly is important to US consumers and most are willing to put their money where their mouth is! Most consumers (79%) will pay more for fruits and vegetables produced by workers under fair wage and working conditions; a sizable portion of consumers (34%) would even pay 50 cents or more per pound.

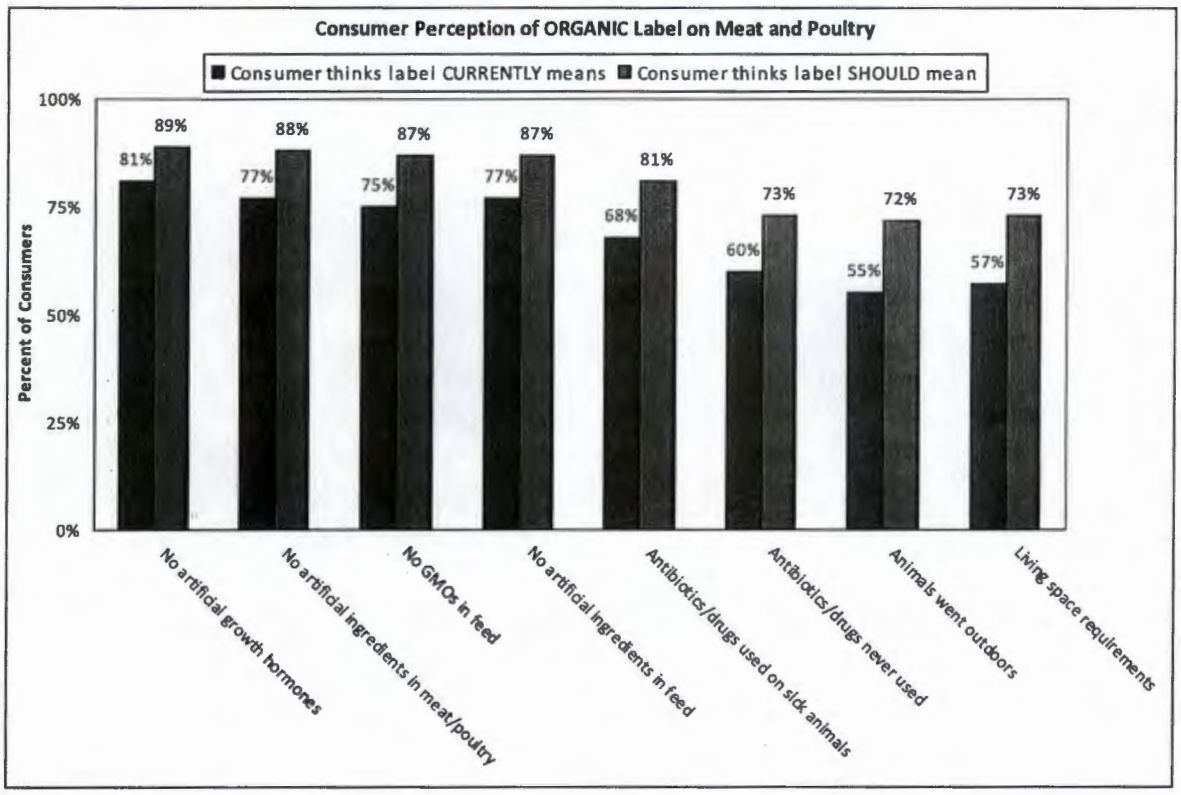




Consumers Want More Stringent Standards for Natural and Organic Labeling on Meat and Poultry
The majority of consumers think that the **natural** label on meat and poultry *currently* means that no artificial ingredients were added to the meat/poultry (70%), no growth hormones were used (68%), the animals' feed contained no GMOs (64%) or artificial ingredients (60%), and no antibiotics or other drugs were used (60%). Still, an even greater amount of consumers feel that this label *should* mean that no artificial ingredients were added to the meat/poultry (87%), no growth hormones were used (89%), the animals' feed contained no GMOs (85%) or artificial ingredients (85%), and no antibiotics or other drugs were used (81%). Moreover, while less than half of consumers think this label *currently* means that the animals went outdoors; the majority of consumers (66%) want this label to reflect this.

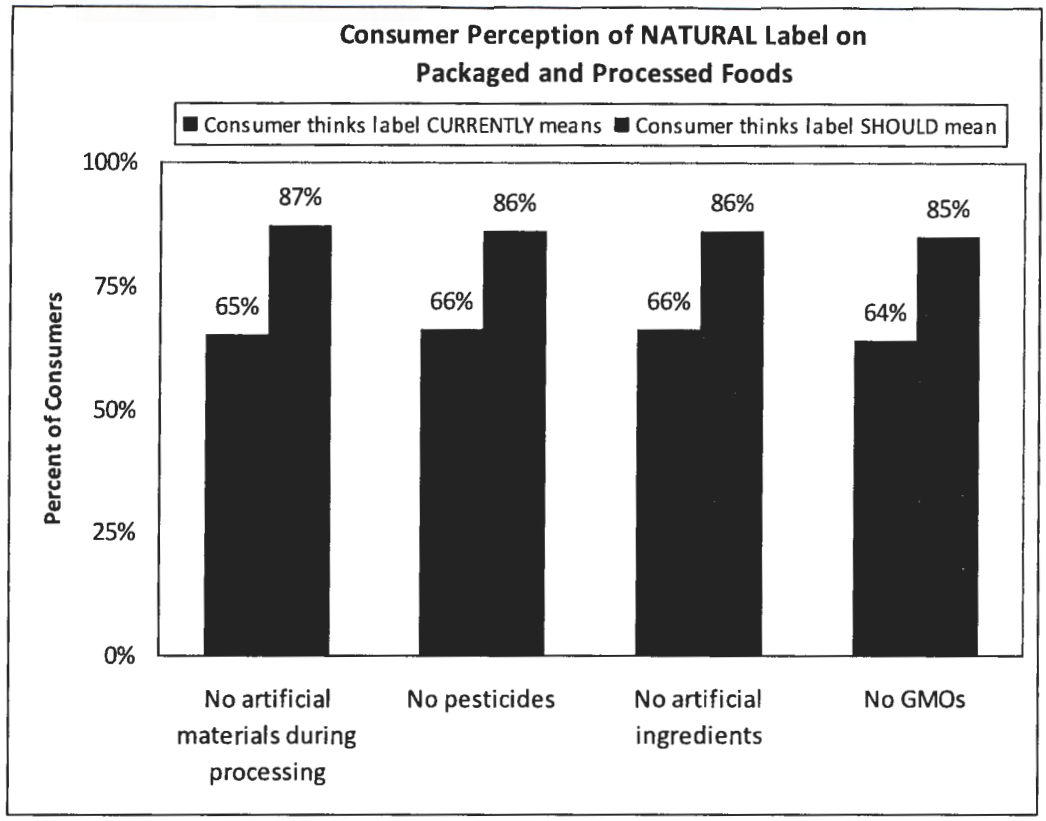
Consumers also want stronger standards for the **organic** label on meat and poultry. Many consumers think this label *currently* means no artificial growth hormones were used (81%), the animals feed contained no artificial ingredients (77%) or GMOs (75%), no artificial ingredients were added to the meat/poultry (77%), antibiotics or other drugs were only used on sick animals (68%), no antibiotics or other drugs were ever used on healthy or sick animals (60%), the animals had adequate living space (57%), and the animals went outdoors (55%). An even greater amount of consumers demand that this label *should* mean no artificial growth hormones were used (89%), no artificial ingredients were added to the meat/poultry (88%), the animals feed contained no artificial ingredients (87%) or GMOs (87%), antibiotics/drugs were only used on sick animals (81%), no antibiotics/drugs were ever used on healthy or sick animals (73%), the animals had adequate living space (73%), and the animals went outdoors (72%).

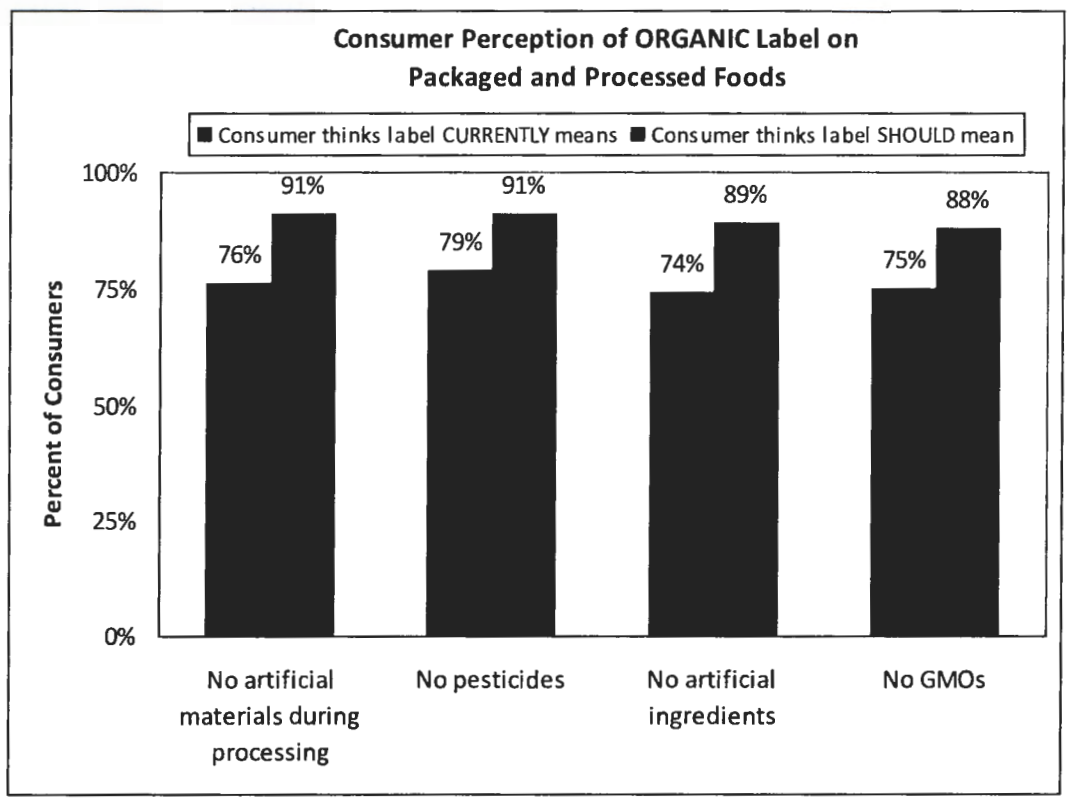

Consumer Perception of NATURAL Label on Meat and Poultry
Consumer thinks label CURRENTLY means
Consumer thinks label SHOULD mean
Percent of Consumers
100%
75%
50%
25%
0%
68%
89%
70%
87%
64%
85%
60%
85%
60%
81%
48%
66%
No artificial growth hormones
No artificial ingredients in meat/poultry
No GMOs in feed
No artificial ingredients in feed
No antibiotics or other drugs
Animals went outdoors


Consumer Perception of ORGANIC Label on Meat and Poultry
Consumer thinks label CURRENTLY means
Consumer thinks label SHOULD mean
Percent of Consumers
100%
75%
50%
25%
0%
81%
89%
77%
88%
75%
87%
77%
87%
68%
81%
60%
73%
55%
72%
57%
73%
No artificial growth hormones
No artificial ingredients in meat/poultry
No GMOs in feed
No artificial ingredients in feed
Antibiotics/drugs used on sick animals
Antibiotics/drugs never used
Animals went outdoors
Living space requirements

Consumers Demand More Standards for Natural and Organic Labels on Packaged and Processed Foods
While many consumers feel that the **natural** label on packaged/processed foods *currently* means no pesticides were used (66%), no artificial ingredients were used (66%), no artificial materials were used during processing (65%), and no GMOs were used (64%); an even greater percentage of consumers think the label *should* mean no pesticides were used (86%), no artificial ingredients were used (86%), no artificial materials were used during processing (87%), and no GMOs were used (85%).

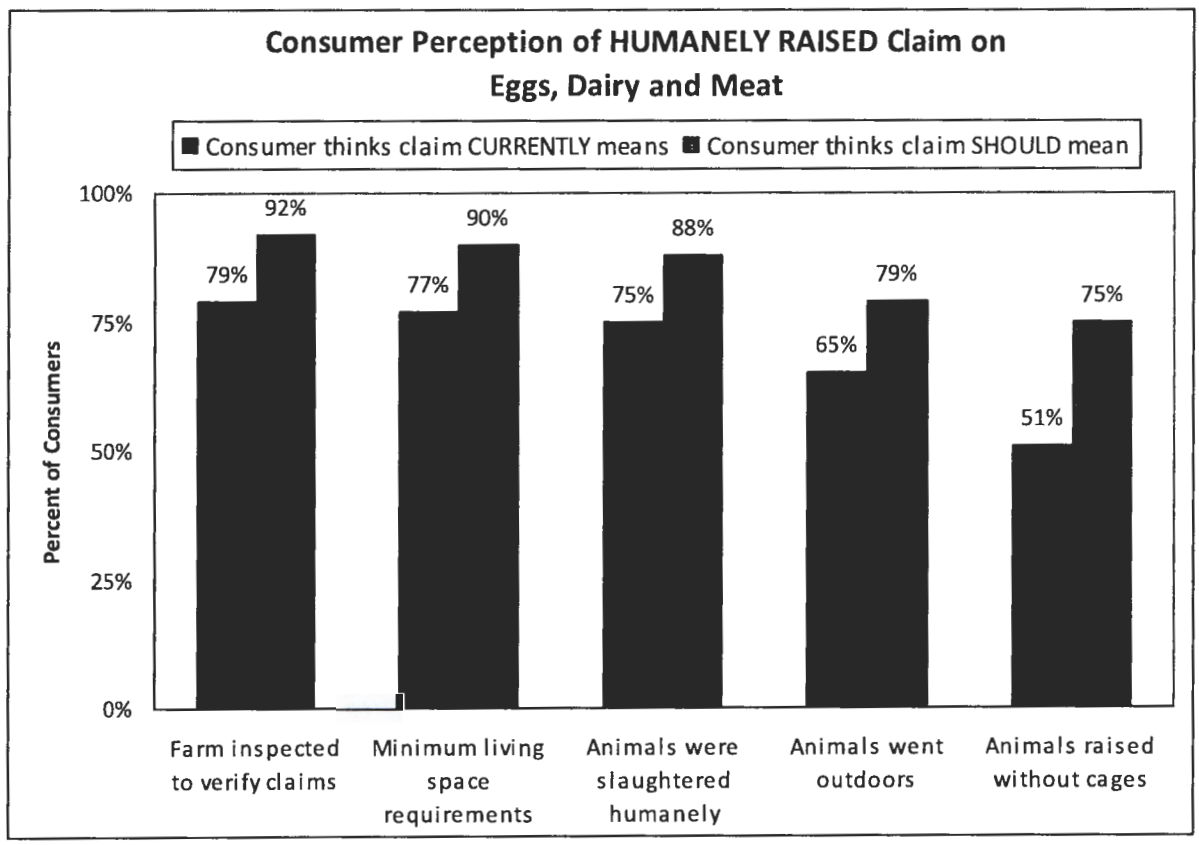
Consumers are even more stringent when it comes to what they want from the **organic** label on packaged/processed foods. While many consumers think this label *currently* means no toxic pesticides were used (79%), no artificial materials were used during processing (76%), no artificial ingredients were used (74%), and no GMOs were used (75%); an outstanding percentage of consumers demand that this label *should* mean no toxic pesticides were used (91%), no artificial materials were used during processing (91%), no artificial ingredients were used (89%), and no GMOs were used (88%).


Consumer Perception of NATURAL Label on Packaged and Processed Foods
Consumer thinks label CURRENTLY means
Consumer thinks label SHOULD mean
Percent of Consumers
100%
75%
50%
25%
0%
65%
87%
66%
86%
66%
86%
64%
85%
No artificial materials during processing
No pesticides
No artificial ingredients
No GMOs


Consumer Perception of ORGANIC Label on Packaged and Processed Foods
Consumer thinks label CURRENTLY means
Consumer thinks label SHOULD mean
Percent of Consumers
100%
75%
50%
25%
0%
76%
91%
79%
91%
74%
89%
75%
88%
No artificial materials during processing
No pesticides
No artificial ingredients
No GMOs

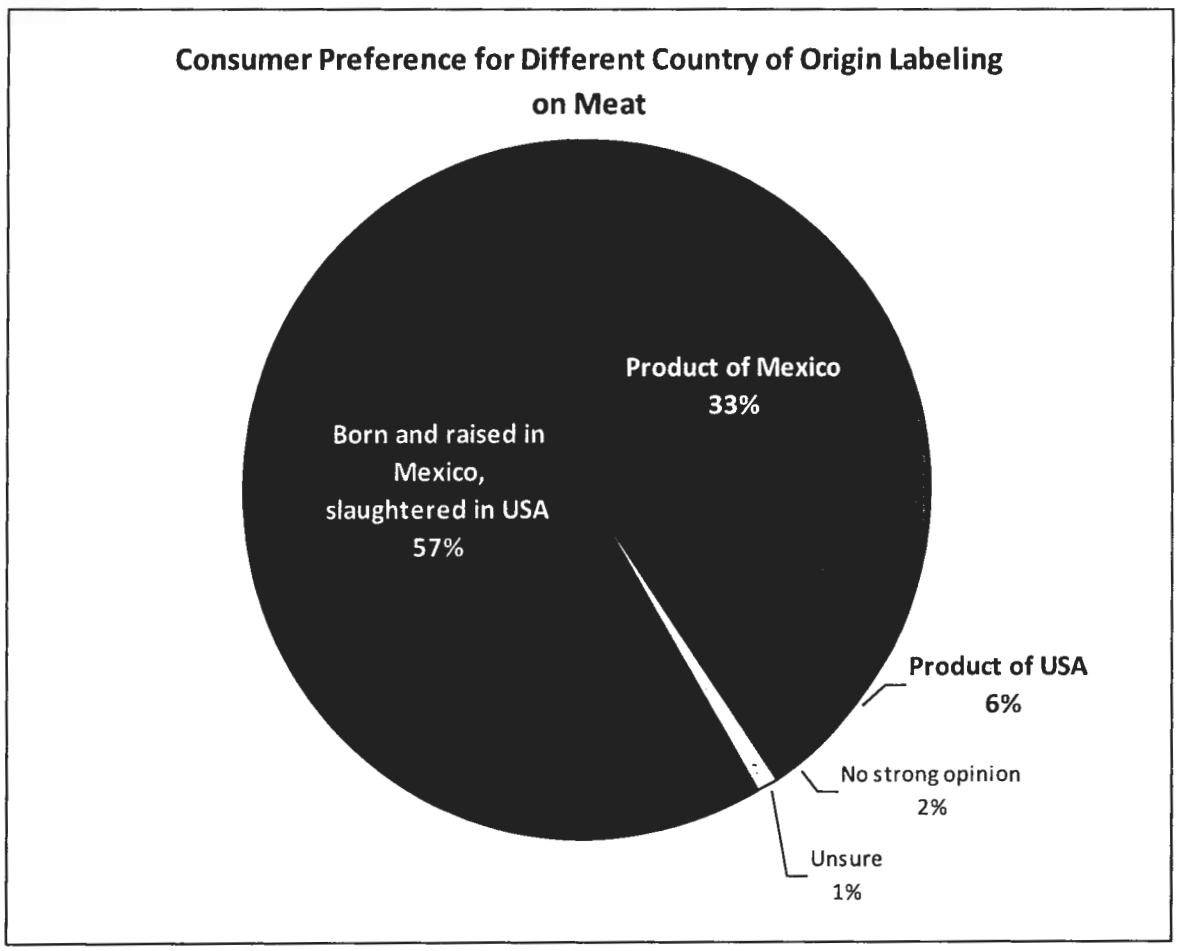
Consumers Have High Expectations for Humanely Raised Claims on Eggs, Dairy and Meat
The majority of consumers think a **humanely raised** claim on eggs, dairy and meat *currently* means the farm was inspected to verify this claim (79%), the animals had adequate living space (77%), the animals were slaughtered humanely (75%), and the animals went outdoors (65%). Accordingly, the vast majority of consumers believe this claim *should* mean that the farm was inspected to verify this claim (92%), the animals had adequate living space (90%), the animals were slaughtered humanely (88%), and the animals went outdoors (79%).

While only half of consumers think this claim *currently* means the animals were raised without cages, a clear majority of consumers (75%) think this claim *should* mean this.



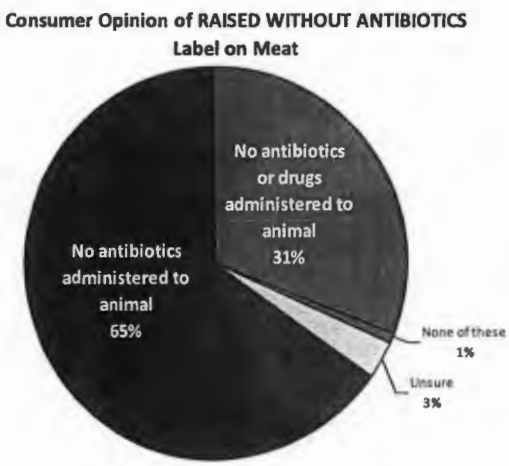
Consumer Demand Information about Food Origin
The overwhelming majority of consumers want food labels to reflect country of origin (92% of consumers) and state of origin (82%).

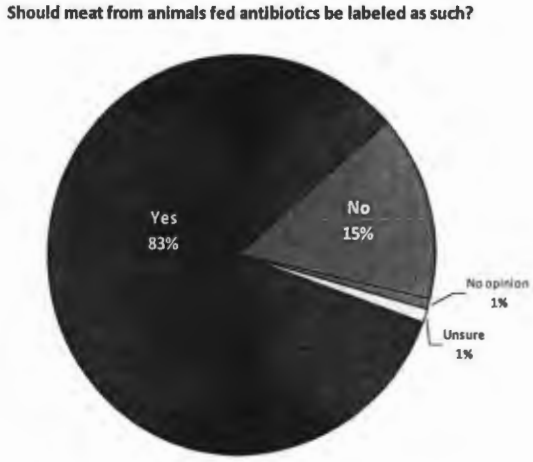
An outstanding percentage of consumers (90%) want to know if their meat is from outside the US. Consumers were asked about their preference for country of origin labeling on meat that came from a different country like Mexico. The majority of consumers (57%) want the labeling to include where the animal was born/raised *and* where the animal was slaughtered. A sizable portion of consumers (33%) want more stringent labeling; if the animal was born or raised in a different country, these consumers feel this food is a product of that country. Few consumers (6%) adopt the more lenient view that being slaughtered in the USA is sufficient for this meat to be labeled as a USA product.



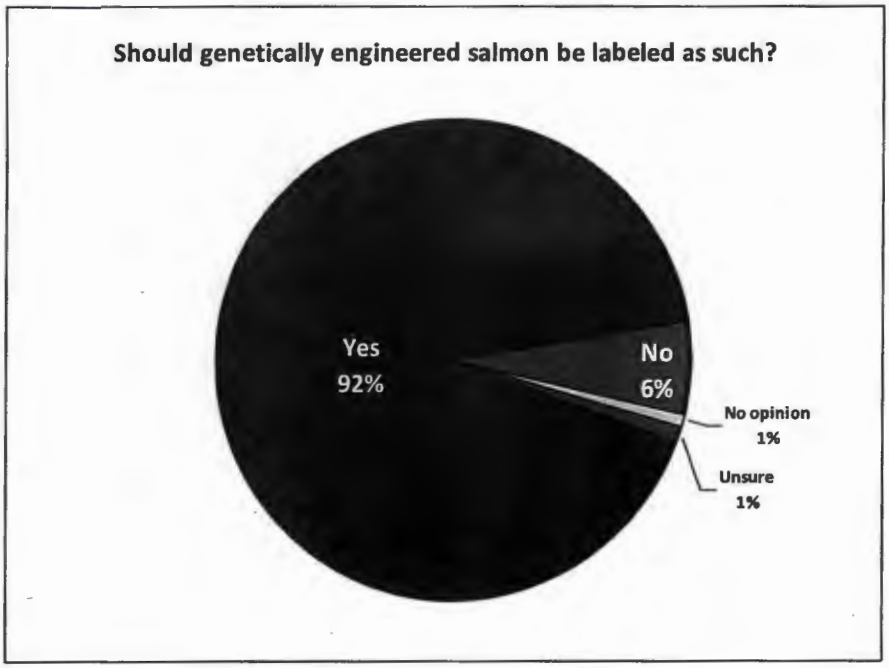
Consumers Want Strong Federal Standards for Meat Raised with Antibiotics
When most consumers (65%) see the **raised without antibiotics** label, they think this label means no antibiotics were used; one third of consumers mistakenly think this label means no antibiotics or *any* other drugs were used.

In addition, if an animal was routinely given antibiotics, the vast majority of consumers (83%) demand that the government require that this meat be labeled as "raised with antibiotics."



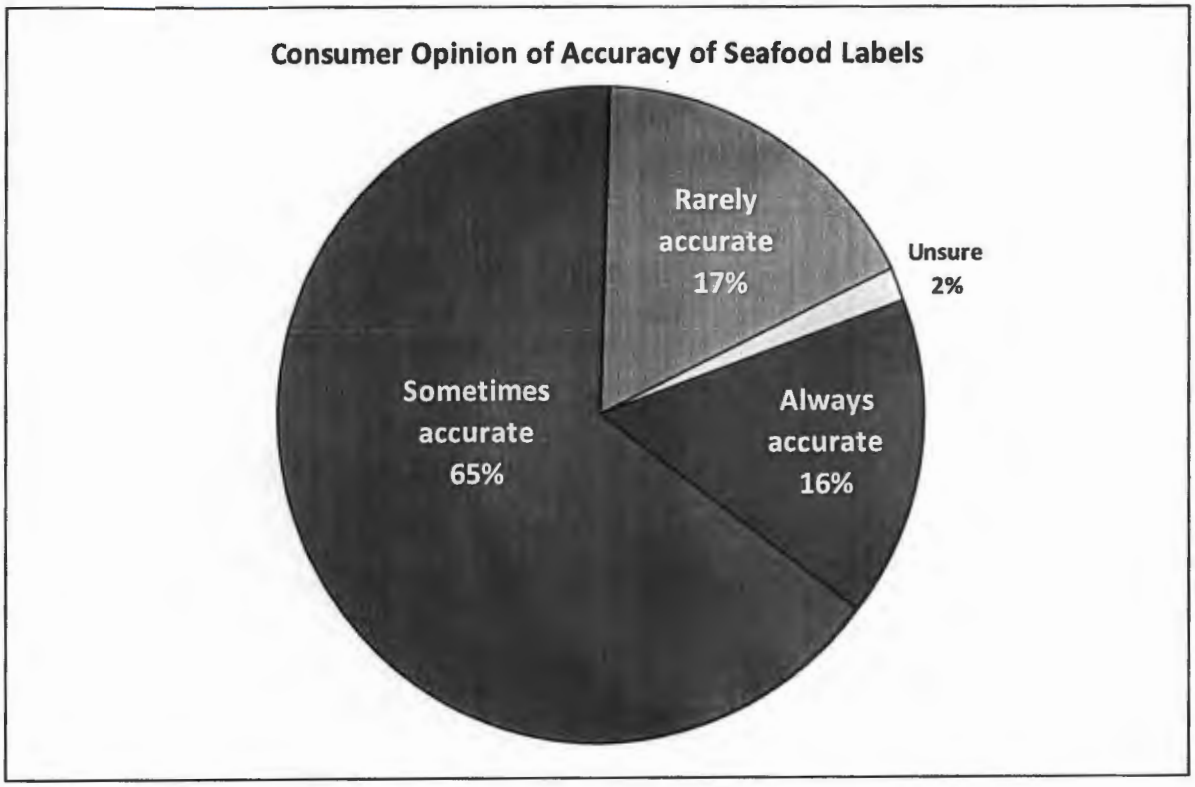


Consumer Mandate for Labeling and Strong Federal Safety Standards for Genetically Engineered Food
An overwhelming majority of US consumers think that before genetically engineered food can be sold it must be labeled as such (92% of consumers) and meet government safety standards (92%). Moreover, an outstanding percentage of Americans (92%) demand that the government require that genetically engineered salmon be labeled as such.



Consumers Skeptical about Labels on Seafood

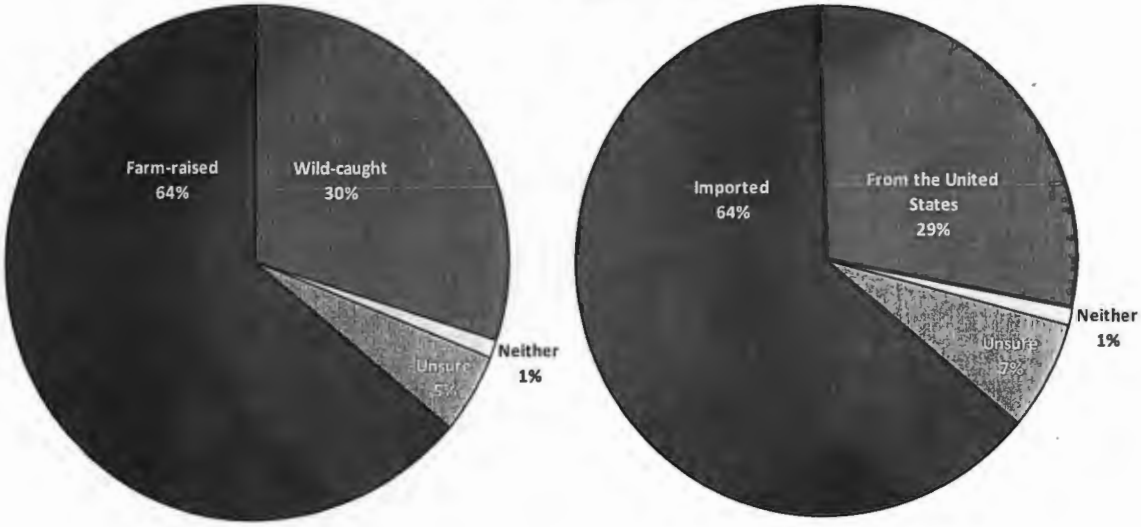
Most consumers who buy seafood (83%) have some doubt about the accuracy of labels on seafood at the fish counter. Many (65% of consumers) think these labels are only sometimes accurate; a notable portion of consumers (17%) are even more doubtful and feel these labels are *rarely* accurate.

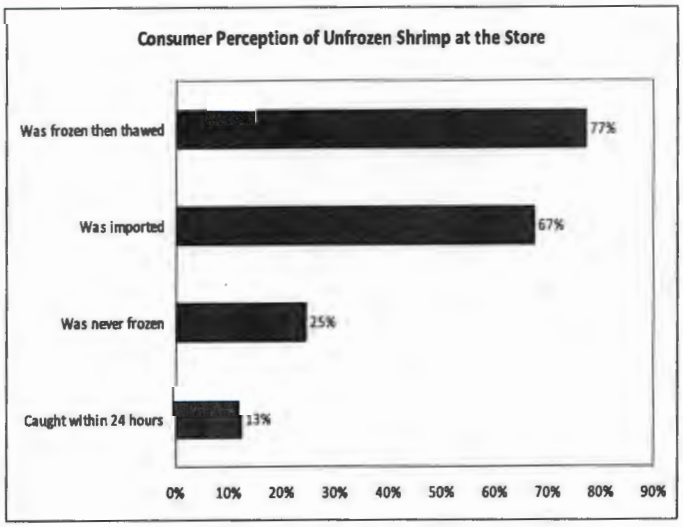


Consumers Think Most Shrimp in US Farm Raised, Imported and Not Fresh

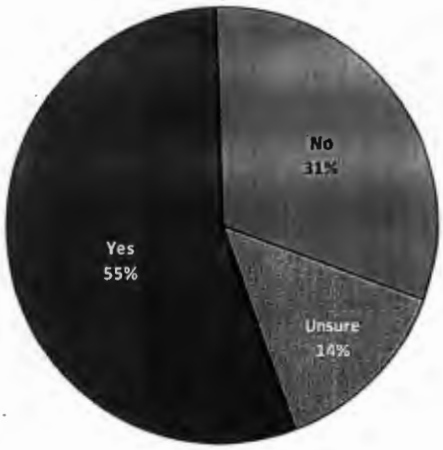
The majority of consumers think that most of the shrimp in the US is farm-raised (64% of consumers) and imported (64% of consumers). Accordingly, when buying unfrozen shrimp at the store, the majority of consumers (67%) think this shrimp was imported. Many consumers (77%) believe this shrimp was originally frozen and then thawed. Few think the shrimp was never frozen (25%) or caught within the past day (13%). Finally, the majority of consumers (55%) think antibiotics and other drugs or pesticides are commonly used in shrimp farming.

Consumer Opinion of Shrimp Sold in the US





Are antibiotics or other drugs commonly used in shrimp farming?

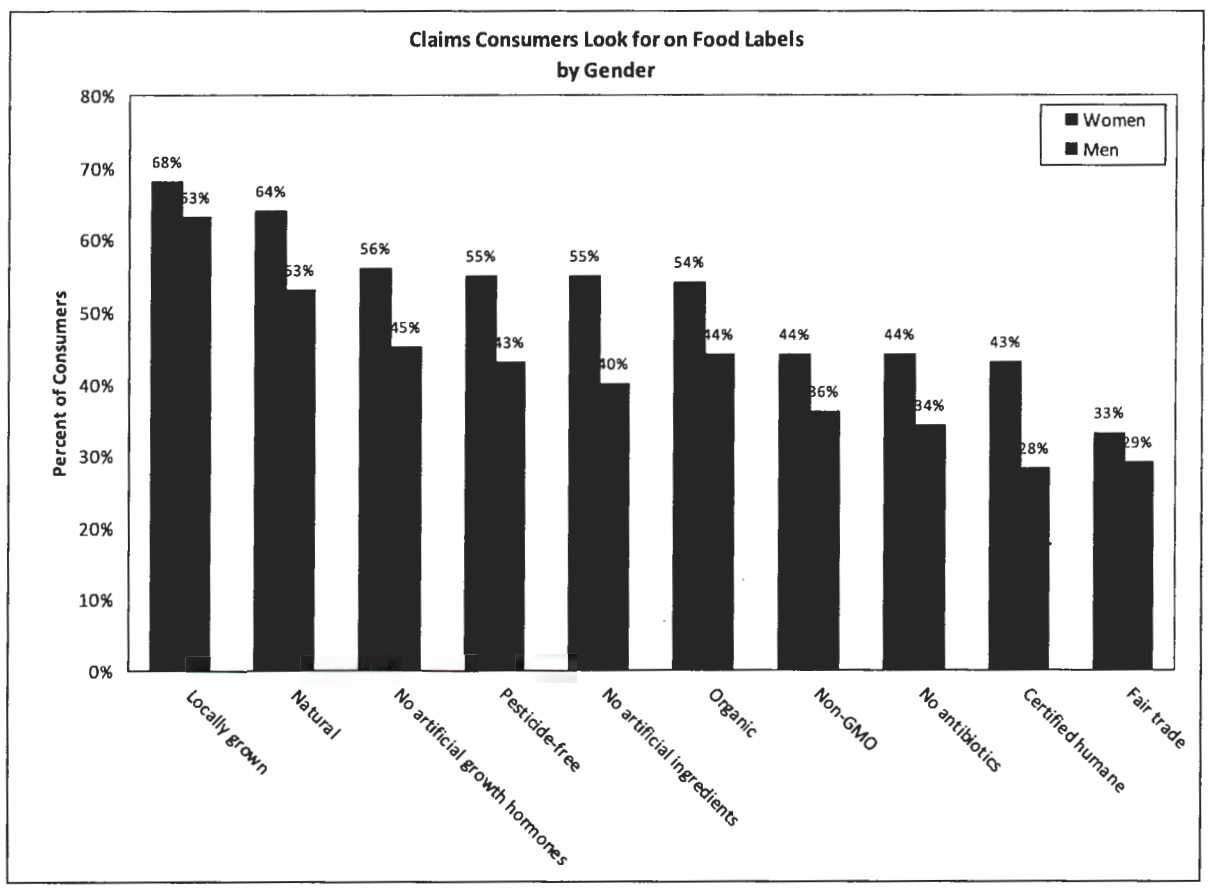


Demographic Differences

For the most part, there were no compelling differences in age, region, income and having children in the household; for some survey questions, however, there were some gender differences (tables by gender are included in attached spreadsheet). The survey findings suggest that, generally, women US consumers are more environmentally and socially conscious when it comes to the food they eat.

When shopping for food, more women (than men) are looking for the following claims: natural, no artificial growth hormones, pesticide-free, organic, non-GMO, no antibiotics, and certified humane. Accordingly, when purchasing food, more women report that the following objectives are crucial (*very important/important*): supporting local farmers, protecting the environment from chemicals, fair trade, reducing pesticide exposure, living condition of animals, reducing antibiotic use in food, and avoiding artificial ingredients. In addition, more women are willing to pay more per pound for fair trade produce.

The survey findings also showed that while men and women are similar on what they feel food labels *currently* mean, women were more stringent about what they think these labels *should* mean. More women think the **natural** label on meat and poultry *should* mean no artificial growth hormones were used, no artificial ingredients were added to the meat/poultry and that there were no artificial ingredients in the animals' feed. More women also think the **organic** label on packaged/processed foods *should* mean no pesticides, artificial ingredients, or GMOs were used. Finally, more women also believe that the **humanely raised** claim on eggs, dairy and meat *should* mean the farm was inspected to verify these claims and that the animals went outdoors.



Summary

Our survey showed that most US consumers are environmentally and socially conscious when it comes to the food they eat; popular guiding principles when purchasing food include supporting local farmers, protecting the environment, and fair conditions for farmworkers. In fact, fair trade conditions are so important to Americans, that most are willing to pay more to ensure their food was produced via fair working conditions. Our findings also showed consumers expect more from natural and organic food labels. In addition, the vast majority of consumers want food labels to reflect different country origin, and if antibiotics or genetically modified ingredients were used at any stage of food production. Among Americans there is growing awareness of misleading food labeling practices; our findings equivocally show that there is a consumer mandate for greater standardization and regulation of food labeling.

Methodology

This phone survey was fielded by ORC using a nationally-representative sample. The survey was conducted April 17-21, 2014. The margin of error is +/- 3 percentage points at a 95% confidence level. The margin of error may be higher for subgroup analysis.

Appendix: Tables

Q1: When you shop for food do you look for any of the following claims?			
	Respondents		
	Yes	No	Unsure
Locally grown or produced	66%	33%	1%
Natural	59%	40%	1%
No artificial growth hormones in meat and dairy	50%	48%	1%
Organic	49%	49%	1%
Pesticide-free	49%	48%	1%
No artificial ingredients or colors	48%	50%	1%
Non-GMO, that is, non-genetically engineered or modified	40%	57%	1%
No antibiotics	39%	59%	0%
Humanely raised, certified humane or any other animal welfare label	36%	62%	1%
Fair trade, meaning food producers were paid a living wage	31%	66%	2%
I do not shop for food			1%
Base: All Respondents			

Q2: When purchasing food, how important is each of the following as an objective for you? Would you say each is very important, important, or not important?					
	Respondents				
	Crucial (Very important/ Important subnet)	Very important	Important	Not important	Unsure
Supporting your local farmers	*92%*	51%	41%	7%	0%
Protecting the environment from chemicals such as pesticides	*89%*	47%	42%	10%	0%
Supporting companies that provide good working conditions and fair pay to farmworkers	*86%*	46%	41%	13%	0%
Reducing exposure to pesticides in foods	*87%*	45%	41%	12%	1%
Providing better living conditions for farm animals	*80%*	40%	40%	19%	1%
Reducing the use of antibiotics in food production	*78%*	37%	41%	20%	1%
Avoiding genetically engineered or modified ingredients	*72%*	39%	33%	26%	1%
Avoiding artificial ingredients such as preservatives, colors or flavors	*69%*	31%	38%	30%	0%
I do not purchase food					1%
Base: All Respondents					

Q3: How much more would you be willing to pay PER POUND for FRUITS and VEGETABLES produced by workers who earned a living wage and were treated fairly?	
	Respondents
Would pay any more (Net)	*79%*
10 cents more per pound	22%
25 cents more	22%
50 cents more or more (Subnet)	*34%*
50 cents more	20%
One dollar more	9%
More than one dollar more per pound	5%
Would you not pay any more	18%
Don't know/Unsure	3%
Base: All Respondents	

Q4: Do you think that the 'NATURAL' label on MEAT and POULTRY means any of the following?			
	Respondents		
	Yes	No	Unsure
No artificial ingredients or colors were added to the meat or poultry	70%	28%	2%
No artificial growth hormones were used	68%	30%	2%
The animals' feed contained no GMOs, that is, genetically modified ingredients	64%	34%	3%
No antibiotics or other drugs were used	60%	37%	3%
The animals' feed contained no artificial ingredients or colors	60%	37%	3%
The animals went outdoors	48%	49%	4%
Base: All Respondents			

Q5: SHOULD the 'NATURAL' label on MEAT and POULTRY mean any of the following?	
	Respondents
Any (Net)	*95%*
No artificial growth hormones were used	89%
No artificial ingredients or colors were added to the meat or poultry	87%
The animals' feed contained no artificial ingredients or colors	85%
The animals' feed contained no GMOs, that is, genetically modified ingredients	85%
No antibiotics or other drugs were used	81%
The animals went outdoors	66%
None of these	4%
Don't know/Unsure	1%
Base: All Respondents	

Q6: Do you think that the 'ORGANIC' label on MEAT and POULTRY means any of the following?			
	Respondents		
	Yes	No	Unsure
No artificial growth hormones were used	81%	17%	2%
The animals' feed contained no artificial ingredients or colors	77%	21%	2%
No artificial ingredients or colors were added to the meat or poultry	77%	21%	2%
The animals' feed contained no GMOs, that is, genetically modified ingredients	75%	23%	2%
Antibiotics or other drugs were only used to treat sick animals, but were never used on healthy animals	68%	29%	2%
No antibiotics or other drugs were ever used on healthy or sick animals	60%	37%	3%
The animals' living space met some meaningful minimum size requirements	57%	41%	3%
The animals went outdoors	55%	42%	3%
Base: All Respondents			

Q7: SHOULD the 'ORGANIC' label on MEAT and POULTRY mean any of the following?	
	Respondents
Any (Net)	*97%*
No artificial growth hormones were used	89%
No artificial ingredients or colors were added to the meat or poultry	88%
The animals' feed contained no GMOs, that is, genetically modified ingredients	87%
The animals' feed contained no artificial ingredients or colors	87%
Antibiotics or other drugs were only used to treat sick animals, but were never used on healthy animals	81%
No antibiotics or other drugs were ever used on healthy or sick animals	73%
The animals' living space met some meaningful minimum size requirements	73%
The animals went outdoors	72%
None of these	2%
Don't know/Unsure	1%
Base: All Respondents	

Q8: Do you think that the 'NATURAL' label on PACKAGED and PROCESSED FOODS means any of the following?			
	Respondents		
	Yes	No	Unsure
No toxic pesticides were used	66%	32%	2%
No artificial ingredients or colors were used	66%	32%	2%
No artificial materials or chemicals were used during processing	65%	33%	2%
No GMOs, that is, genetically modified ingredients, were used	64%	34%	2%
Base: All Respondents			

Q9: SHOULD the 'NATURAL' label on PACKAGED and PROCESSED FOODS mean any of the following?	
	Respondents
Any (Net)	*92%*
No artificial materials or chemicals were used during processing	87%
No artificial ingredients or colors were used	86%
No toxic pesticides were used	86%
No GMOs, that is, genetically modified ingredients, were used	85%
None of these	7%
Don't know/Unsure	1%
Base: All Respondents	

Q10: Do you think that the 'ORGANIC' label on PACKAGED and PROCESSED FOODS means any of the following?			
	Respondents		
	Yes	No	Unsure
No toxic pesticides were used	79%	19%	2%
No artificial materials or chemicals were used during processing	76%	23%	2%
No GMOs, that is, genetically modified ingredients, were used	75%	23%	2%
No artificial ingredients or colors were used	74%	24%	2%
Base: All Respondents			

Q11: SHOULD the 'ORGANIC' label on PACKAGED and PROCESSED FOODS mean any of the following?	
	Respondents
Any (Net)	*95%*
No toxic pesticides were used	91%
No artificial materials or chemicals were used during processing	91%
No artificial ingredients or colors were used	89%
No GMOs, that is, genetically modified ingredients, were used	88%
None of these	4%
Don't know/Unsure	1%
Base: All Respondents	

Q12: Do you THINK a 'HUMANELY RAISED' claim on EGGS, DAIRY and MEAT means any of the following?			
	Respondents		
	Yes	No	Unsure
The farm was inspected to verify claims of humane treatment of animals	79%	18%	2%
The animals' living space met some meaningful minimum size requirements	77%	20%	2%
The animals were slaughtered humanely	75%	21%	3%
The animals went outdoors	65%	32%	4%
The animals were raised without cages	51%	45%	3%
Base: All Respondents			

Q13: SHOULD a 'HUMANELY RAISED' claim on EGGS, DAIRY and MEAT mean any of the following?	
	Respondents
Any (Net)	*96%*
The farm was inspected to verify claims of humane treatment of animals	92%
The animals' living space met some meaningful minimum size requirements	90%
The animals were slaughtered humanely	88%
The animals went outdoors	79%
The animals were raised without cages	75%
None of these	2%
Don't know/Unsure	1%
Base: All Respondents	

Q14: Which, if any, of the following information should be provided on labels for meat, poultry, fish and produce?	
	Respondents
Country of origin	92%
State of origin, if from the United States	82%
I do not have a strong opinion about this	1%
None of these	2%
Don't know/Unsure	1%
Base: All Respondents	

Q15: If MEAT came from an animal that was born and raised in a different country, such as Mexico, and then slaughtered in the United States, which of the following labels would you prefer to convey this?	
	Respondents
Born and raised in Mexico, slaughtered in the USA	57%
Product of Mexico	33%
Product of USA	6%
I do not have a strong opinion about this	2%
None of these	0%
Don't know/Unsure	1%
Base: All Respondents	

Q16: When you see the 'raised without antibiotics' label on meat, which ONE of the following do you think it means?	
	Respondents
No antibiotics were administered to the animal	65%
No antibiotics or ANY other drugs were administered to the animal	31%
None of these	1%
Don't know/Unsure	3%
Base: All Respondents	

Q17: Healthy animals can be routinely fed antibiotics to prevent disease. Should the government require that such meat be labeled as 'raised with antibiotics'?	
	Respondents
Yes	83%
No	15%
I do not have a strong opinion about this	1%
Don't know/Unsure	1%
Base: All Respondents	

Q18: In your opinion, which, if any, of the following conditions should be met before genetically engineered food can be sold on the market?	
	Respondents
It should be labeled accordingly	92%
It should meet mandatory government standards for long term safety	92%
I do not have a strong opinion about this	1%
None of these	1%
Don't know/Unsure	1%
Base: All Respondents	

Q19: Genetically engineered salmon, whose DNA has been altered to grow faster than conventional salmon, may soon be approved and sold in stores. In your opinion, should the government LEGALLY require that it be labeled as 'genetically engineered'?	
	Respondents
Yes	92%
No	6%
I do not have a strong opinion about this	1%
Don't know/Unsure	1%
Base: All Respondents	

Q20: When you buy seafood from the fish counter at the store, how often do you think the labels regarding species or origin are accurate?	
	Respondents
Always accurate	16%
Sometimes/Rarely (Subnet)	*83%*
Sometimes accurate	65%
Rarely accurate	17%
Don't know/Unsure	2%
Base: Respondents who buy/eat seafood	

Q21: Do you think that MOST shrimp sold in the United States are...	
	Respondents
Farm-raised	64%
Wild-caught	30%
None of these	1%
Don't know/Unsure	5%
Base: All Respondents	

Q22: Is it your understanding that MOST of the shrimp sold in the United States are...	
	Respondents
Imported	64%
From the United States	29%
None of these	1%
Don't know/Unsure	7%
Base: All Respondents	

Q23: When you last bought UNFROZEN shrimp in the store, which, if any, of the following do you think was true regarding the shrimp?			
	Respondents		
	Yes/True	No/False	Unsure
It was frozen and then thawed	77%	20%	3%
It was imported	67%	28%	4%
It had never been frozen	25%	72%	4%
It was caught within the last 24 hours	13%	85%	2%
Base: Respondents who buy/eat shrimp			

Q24: Do you think antibiotics and other drugs or pesticides are commonly used in shrimp farming?	
	Respondents
Yes	55%
No	31%
Don't know/Unsure	14%
Base: All Respondents	

Labeling Compliance Guidance

Labeling that Needs to be Submitted to the Labeling and Program Delivery Staff for Evaluation and Approval

November 2013

On November 7, 2013, the Food Safety and Inspection Service (FSIS) amended its prior label approval system regulations to expand the circumstances in which certain types of labels and labeling are generically approved. This rule will be effective on January 6, 2014. Once this rule is effective, only certain types of labeling (i.e., 1) labels for temporary approval, 2) labels for products produced under religious exemption, 3) labels for products for export with labeling deviations, and 4) labels with claims and special statements) will have to actually be submitted to the Agency for evaluation and approval. Examples of special statements and claims that must be submitted include: (1) claims relating a product's nutrient content to a health or a disease condition; (2) statements that identify a product as "organic" or containing organic ingredients; (3) claims that are undefined in FSIS's regulations or Food Standards and Labeling Policy Book, for example, claims regarding the raising of animals, such as "no antibiotics administered" or "vegetarian fed"; (4) instructional or disclaimer statements concerning pathogens, e.g., "for cooking only" or "not tested for *E. coli* O157:H7"; and (5) statements that identify a product as "natural."

FSIS is publishing this compliance guide to provide information about the types of labels and labeling that need to be submitted to the Agency for approval, including specific examples of certain special statements and claims that are not generically approved. This guidance also includes information about statements and claims that previously needed to be submitted but will be considered generically approved when the final rule is effective. The Agency will update these lists periodically as it evaluates new statements and claims on the labeling of meat and poultry products.

Labels that ALWAYS need to be submitted to the Agency for approval (9 CFR 412.1)

- Temporary approvals
- Labels for export only that bear labeling deviations
- Religious exemption, e.g., Buddhist exemptions, Confucian exemptions
- Labels bearing special statements and claims (see chart below)

Examples of statements on labels that are special claims and that need to be submitted for approval

Claims	• 3rd party raising claims or programs, for example, AMS processed verified or certified programs; Global Animal Partnership and Certified Humane, American Heart Association (AHA) claims; labels bearing the AHA logo • Animal production claims, for example, acorn fed, corn fed, grass fed, vegetarian fed, no added hormones, no added antibiotics, raised without antibiotics

	• Breed Claims, for example, Angus, Berkshire, Hereford • Certified claims, Certified Halal • Gluten free- certified and non certified • Health claims defined in 21 CFR 343(r)(2) • Implied Nutrition Claims, for example, Heart Smart, Baked not Fried, Made without Butter • Instructional or disclaimer statements addressing pathogens on products going to another Federal establishment, for example, for cooking only, for full lethality treatment , for high pressure processing at establishment XXXX • Sampled and tested claims regarding STEC organisms • Natural claims, for example, All Natural, 100% Natural • Negative claims or free claims, e.g., no animal by products, no MSG, no MSG added, no preservatives • Undefined Nutrition Claims, for example, Very low in fat, Super source of protein, Trans Fat Free • Organic claims • Omega 3 factual statements, for example, 200mg omega 3 fatty acids per serving, or any other use of the word omega 3, synonym for omega 3, or type of omega 3 fatty acid, for example, alpha linoleic acid • Pet Food, Certified • Serving sizes in Nutrition Facts panel that are not provided for in 9 CFR 317.309 and 9 CFR 317.381 or guidance documents; for example, appetizers using a RACC of 85 grams, meal for 2 where the serving size might state ½ package (300g) and is not in accordance with the RACC in 9 CFR 317.312 or 381.412, or the serving size rules in 9 CFR 317.309(b) or 381.409(b). • "Whole Grain," "Made with whole grains," "Made with whole wheat" claims • Nutritional Front of Pack statements, for example, 0 grams trans fat per serving, 0 grams carbohydrate per serving, Nutrition Facts Up Front, and "Vegetable" claims (½ cup vegetables per serving; made with vegetables). FSIS views statements related to the quantity of vegetables in a product as an implied "good source of vegetables" claim, which is undefined. Such products would need to provide a significant amount of vegetables per serving, that is, at least ½ cup vegetables per serving or ¼ cup per serving for toddler or infant foods.

Labeling that does not need to be submitted to the Labeling and Program Delivery Staff for approval

This is a list of statements or claims and do not have to be submitted for review and approval. As new items are added to the list, this chart will be updated appropriately.

Generic	• All, 100%, Pure
	• Allergen or "contains (name of ingredient)" statements (e.g., "contains: soy" or "allergens: contains milk")
	• AMS Grading, for example, Prime, Choice, Grade A
	• Flavor profiles, for example:
	  o Made in USA, Product of USA
	  o Made with fennel
	  o Made with Italian cheese
	  o Made with only white meat
	  o Made with any type of cheese
	  o Made with real cheese/Made with 100% real cheese
	  o Made with Spanish pimento
	  o Made with tomatoes/Made with fresh tomatoes
	  o Teriyaki Flavored
	  o Garlic flavored
	  o Chipotle flavored
	  o BBQ flavored
	• Foreign Language on domestic products
	• Geographic claims - defined and undefined
	• Green Claims/Environmental Claims
	• Halal, uncertified/not certified
	• Hand pulled style/Hand pinched style
	• Handcrafted, Handmade, Hand slaughtered, Hand crafted style
	• Home style
	• Kosher
	• Nutrition Claim, defined
	• Ready in/Cooks in (number of minutes or seconds)

GreenerChoices.org℠
Products for a Better Planet

Consumer Reports®

Food Labeling Poll

Wednesday, July 11, 2007

Key Findings:

- 92 percent of Americans agree that imported foods should be labeled by their country of origin.
- 88 percent of consumers expect that meat labeled "natural" comes from animals that were raised on a natural diet without drugs, chemicals or other artificial ingredients.
- 90 percent of consumers agree that "organic" fish should be produced without environmental pollution and be free-of or low-in contaminants like mercury and PCBs.

Responsibility for Food-Shopping

- Half of respondents have primary responsibility for the household food-shopping.
- Women, and consumers with income under $40,000, aged 35+ years, or residing in the Northeast were most likely to be the primary shopper.

INTRODUCTION:

SF - Do you have primary or equally shared responsibility for food shopping for your household?

Food-Shopping Responsibility

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Primary responsibility for food shopping	51	38	63	34	58	58	61	44	45	57	52	48	49
Equal responsibility for food shopping	37	45	30	48	35	30	28	46	43	34	36	37	42
No responsibility for food shopping	11	17	6	17	7	11	10	10	11	9	12	13	8

Natural/Organic Purchase Frequency

- Consumers are frequent purchasers of "natural" or "organic" food items. On their last five trips to the grocery store, 61% bought an item labeled "natural" or "organic" at least once, and 29% did so on all five trips.
  - → Women were far more likely than men to buy "natural" or "organic" products on one or more grocery trips (66% vs. 55%).
  - → The same was true of high-income consumers relative to others: 70% of those earning at least $75,000 purchased "natural" or "organic" at least once, compared with 58% of consumers reporting income under $75,000.
  - → Behavior also differed regionally: Westerners were most likely to choose "natural" or "organic" products (67%), while residents of the North Central region were least likely (55%).

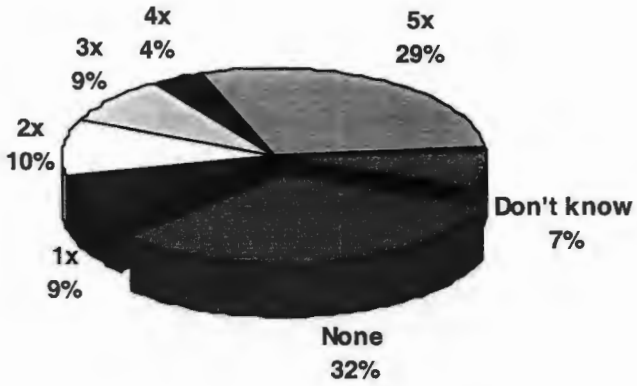
- Overall, consumers purchased "natural" or "organic" food items on nearly half of their last five grocery excursions—an average of 2.3 times.
  - → Young consumers and those with the highest income registered the greatest frequency—an average of 2.6 times.
  - → Those aged 55+ years and residents of the North Central region bought an average of 2.0 times during the last five trips.

INTRODUCTION:

C1 - Thinking of your last five grocery trips, on how many of these did you buy something labeled natural or organic?

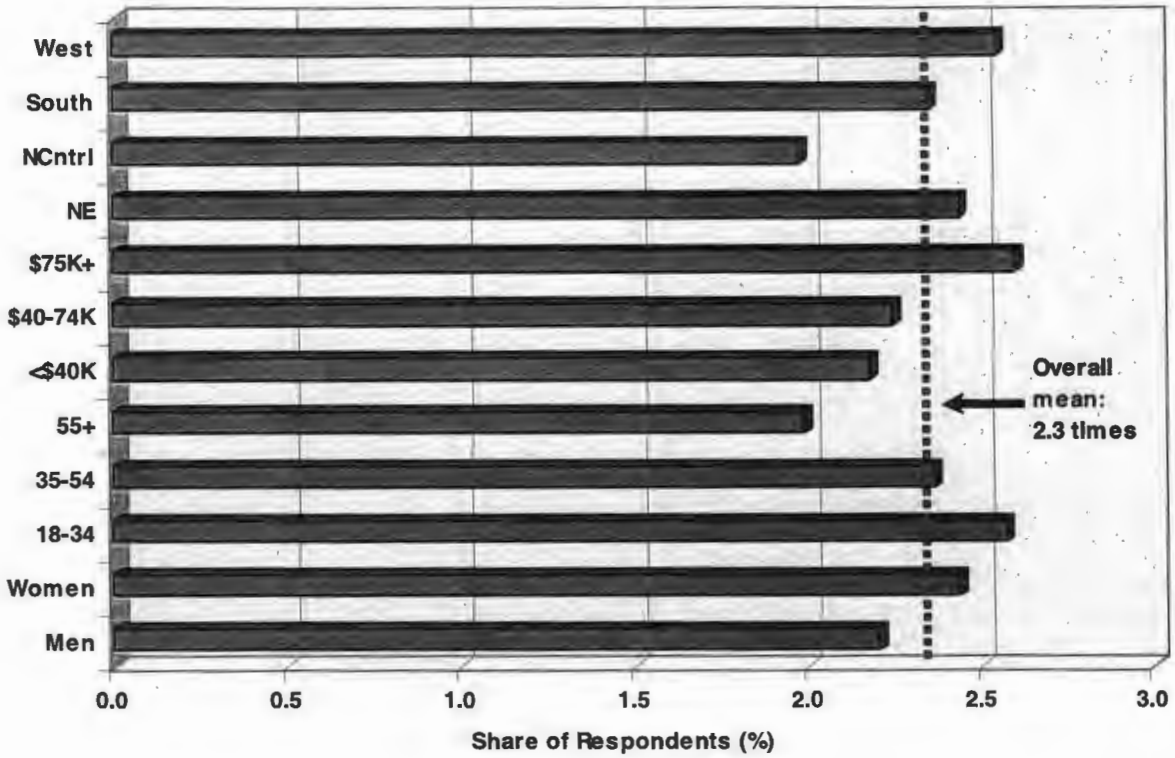
Purchased Natural or Organic

No. times, past 5 grocery trips



Purchased Natural or Organic, Past 5 Grocery Trips

Mean number of times



Importance of Natural/Organic Label

- Consumers assigned high importance to a "natural" or "organic" label when buying food. Half or more said the label is *very* or *somewhat important* (top-two box of four boxes) in five categories:
  - → Meat (61%)
  - → Bread (57%)
  - → Fish (55%)
  - → Milk (54%)
  - → Snacks (50%)

- "Natural" or "organic" soft drinks had the lowest importance at 30%.

- Importance averaged across all six categories was highest in two segments:
  - → Women (54% vs. 48% for men)
  - → Income <$40,000 (59% vs. 47% for income $40,000+)

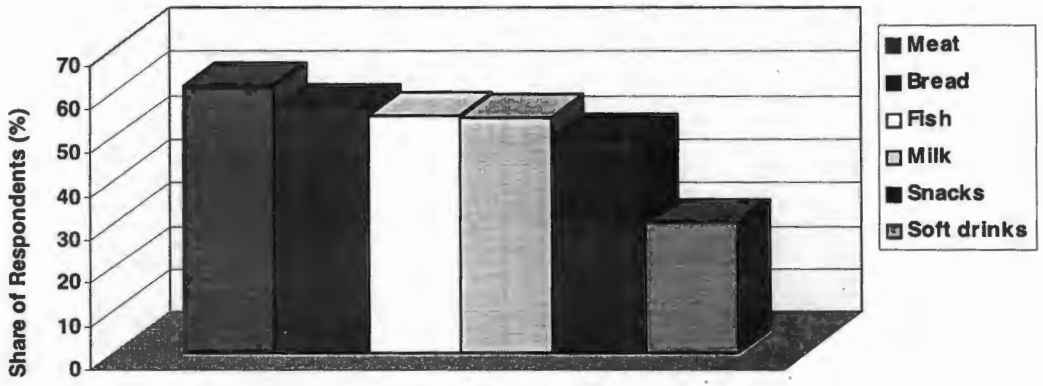
- Women were particularly sensitive to labels with these categories:
  - → Snacks (55% vs. 44% for men)
  - → Fish (59% vs. 50% for men)

INTRODUCTION:

How important is it to you to buy [CATEGORY] labeled natural or organic? Would you say very important, somewhat important, somewhat unimportant or very unimportant?

Top-Two Box: Importance of Natural/Organic Label

Very/somewhat important



Natural/Organic Food Preferences

- Labels communicate essential information about products and help consumers to make informed choices. According to the poll, foods that are labeled as "natural" or "organic", or as free of disease or hormones, are highly popular, but consumers will avoid irradiated meat.
  - → More than 6 in 10 consumers would buy food labeled "natural" (63%), or meat expressly tested for mad cow disease (62%).
  - → More than half would purchase milk labeled free of synthetic bovine growth hormone (55%), or "organic" seafood (53%).
  - → Under one-third of consumers (29%) would purchase meat that they knew to be irradiated.

- With most categories, affinity for clearly labeled food increased with income. The income effect was strongest milk labeled hormone-free: Consumers earning at least $75,000 were 30% more likely than those earning under $40,000 to purchase this type of milk.

- In some cases, specially designated food products that appear to be more healthful than conventional types actually may not have an advantage.
  - → The "natural" label is not necessarily meaningful, and there are only weak standards defined by the government.
  - → In addition, the "organic" label is meaningless with seafood. Consequently, consumers who seek out fish or shellfish bearing an "organic" label are being misled to believe that the food satisfies the requirements applied to "organic" farm products.

C3ALL - Which of the following food types would you buy if they were available?

	TOTAL	Gender		Age			Household Income			Region			
		Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Food, such as bread or soft drinks labeled natural	63	63	64	68	62	62	66	65	66	65	65	63	61
Meat labeled tested for mad cow disease	62	62	63	66	66	55	53	73	66	64	64	59	66
Milk labeled without synthetic bovine growth hormone	55	52	57	55	61	47	48	56	63	53	59	49	61
Fish or shellfish labeled organic	53	50	55	52	55	50	49	53	60	52	54	49	58
Meat labeled irradiated	29	30	28	31	32	24	23	36	30	25	34	26	32
None of these	9	9	9	7	9	11	9	9	6	10	9	9	8

Concern With Food-Related Issues

- More than 6 in 10 consumers expressed concern with all tested issues relating to food safety or purity. Concern was high across gender, age, income and region.

- Three issues registered the most concern (top-two box = *very/somewhat concerned*):
  - → Bacteria or chemicals in food (87%)
  - → Poor hygiene standards for farmed animals (83%)
  - → Food animals that are raised with daily antibiotics, other drugs or pesticides (82%)

- Three-quarters of consumers expressed concern with:
  - → Foods labeled natural that contain artificial ingredients like trans fats or high-fructose corn syrup (76%)
  - → Dairy cows given synthetic growth hormones (76%)
  - → Chicken coop waste used in cattle feed (76%)
  - → Ocean pollution caused by fish farms advertised as organic (76%)

- The lowest-scoring issues still elicited concern among a strong majority:
  - → Eating meat or milk products from cloned animals (69%)
  - → Sale of irradiated foods (69%)
  - → Genetic engineering of food crops to produce drugs, such as insulin (69%)

INTRODUCTION:

I will read you several issues that may or may not be relevant to you. For each issue, please indicate whether you are very concerned, somewhat concerned, a little concerned or not concerned at all.

C4A-J All - Top-Two Box: Concern With Issues
[4 boxes: Very Concerned/Somewhat Concerned/A Little Concerned/Not Concerned At All]

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Bacteria or chemicals in food	87	83	90	85	93	82	84	91	88	90	89	84	87
Poor hygiene standards for farmed animals	83	76	89	78	85	85	83	87	83	88	84	78	86
Food animals that are raised with daily antibiotics, other drugs or pesticides	82	75	88	79	86	80	85	81	82	82	82	81	83
Foods labeled natural that contain artificial ingredients like trans fats or high-fructose corn syrup	76	70	82	72	81	75	76	77	79	79	75	73	80
Dairy cows given synthetic growth hormones	76	70	82	69	82	76	75	80	76	78	78	75	74
Chicken coop waste used in cattle feed	76	69	81	67	81	78	76	80	74	81	77	73	74
Ocean pollution caused by fish farms advertised as organic	74	65	82	73	76	72	77	74	74	75	71	75	74
Eating meat or milk products from cloned animals	69	61	77	68	75	64	75	72	66	71	70	70	67
Sale of irradiated foods	64	59	68	57	68	65	68	63	59	71	68	59	60
Genetic engineering of food crops to produce drugs, such as insulin	62	56	67	59	67	58	68	64	53	62	65	61	61

Food-Labeling Protections

- Around 9 in 10 consumers agreed with the five statements that would strengthen labeling requirements (top-two box = *strongly/somewhat agree*):
  - → Imported foods should be labeled by their country of origin (92%)
  - → Fish labeled organic should be produced without environmental pollution and be free of or low in contaminants like mercury and PCBs (91%)
  - → Meat companies should be allowed to test and label meat products as tested for mad cow disease (90%)
  - → Meat and dairy products from cloned animals should be labeled as such (89%)
  - → Milk from cows raised without synthetic bovine growth hormone should be allowed to be labeled as such (88%)

- Under half of respondents approved of diluting the "pasteurized" label to include irradiation:
  - → Food that is irradiated should be allowed to be labeled pasteurized instead of irradiated (46%)

- Sentiment in favor of strict labeling requirements was firm across all demographic segments.

INTRODUCTION:

For each of the following statements, please indicate whether you strongly agree, somewhat agree, somewhat disagree or strongly disagree.

C5A-F All - Top-Two Box: Agreement With Statements
[4 boxes: Strongly Agree/Somewhat Agree/Somewhat Disagree/Strongly Disagree]

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Imported foods should be labeled by their country of origin	92	93	91	92	92	94	90	92	97	88	94	93	93
Fish labeled organic should be produced without environmental pollution and be free of or low in contaminants like mercury and PCBs	91	89	93	94	94	87	89	92	96	91	92	92	90
Meat companies should be allowed to test and label meat products as tested for mad cow disease	90	88	92	92	91	89	89	94	92	89	92	90	91
Meat and dairy products from cloned animals should be labeled as such	89	86	91	91	89	87	88	90	89	87	90	88	89
Milk from cows raised without synthetic bovine growth hormone should be allowed to be labeled as such	88	85	91	87	91	85	86	90	93	88	88	87	90
Food that is irradiated should be allowed to be labeled pasteurized instead of irradiated	46	44	48	47	48	44	49	45	47	43	47	50	42

Meat Label Expectations

- With meat, consumers have high expectations of the "natural" label, and this was true regardless of gender, age, income or region. More than 8 in 10 said the "natural" label on meat should mean:
  - → It came from an animal whose diet was natural and free of chemicals, drugs and other artificial ingredients (89%)
  - → No artificial colorings or other ingredients were used in the cut of the meat or meat product (84%)
  - → It came from an animal that was raised in a natural environment (83%)

- A strong majority of consumers expressed sensitivity to brine in "natural" meat:
  - → No salt water was added to the meat (70%)

C6ALL - Do you think that the natural label on MEAT should mean...

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
It came from an animal whose diet was natural and free of chemicals, drugs and other artificial ingredients	88	85	90	90	87	87	88	88	88	86	91	86	89
No artificial colorings or other ingredients were used in the cut of the meat or meat product	84	84	84	85	86	81	83	84	86	82	86	83	86
It came from an animal that was raised in a natural environment	83	81	85	83	83	83	87	84	80	85	84	82	82
No salt water was added to the meat	70	66	73	63	71	75	74	71	62	74	75	65	68
None of these	3	3	3	2	3	3	4	1	2	2	2	3	3

Packaged-Food Label Expectations

- Consumers also expect a lot of packaged foods labeled "natural". More than 8 in 10 said the "natural" label on these items should mean:
  - → No artificial colorings, additives or preservatives were used (86%)
  - → All ingredients included occur naturally or in nature (85%)
  - → It does not contain artificial oils or sugars like partially hydrogenated oils or high-fructose corn syrup (83%)
  - → Only sugars that occur naturally were used (81%)

C7ALL - Do you think that the natural label on PACKAGED FOOD should mean...

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
No artificial colorings, additives or preservatives were used	86	86	86	88	87	84	85	87	87	84	87	86	88
All ingredients included occur naturally or in nature	85	83	87	84	87	85	87	85	85	83	85	88	84
It does not contain artificial oils or sugars like partially hydrogenated oils or high-fructose corn syrup	83	81	86	82	87	81	83	87	84	85	85	82	82
Only sugars that occur naturally were used	81	78	84	80	85	78	81	82	83	82	83	80	81
None of these	3	3	2	2	2	3	2	3	1	1	3	3	3

Profile

- Women and men were equally represented in the poll, and the median age of respondents was 44 years.
- Nearly 4 in 10 consumers reported a four-year college degree or more, but a similar share had no education beyond high school.
- Median household income of the sample was about $48,000, and nearly half said they are employed full time.
- Roughly half of respondents are married, and three in four are Caucasian.

Profile

	TOTAL	Gender		Age			Household Income		
		Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+
	%	%	%	%	%	%	%	%	%
UNWEIGHTED BASE	1,004	502	502	193	360	441	317	240	232
GENDER									
Male	48	100		58	45	43	45	56	52
Female	52		100	42	55	57	55	44	48
AGE									
18-34	30	36	25	100			35	32	21
35-44	19	18	21		50		14	19	33
45-54	19	18	20		50		16	23	24
55-64	14	14	14			47	13	15	15
65+	16	13	19			53	21	11	6
Refused/Nr	1	1	1					0	0
MEDIAN (Years)	43.9	41.6	46.8	26.0	43.9	66.6	45.2	43.5	42.7
EDUCATION									
Some HS or less	7	6	8	7	6	9	13	4	2
HS graduate	32	31	32	39	27	30	42	33	14
Some college	23	24	22	24	23	22	27	28	17
College grad+ [Net]	*37*	*37*	*37*	*28*	*44*	*37*	*17*	*34*	*67*
College grad	24	24	23	21	27	22	12	22	42
Postgrad degree	13	12	14	6	17	15	5	12	26
Refused/Nr	1	1	1	2	1	2	1		
HOUSEHOLD INCOME									
Under $25,000	19	18	20	23	13	24	50		
$25,000 but less than $50,000	30	29	32	31	28	33	50	41	
$50,000 but less than $75,000	17	20	14	21	15	15		59	
$75,000 but less than $100,000	10	10	11	6	16	7			38
$100,000 or more	17	18	16	14	22	13			62
Refused	7	5	8	5	5	8			
MEDIAN (000s)	$47.7	$50.9	$44.5	$42.8	$58.8	$40.0	$24.9	$53.3	$118.9

Profile (cont.)

	TOTAL	Gender		Age			Household Income		
		Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+
	%	%	%	%	%	%	%	%	%
UNWEIGHTED BASE	1,004	502	502	193	360	441	317	240	232
EMPLOYMENT									
Employed full time	48	58	40	54	62	26	37	55	65
Employed part time	13	10	16	20	12	8	15	12	12
Retired	21	17	24	1	6	59	26	17	11
Not employed	18	15	20	26	20	7	22	16	12
Refused/Nr	0	0	0		1			1	
MARITAL STATUS									
Married	49	45	53	36	59	50	29	56	72
Living as married	3	4	2	6	2	1	6	3	2
Single and never been married	28	35	21	53	23	10	37	26	18
Divorced	10	9	11	2	12	16	16	11	5
Separated	2	1	2	0	3	2	3	1	1
Widowed	7	5	9	2	1	19	10	3	2
Refused/Nr	1	1	2	1	1	2	1	0	
RACE									
White/Caucasian	73	71	76	60	75	85	66	80	79
Black/African-American	12	14	10	14	12	9	16	10	8
Asian/Asian-American	2	2	2	2	2	1	1	2	4
Some other race	13	13	12	23	11	6	18	10	9
Refused/Nr	1	1	2	2	2	1	0		1
REGION									
Northeast	19	19	19	21	17	19	17	20	19
North Central	22	23	22	21	24	22	23	26	21
South	36	36	37	35	36	38	38	30	38
West	22	21	23	23	23	20	22	23	21

United States Department of Agriculture

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February 2014

Genetically Engineered Crops in the United States

Jorge Fernandez-Cornejo, Seth Wechsler, Mike Livingston, and Lorraine Mitchell

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Genetically Engineered Crops in the United States

Jorge Fernandez-Cornejo, Seth Wechsler, Mike Livingston, and Lorraine Mitchell

Abstract

More than 15 years after their first successful commercial introduction in the United States, genetically engineered (GE) seeds have been widely adopted by U.S. corn, soybean, and cotton farmers. Still, some questions persist regarding the potential benefits and risks of GE crops. The report finds that, although the pace of research and development (measured by the number of USDA-approved field tests) peaked in 2002, other measures show that biotech firms continue to develop new GE seed varieties at a rapid pace. Also, U.S. farmers continue to adopt GE seeds at a robust rate, and seed varieties with multiple (stacked) traits have increased at a very rapid rate. Insecticide use has decreased with the adoption of insect-resistant crops, and herbicide-tolerant crops have enabled the substitution of glyphosate for more toxic and persistent herbicides. However, overreliance on glyphosate and a reduction in the diversity of weed management practices have contributed to the evolution of glyphosate resistance in some weed species.

Keywords: Genetically engineered crops, agricultural biotechnology, seed industry, research and development, adoption, crop yields, pesticide use, corn, soybeans, cotton

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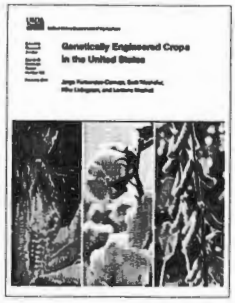

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Genetically Engineered Crops in the United States

Jorge Fernandez-Cornejo, Seth Wechsler, Mike Livingston, and Lorraine Mitchell

What Is the Issue?

Genetically engineered (GE) varieties with pest management traits became commercially available for major crops in 1996. More than 15 years later, adoption of these varieties by U.S. farmers is widespread and U.S. consumers eat many products derived from GE crops—including cornmeal, oils, and sugars—largely unaware that these products were derived from GE crops. Despite the rapid increase in the adoption of corn, soybean, and cotton GE varieties by U.S. farmers, questions persist regarding their economic and environmental impacts, the evolution of weed resistance, and consumer acceptance.

What Did the Study Find?

This report examines issues related to three major stakeholders in agricultural biotechnology: GE seed suppliers and technology providers (biotech firms), farmers, and consumers.

GE seed suppliers/technology providers. The number of field releases for testing of GE varieties approved by USDA's Animal and Plant Health Inspection Service (APHIS) is an important measure of research and development (R&D) activities in agricultural biotechnology. The number of releases grew from 4 in 1985 to 1,194 in 2002 and averaged around 800 per year thereafter. However, while the number of releases peaked in 2002, other measures of research and development activity—the number of sites per release and the number of gene constructs (ways that the gene of interest is packaged together with other elements)—have increased very rapidly since 2005. Also, releases of GE varieties with agronomic properties (like drought resistance) jumped from 1,043 in 2005 to 5,190 in 2013.

As of September 2013, about 7,800 releases were approved for GE corn, more than 2,200 for GE soybeans, more than 1,100 for GE cotton, and about 900 for GE potatoes. Releases were approved for GE varieties with herbicide tolerance (6,772 releases), insect resistance (4,809), product quality such as flavor or nutrition (4,896), agronomic properties like drought resistance (5,190), and virus/fungal resistance (2,616). The institutions with the most authorized field releases include Monsanto with 6,782, Pioneer/DuPont with 1,405, Syngenta with 565, and USDA's Agricultural Research Service with 370. As of September 2013, APHIS had received 145 petitions for deregulation (allowing GE seeds to be sold) and had approved 96 petitions: 30 for corn; 15 for cotton; 11 for tomatoes; 12 for soybeans; 8 for rapeseed/canola; 5 for potatoes; 3 for sugarbeets; 2 each for papaya, rice, and squash; and 1 each for alfalfa, plum, rose, tobacco, flax, and chicory.

Farmers. Three crops (corn, cotton, and soybeans) make up the bulk of the acres planted to GE crops. U.S. farmers planted about 169 million acres of these GE crops in 2013, or about half of total land used to grow crops. Herbicide-tolerant (HT) crops have traits that allow them to tolerate more effective herbicides, such as glyphosate, helping adopters control pervasive weeds more effectively. U.S. farmers used HT soybeans on 93 percent of all planted soybean acres in 2013.

ERS is a primary source of economic research and analysis from the U.S. Department of Agriculture, providing timely information on economic and policy issues related to agriculture, food, the environment, and rural America.

HT corn accounted for 85 percent of corn acreage in 2013, and HT cotton constituted 82 percent of cotton acreage. Farmers planted insect-resistant (Bt) cotton to control pests such as tobacco budworm, cotton bollworm, and pink bollworm on 75 percent of U.S. acreage in 2013. Bt corn—which controls the European corn borer, the corn rootworm, and the corn earworm—was planted on 76 percent of corn acres in 2013.

The adoption of Bt crops increases ***yields*** by mitigating yield losses from insects. However, empirical evidence regarding the effect of HT crops on yields is mixed. Generally, stacked seeds (seeds with more than one GE trait) tend to have higher yields than conventional seeds or than seeds with only one GE trait. GE corn with stacked traits grew from 1 percent of corn acres in 2000 to 71 percent in 2013. Stacked seed varieties also accounted for 67 percent of cotton acres in 2013.

Planting Bt cotton and Bt corn seed is associated with higher ***net returns*** when pest pressure is high. The extent to which HT adoption affects net returns is mixed and depends primarily on how much weed control costs are reduced and seed costs are increased. HT soybean adoption is associated with an increase in total household income because HT soybeans require less management and enable farmers to generate income via off-farm activities or by expanding their operations.

Farmers generally use less ***insecticide*** when they plant Bt corn and Bt cotton. Corn insecticide use by both GE seed adopters and nonadopters has decreased—only 9 percent of all U.S. corn farmers used insecticides in 2010. Insecticide use on corn farms declined from 0.21 pound per planted acre in 1995 to 0.02 pound in 2010. This is consistent with the steady decline in European corn borer populations over the last decade that has been shown to be a direct result of Bt adoption. The establishment of minimum refuge requirements (planting sufficient acres of the non-Bt crop near the Bt crop) has helped delay the evolution of Bt resistance. However, there are some indications that insect resistance is developing to some Bt traits in some areas.

The adoption of HT crops has enabled farmers to substitute glyphosate for more toxic and persistent ***herbicides***. However, an overreliance on glyphosate and a reduction in the diversity of weed management practices adopted by crop producers have contributed to the evolution of glyphosate resistance in 14 weed species and biotypes in the United States. Best management practices (BMPs) to control weeds may help delay the evolution of resistance and sustain the efficacy of HT crops. BMPs include applying multiple herbicides with different modes of action, rotating crops, planting weed-free seed, scouting fields routinely, cleaning equipment to reduce the transmission of weeds to other fields, and maintaining field borders.

The ***price*** of GE soybean and corn seeds grew by about 50 percent in real terms (adjusted for inflation) between 2001 and 2010. The price of GE cotton seed grew even faster. The yield advantage of Bt corn and Bt cotton over conventional seed has become larger in recent years as new Bt traits have been incorporated and stacked traits have become available. Planting Bt cotton and Bt corn continues to be more profitable, as measured by net returns, than planting conventional seeds.

Consumers. Consumer acceptance of foods with GE ingredients varies with product characteristics, geography, and the information that consumers are exposed to. Most studies in industrialized nations find that consumers are willing to pay a premium for foods that don't contain GE ingredients. However, studies in developing countries yield more mixed results. Some studies, including some with a focus on GE ingredients with positive enhancements (such as nutrition), find consumers to be willing to try GE foods and even to pay a premium for them, while others find a willingness to pay a premium for non-GE foods. Most studies have shown that willingness-to-pay for non-GE foods is higher in the EU, where some retailers have policies limiting the use of GE ingredients. Non-GE foods are available in the United States, but there is evidence that such foods represent a small share of retail food markets.

How Was the Study Conducted?

This report updates the ERS report titled *The First Decade of Genetically Engineered Crops in the United States*. To consider biotech seed firms, we use information from the literature and analyze USDA data on field testing approvals by APHIS for new GE varieties. To study farmers' use of GE crops, we analyze USDA farm surveys, particularly the Agricultural Resource Management Survey (ARMS), and summarize the literature. To understand consumers' perspectives, we summarize surveys of consumers' attitudes from the literature.

Genetically Engineered Crops in the United States

Introduction

Genetic engineering is a key component of modern agricultural biotechnology.[1] The first genetically engineered (GE) plant, a tomato, was developed in 1982 (USDA/ARS, 2012). By 1985, the USDA had approved four releases of GE organisms for field testing. Commercial use of major GE crops began in 1996.[2]

Genetically engineered crop traits have been classified into one of three generations (Fernandez-Cornejo, 2004). The first generation features enhanced input traits such as herbicide tolerance, resistance to insects, and resistance to environmental stress (like drought). The second features value-added output traits such as nutrient-enhanced seeds for feed. The third generation of GE crops would include traits to allow production of pharmaceuticals and products beyond traditional food and fiber.

While the first GE crop approved by USDA's Animal and Plant Health Inspection Service (APHIS) and commercialized in 1994 was a crop with a strictly second-generation trait (FlavrSavr tomato), most GE crops planted in the United States have first-generation traits. All three generations of GE crop traits are in various stages of research and development.[3]

Most U.S. acres planted to GE crops have traits that provide herbicide tolerance (HT) and/or insect resistance. These seeds became commercially available in 1996. HT crops are able to tolerate certain highly effective herbicides, such as glyphosate, allowing adopters of these varieties to control pervasive weeds more effectively. Commercially available HT crops include soybeans, corn, cotton, canola, sugarbeets, and alfalfa. Insect-resistant or Bt crops contain a gene from the soil bacterium *Bacillus thuringiensis* (Bt) that produces a protein which is toxic to certain insects, protecting the plant over its entire life (Fernandez-Cornejo and McBride, 2002). Commercially available Bt crops include corn and cotton.

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[1]Genetic engineering is a technique used to alter genetic material (genes) of living cells. A gene is a segment of DNA that expresses a particular trait. It is a unit of heredity transmitted from generation to generation during reproduction (Zaid et al., 1999). DNA constitutes the genetic material of most known organisms.

[2]Plant biotechnology in general and genetic engineering in particular have significantly reduced the time needed to develop improved plant varieties, increasing the range and precision of characteristics incorporated into these new varieties (Fernandez-Cornejo, 2004). By allowing scientists to target single plant traits through genetic recombination techniques, plant biotechnology decreases the number of residual unwanted characteristics that often result from traditional plant breeding crosses, enabling breeders to develop desirable new varieties more rapidly.

[3]Several second-generation GE crops have been approved by APHIS: high-lysine corn, reduced-nicotine tobacco, high-oleic acid soybean oil, stearidonic acid-producing soybeans, improved fatty acid-profile soybeans, altered-flower color roses (blue), oil profile-altered canola, and alpha amylase corn. Overall, nearly 20 percent of the approvals for deregulation (as of September 2013) are second-generation crops.

More than 15 years after commercial introduction, adoption of first-generation GE crop varieties by U.S. farmers has reached about 90 percent of the planted acres of corn, soybeans, and cotton. U.S. consumers eat many products derived from these crops—including cornmeal, oils, and sugars—largely unaware of their GE origins. Despite the rapid increase in adoption rates for GE corn, soybean, and cotton varieties by U.S. farmers, some continue to raise questions regarding the potential benefits and risks of GE crops.

This report updates ERS' 2006 report, *The First Decade of Genetically Engineered Crops in the United States.* As in the previous report, this report examines the three major stakeholders of agricultural biotechnology: GE seed suppliers and technology providers (biotech firms), farmers, and consumers.

From the Laboratory to the Field

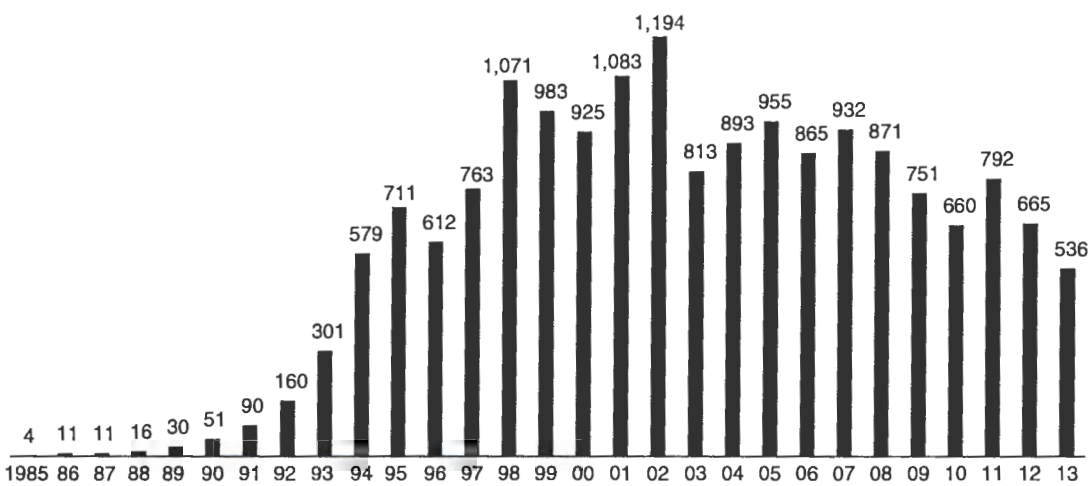
Over the last century, private research and development (R&D) expenditures in the seed industry have increased rapidly both in absolute terms and relative to public expenditures, altering the focus of R&D and of the crops studied (Fernandez-Cornejo, 2004). Over the past two decades, technological innovation in the form of modern biotechnology and changes in property rights have enabled private-sector firms to capture more value from the seeds that they develop, and seed remains the most research-intensive of the agricultural input sectors to date (Heisey and Fuglie, 2012).

While the rapid commercial success of GE varieties is the fulfillment of R&D efforts, earlier benchmarks include the number of releases for field testing of GE plant varieties approved by APHIS as well as the determination of nonregulated status (see box, "Regulatory Oversight").[4] Field testing is a critical part of seed development (Fernandez-Cornejo and Caswell, 2006).

Field Releases

The number of field release permits and notifications issued by APHIS for GE organisms (mostly plant varieties) grew from 4 in 1985 to 1,194 in 2002 and then averaged around 800 per year (fig. 1). The cumulative number (beginning in 1985 and ending in September 2013) of releases for field testing increased from 10,700 in 2005 to more than 17,000 in 2013. Field releases approved for corn increased from close to 5,000 in 2005 to 7,800 in 2013. Approved releases for GE varieties with herbicide tolerance traits increased from 3,587 in 2005 to 6,772 in 2013, insect resistance from 3,141 to 4,909, and product quality such as flavor or nutrition from 2,314 to 4,896.

Figure 1
Number of releases of genetically engineered (GE) organisms varieties approved by APHIS, 1985-2013* (Includes permits and notifications)



*As of September 24, 2013.
Authorizations for field releases of GE organisms (mostly plant varieties) are issued by USDA's Animal and Plant Health Inspection Service (APHIS) to allow technology providers to pursue field testing.
Source: Information Systems for Biotechnology (ISB, 2013).

[4]Another indicator of R&D activity is the number of patents issued by the U.S. Patent and Trademark Office. More than 4,200 new agricultural biotech patents were issued between 1996 and 2000 (King and Heisey, 2003, 2004).

Regulatory Oversight

Before commercial introduction, genetically engineered (GE) crops must conform to standards set by State and Federal statutes (Fernandez-Cornejo and Caswell, 2006; USDA/APHIS, 2013). Under the Coordinated Framework for the Regulation of Biotechnology, Federal oversight is shared by the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA).

USDA's Animal and Plant Health Inspection Service (APHIS) plays a central role in regulating field testing of agricultural biotechnology products. Through either a notification or permit procedure, such products—which include certain genetically engineered plants, microorganisms, and invertebrates—are considered "regulated articles." APHIS issues authorizations for field releases of those GE organisms (mostly GE plants) that are categorized as "regulated articles" under its regulations, to allow technology providers to pursue field testing. GE plants that meet six specific criteria described in the regulations undergo an administratively streamlined process, known as a *notification*. Under a *notification*, applicants provide information on the nature of the plant and introduced genes, descriptions of genetic modifications, size of the introduction, and origin and destinations for movement or the location of a field test. For GE plants that do not meet the criteria for a *notification*, an APHIS *permit* is required. This process involves a more comprehensive review. In addition to the data required for notification, permit applicants must describe how they will perform the test, including specific measures to reduce the risk of harm to other plants, so the tested organisms remain confined and do not persist after completion of the field test.

After years of field tests, an applicant may petition APHIS for a determination of nonregulated status in order to facilitate commercialization of the product. If, after extensive review, APHIS determines that the GE organism is unlikely to pose a plant pest risk, the organism is issued a "determination of nonregulated status." At this point, the organism is no longer considered a regulated article and can be moved and planted without APHIS oversight under the biotechnology regulations (USDA/APHIS, 2012).

If a plant is engineered to produce a substance that "prevents, destroys, repels, or mitigates a pest," it is considered a pesticide and is subject to regulation by EPA (*Federal Register*, November 23, 1994). FDA regulates all food applications of crops, including those crops that are developed through the use of biotechnology, to ensure that foods derived from new plant varieties are safe to eat. A more complete description of the regulations of GE products may be found in USEPA, 2003; Belson, 2000; and USDA/APHIS, 2013).

Though the current regulatory system is considered to be effective, USDA, EPA, and FDA update regulations as needed to address new trends and issues of the future.

However, these numbers do not fully indicate the amount of R&D activity. A permit or notification can include many release sites and authorize many different gene constructs (ways that the gene of interest is packaged with other elements, like promoters that allow gene expression) to be tested at each site.[5] Thus, while the number of APHIS notifications and permits peaked in 2002, a more comprehensive measure of the amount of R&D activity in agricultural biotechnology—the number of authorized sites and authorized constructs—has increased very rapidly since 2005. For example, while the number of releases authorized in fiscal year (FY) 2012 was lower than in FY2005, the

[5]A gene construct is the technical name used for a functional unit necessary for the transfer or the expression of a gene of interest (http://www.gmo-safety.eu/glossary/667.gene-construct.html). Typically, a construct comprises the gene or genes of interest, a marker gene (to facilitate detection inside the plant), and appropriate control sequences as a single package (FAO, 2001).

number of authorized sites in FY2012 almost doubled those in FY2005 and the number of constructs increased more than 150-fold (table 1).[6]

Most field releases have involved major crops, particularly corn, which had about 7,800 field releases approved as of September 2013. More than 2,200 field releases were approved for GE soybeans, more than 1,100 for GE cotton, and about 900 for GE potatoes (fig. 2). Releases approved between 1985 and September 2013 included GE varieties with herbicide tolerance (6,772), insect resistance (4,809), product quality such as flavor or nutrition (4,896), agronomic properties (like drought resistance) (5190), and virus/fungal resistance (2,616) (fig. 3). A notable change in R&D activities

Table 1
Number of releases, sites, and constructs authorized by APHIS for evaluation

	Releases	Authorized sites	Authorized constructs
FY2012	767	9,133	469,202
FY2011	967	10,128	395,501
FY2010	754	6,626	297,422
FY2009	846	6,751	217,502
FY2008	948	7,744	125,365
FY2007	1,066	3,623	63,217
FY2006	974	4,327	18,532
FY2005	1011	4,939	3,042
FY2004	997	4,523	2,851
FY2003	824	2,910	2,650
FY2002	1,226	5,111	3,234
FY2001	1,190	5,831	3,208
FY2000	1,002	3,836	3,126
FY1999	1,068	4,134	3,502
FY1998	1,151	4,781	3,830
FY1997	782	3,427	2,650
FY1996	653	2,745	2,305
FY1995	734	3,690	2,666
FY1994	569	1,669	1,926
FY1993	341	455	870
FY1992	164	121	427
FY1991	90	10	226
FY1990	46	14	142
FY1989	32	12	74

A gene construct is the name used for a functional unit necessary for the transfer or the expression of a gene of interest (http://www.gmo-safety.eu/glossary/667.gene-construct.html). Typically, a construct comprises the gene or genes of interest, a marker gene (to facilitate detection inside the plant), and appropriate control sequences as a single package (Food and Agriculture Organization, 2001). A construct is a piece of DNA which functions as the vehicle or vector carrying the target gene into the recipient organism. It has several different regions.

Source: Unpublished USDA Animal and Plant Health Inspection Service database

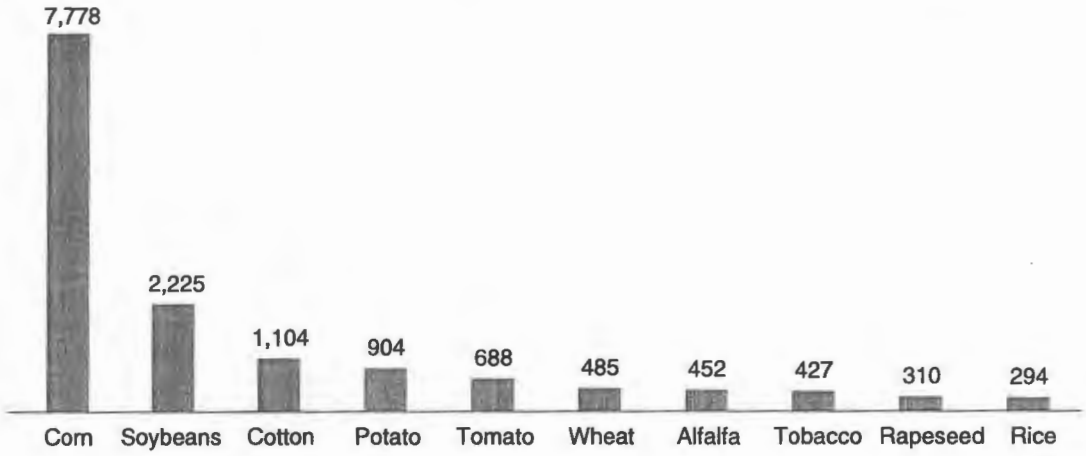
[6]Within each location there can be multiple sites or fields where the trial will be carried out (Information Systems for Biotechnology, 2013).

between 2005 and 2013, as measured by the field releases of GE varieties, is the five-fold jump in releases of GE varieties with agronomic properties (like drought resistance) from 1,043 in 2005 to 5,190 in 2013 (fig. 3).

The top release permit-holding institutions include Monsanto (6,782 permits/notifications held), Pioneer/DuPont (1,405), Syngenta (565), and USDA/ARS (370) (fig. 4).

Figure 2

Number of releases approved by APHIS: Top 10 crops (includes permits and notifications)*

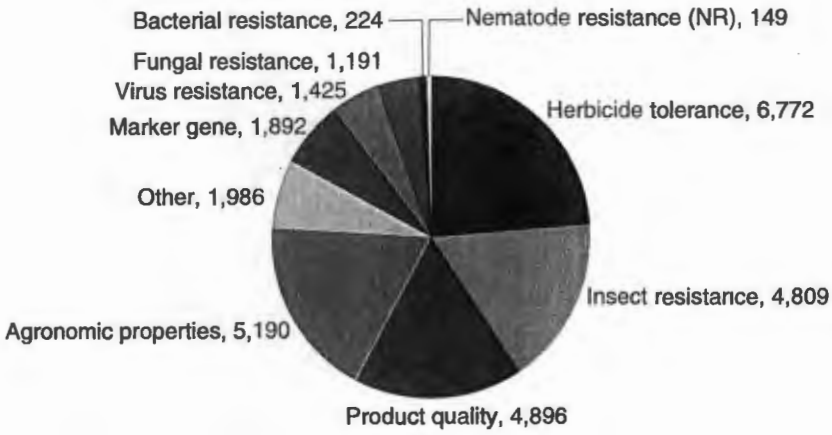


*As of September 24, 2013.
Authorizations for field releases of GE plant varieties are issued by USDA's Animal and Plant Health Inspection Service (APHIS) to allow technology providers to pursue field testing.

Source: Information Systems for Biotechnology (ISB, 2013).

Figure 3

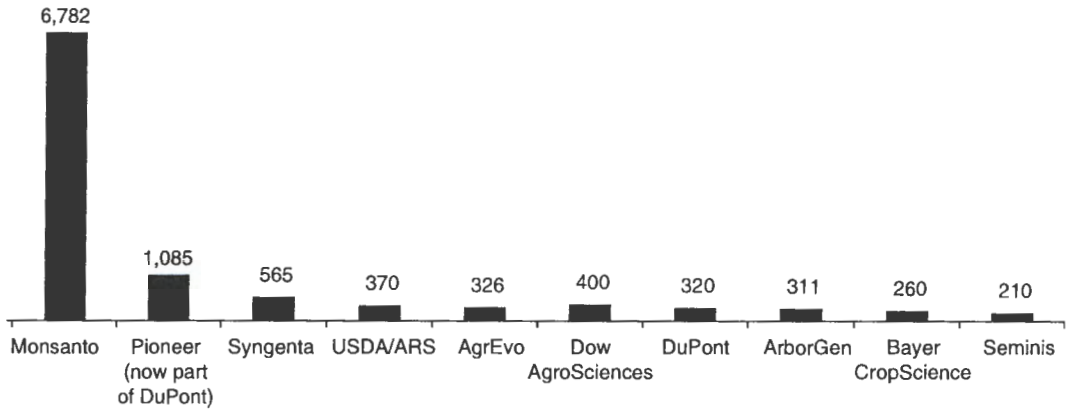
Number of releases approved by APHIS by GE trait (includes permits and notifications)*



*As of September 24, 2013.
Authorizations for field releases of GE plant varieties are issued by USDA's Animal and Plant Health Inspection Service (APHIS) to allow technology providers to pursue field testing. Counts refers to the actual number of approved release locations per phenotype category. http://www.aphis.usda.gov/biotechnology/status.shtml

Source: Information Systems for Biotechnology (ISB, 2013).

Figure 4
Institutions having the most authorized permits and notifications (number held)



*As of September 24, 2013.

Authorizations for field releases of GE plant varieties are issued by USDA's Animal and Plant Health Inspection Service (APHIS) to allow technology providers to pursue field testing.

Source: Information Systems for Biotechnology (ISB, 2013).

Determination of Nonregulated Status

Nonregulated status allows seed companies to commercialize the GE seeds that they have developed. After successful field testing, technology providers petition APHIS for a determination of non-regulated status. If, after review, APHIS determines that the organism (i.e., GE plant) is unlikely to pose a plant pest risk, the organism is deregulated (see box, "Regulatory Oversight") and can be moved and planted without APHIS oversight. As of September 2013, APHIS had received 145 petitions for deregulation—compared with 103 petitions received in 2005—and had granted 96 (31 were withdrawn, 17 were pending, and 1 was incomplete) (Information Systems for Biotechnology, 2013). For corn, 30 petitions were granted nonregulated status; 15 were granted for cotton; 11 for tomatoes; 12 for soybeans; 8 for canola/rapeseed; 5 for potatoes; 3 for sugarbeet; 2 each for papaya, rice, and squash; and 1 each for alfalfa, plum, rose, tobacco, flax, and chicory. By trait, as of September 2013, 43 petitions were granted nonregulated status for herbicide tolerance, 31 for insect resistance, 17 for product quality, 9 for agronomic properties, 8 for virus resistance, and 2 for others.[7]

The Research and Development Pipeline

APHIS approval for field testing and determination of nonregulated status signals that the GE products are near commercial status. In addition to crops with improved pest management traits, APHIS approvals include crops with traits that provide viral/fungal resistance; favorable agronomic properties (resistance to cold, drought, frost, salinity, more efficient use of nitrogen, increased yield); enhanced product quality such as delayed ripening, flavor, and texture (fruits and vegetables); increased protein or carbohydrate content, fatty acid content or micronutrient content; modified starch, color (cotton, flowers), fiber properties (cotton) or gluten content (wheat); naturally decaffein-

[7]A petition (as well as an approval) may include more than one trait or phenotype category. For example, a petition for corn may include one or more HT traits and one or more Bt traits.

ated (coffee); nutraceuticals (added vitamins, iron, antioxidants such as beta-carotene); and pharmaceuticals (table 2).[8] Additional information is found in the Pew Initiative (2001), Runge and Ryan (2004), Monsanto (2012), and Pioneer (2012).

Table 2
Biotech crops currently available and in development

	Input traits				Output traits	
Crop	Herbicide tolerance	Insect resistance	Virus/fungi, resistance	Agronomic properties[11]	Product quality[14]	Pharmaceuticals/ nutraceuticals[17]
Corn	C	C[5]	D	C[12] D	D	D
Soybeans	C	D		D	C[15] D	
Cotton	C	C[6]		D	D	
Potatoes		W[7]	D	D	D	D
Wheat	C[2]		D			
Other field crops[1]	C[3] D[4]	D	D	D	D	D
Tomato, squash, melon, sweet corn		C[8]	C9 D	D	C[16] D	D
Other vegetables	D				D	
Papaya			C[10]			
Fruit trees			D		D	
Other trees				D[13]	D	
Flowers					D	

[1]Includes barley, canola, peanuts, tobacco, rice, sugar beet, alfalfa, etc.
[2]Monsanto discontinued breeding and field level research on its GE Roundup Ready wheat in 2004.
[3]Canola, sugar beet, alfalfa. [4]Barley, rice. [5]Bt corn to control the corn borer commercially available since 1996; Bt corn for corn rootworm control commercially available since 2003; Bt corn to control the corn earworm commercially available since 2010; stacked versions of them also available.
[6]Bt cotton to control the tobacco budworm, the bollworm, and the pink bollworm, commercially available since 1996.
[7]Bt potatoes, containing built-in resistance to the Colorado potato beetle were commercially introduced in 1996 and withdrawn in 1999.
[8]Sweet corn with insect resistance (to the corn earworm and European corn borer) was planted in anout 20,000 acres and sold in the fresh market in 2008 (NRC, 2010).
[9]VR squash accounted for about 12 percent of the squash produced in in 2005 (NRC, 2010).
[10]Responding to a devastating papaya virus epidemic in the mid-1990s, researchers at Cornell University and at the University of Hawaii developed two virus-resistant varieties of GE papaya. First commercial plantings were made in 1998. The new varieties were successful in resisting a viral epidemic and were planted on more than 30 percent of Hawaii's papaya acreage in 1999.
[11]Such as resistance to drought, frost, salinity; more efficient use of nitrogen.
[12]Drought tolerant corn approved for commercial use in 2011; expected to be introduced in 2012.
[13]Modified lignin content.
[14]Includes delayed ripening (fruits and vegetables with longer shelf life); protein content, carbohydrate content, fatty acid content, micronutrient content, oil content, modified starch content, flavor and texture (fruits and vegetables), color (cotton, flowers), fiber properties (cotton), gluten content (wheat), naturally decaffeinated (coffee), and low phytase.
[15]High oleic soybeans.
[16]FlavrSavr tomato genetically engineered to remain on the vine longer and ripen to full flavor after harvest was pulled out of the market because of harvesting and marketing problems.
[17]Includes increased vitamin, iron, beta-carotene (antioxidant), lycopene (anti-cancer), amino acid content; low-calorie sugar; hypoallergenic crops; antibodies, vaccines. Industrial uses (such as specialty machine oils).

Sources: ISB (2013); Fernandez-Cornejo and Caswell (2006); National Research Council (2010); USDA Animal and Plant Health Inspection Service.

[8]Pharmaceutical plant compounds produced are intended for pharmaceutical use and would need to be approved from at least one of the following agencies prior to commercialization: U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (human biologics), FDA Center for Drug Evaluation and Research (human drugs), FDA Center for Veterinary Medicine (animal drugs), and USDA Center for Veterinary Biologics (animal biologics). None of the plants currently under permit produce pharmacologically active compounds.

Adoption of GE Crops by U.S. Farmers

When farmers adopt a new technology, they typically expect benefits like increased farm net returns, time savings (by making farming less effort intensive), or reduced exposure to chemicals. Net benefits are a function of farm characteristics and location, output and input prices, existing production systems, and farmer abilities and preferences.

Judging by the widespread adoption of GE seeds, farmers have benefited from them. U.S. farmers planted about 169 million acres of GE corn, soybeans, and cotton in 2013 (table 3), accounting for almost half of the estimated total land used to grow all U.S. crops.

On a global scale, approximately 420 million acres of GE crops were planted in 28 countries in 2012 (International Service for the Acquisition of Agri-biotech Applications, 2012). U.S. acreage accounted for approximately 41 percent of acres planted with GE seed, Brazil accounted for 21 percent, Argentina for 14 percent, Canada for 7 percent, India for 6 percent, and China, Paraguay, South Africa, and Pakistan each for roughly 2 percent.

Commercially introduced in the United States in 1996, major GE crops were rapidly adopted. Planting of GE crops (measured in acres) increased by 68 percent between 2000 and 2005 and grew by 45 percent between 2005 and 2013. Three crops (corn, cotton, and soybeans) make up the bulk of U.S. acres planted to GE crops (table 3), mostly for herbicide tolerance (HT) and insect resistance (Bt). Including varieties with HT and/or Bt traits, GE crops accounted for 90 percent of all planted cotton acres, 93 percent of soybean acres, and 90 percent of corn acres in 2013. U.S. farmers have

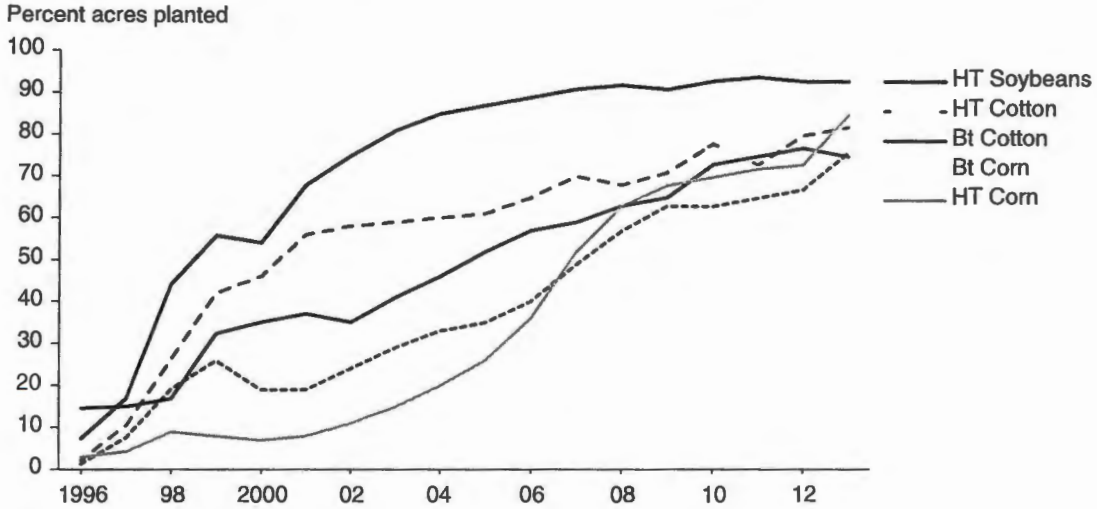
Table 3
Major genetically engineered crops, 2000-2013

	GE corn		GE soybeans		GE cotton	
Year	Million acres planted	Percent of corn acres	Million acres planted	Percent of soybean acre	Million acres planted	Percent of cotton acres
2000	19.89	25	40.10	54	9.47	61
2001	19.68	26	50.37	68	10.88	69
2002	26.82	34	55.47	75	9.91	71
2003	31.44	40	59.46	81	9.84	73
2004	38.04	47	63.93	85	10.38	76
2005	42.53	52	62.67	87	11.25	79
2006	47.78	61	67.21	89	12.68	83
2007	68.27	73	58.91	91	9.42	87
2008	68.79	80	69.66	92	8.15	86
2009	73.42	85	70.48	91	8.05	88
2010	75.85	86	71.99	93	10.21	93
2011	81.21	88	70.46	94	13.25	90
2012	85.50	88	71.79	93	11.58	94
2013	87.64	90	72.29	93	9.23	90

Genetically engineered crops in this table include Bt crops that have insect-resistant traits or HT crops that have herbicide tolerance traits, or both.

Sources: USDA Economic Research Service using data from from USDA/NASS Quick Stats and Fernandez-Cornejo (2013).

Figure 5
Adoption of genetically engineered crops in the United States



Bt crops have insect resistant traits; HT crops have herbicide tolerance traits.
Data for each crop category include varieties with both Bt and HT (stacked) traits.

Source: U.S. Department of Agriculture (USDA), Economic Research Service (ERS). 2013. *Adoption of Genetically Engineered Crops in the U.S.* data product.

tended to adopt HT seeds at higher levels than seeds with insect resistance (fig. 5). In part, this is because weeds are a pervasive problem.[9] HT adoption was particularly rapid in soybeans, with U.S. farmers increasing their planting of HT soybeans from 54 percent of soybean acres in 2000 to 87 percent in 2005 and 93 percent in 2013. HT cotton increased from 46 percent of cotton acres in 2000 to 61 percent in 2005 and 82 percent in 2013. HT corn increased from 7 percent of corn acres in 2000 to 26 percent in 2005 and 85 percent in 2013. Insect infestations tend to be more localized than weed infestations (fig. 6). Farmers planted Bt cotton (to control insects such as tobacco budworm, cotton bollworm, and pink bollworm) on 35 percent of the cotton acres in 2000, 52 percent in 2005, and 75 percent in 2013. Bt corn—commercially introduced to control the European corn borer in 1996, the corn rootworm in 2003, and the corn earworm in 2010—was planted on 19 percent of corn acres in 2000, 35 percent in 2005, and 76 percent in 2013.

Other GE crops commercially grown in the United States are HT canola, HT sugarbeets, HT alfalfa, virus-resistant papaya, and virus-resistant squash.[10] In addition, other traits are being developed and tested, including cold/drought resistance and enhanced protein, oil, or vitamin content (see table 2).[11]

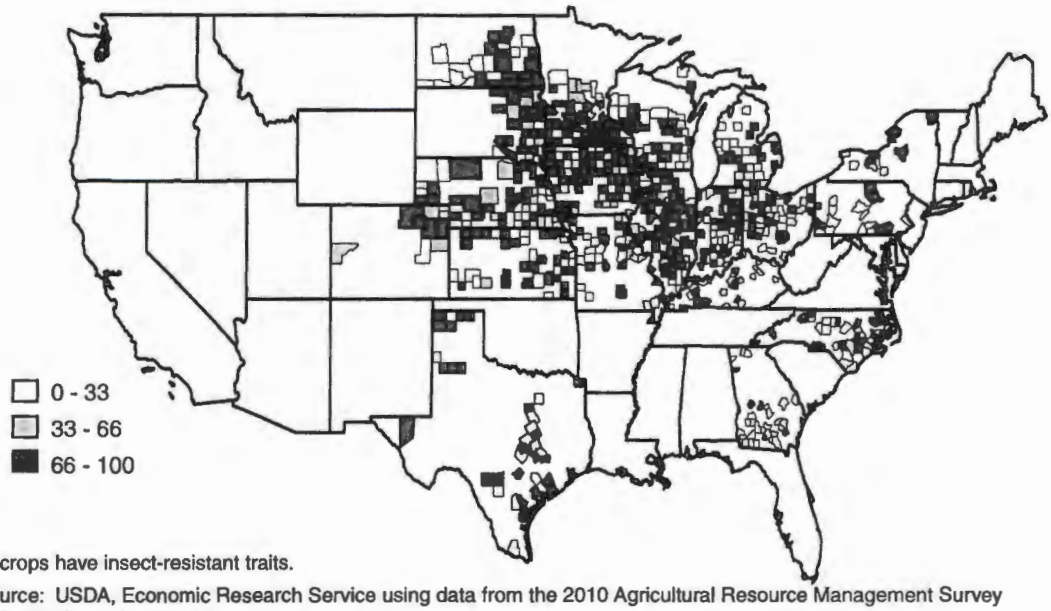
[9]Over 90 percent of U.S. acreage devoted to major crops has been treated with herbicides in recent decades (Osteen and Fernandez-Cornejo, 2012).

[10]Some other GE crops were only on the market for a limited amount of time. Bt potato varieties were introduced in 1996, but withdrawn from the market after the 2001 season. FlavrSavr tomatoes, which were genetically engineered to remain on the vine longer and ripen to full flavor after harvest, were introduced in 1994, but withdrawn from the market after several years.

[11]Drought-tolerant corn was approved for commercial use in 2011 (*Federal Register*, 2011; Monsanto, 2012) and commercially introduced in 2012.

Based on the Agricultural Resource Management Survey (see box, "ARMS Data"),[12] farmers indicate that they adopted GE corn, cotton, and soybeans primarily to increase yields (fig. 7). Other popular reasons for adopting GE crops were to save management time, to facilitate other production practices (such as crop rotation and conservation tillage), and to reduce pesticide costs.

Figure 6
Percentage of U.S. corn farmers who adopted Bt seeds in 2010



Bt crops have insect-resistant traits.

Source: USDA, Economic Research Service using data from the 2010 Agricultural Resource Management Survey (ARMS) Phase II corn survey.

The ARMS Data

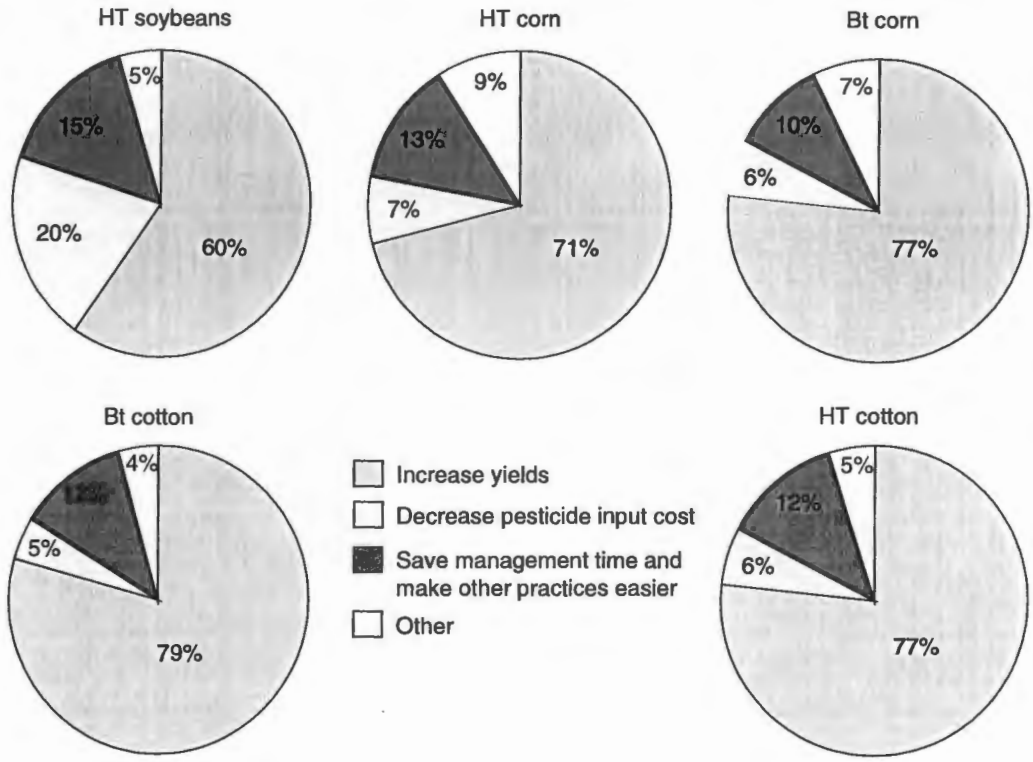
The Agricultural Resource Management Survey (ARMS), sponsored by USDA's National Agricultural Statistics Service (NASS) and the Economic Research Service (ERS), has a multi-phase, multi-frame, stratified, probability-weighted design. In other words, farmers with pre-selected characteristics are administered the ARMS each year. After data collection, NASS generates probability weights to help ensure that the ARMS sample accurately represents the population of U.S. famers.

The ARMS has three phases. Phase I, administered in the summer of the survey year, verifies that all respondents operate a farm or plant a specific crop. Phase II, administered in the fall or winter of the survey year, is a field-level survey that collects data on production practices and input use. Phase III, administered in the spring following the survey year, gathers data on debt, revenue, operating costs, and expenditures for the entire farm.

Phase I and Phase III are annual surveys that are administered to all respondents. Phase II is a commodity-specific survey that is administered annually for a rotating selection of crops. For instance, the ARMS Phase II Corn survey was administered in 2005 and 2010. The Phase II Soybean survey was administered in 2006 and the cotton survey was administered in 2007.

[12]USDA's National Agricultural Statistics Service (NASS) and Economic Research Service (ERS) sponsor the Agricultural Resource Management Survey (ARMS). This survey includes a crop-specific survey of production practices (called ARMS Phase 2) for selected major corps each once every 5 years on a rotating basis. This survey was conducted in 2006 for soybeans, 2007 for cotton, and 2010 for corn.

Figure 7
Farmers' reasons for adopting genetically engineered crops



Bt crops have insect resistant traits; HT crops have herbicide tolerance traits.

Sources: USDA Economic Research Service using data from Agricultural Resource Management Survey (ARMS) Phase II surveys: 2010 for corn, 2007 for cotton, and 2006 for soybeans.

Farm-Level Economic Impacts of GE Crop Adoption

The impacts of GE crop adoption vary by crop and technology. Many studies have assessed the factors that influence adoption as well as the impacts of GE crops on yields, net returns, and pesticide use (table 4; Fernandez-Cornejo and McBride, 2002).

Over the first 15 years of commercial use, GE seeds have not been shown to increase yield potentials of the varieties.[13] In fact, the yields of herbicide-tolerant or insect-resistant seeds may be occasionally lower than the yields of conventional varieties if the varieties used to carry the HT or Bt genes are not the highest yielding cultivars, as in the earlier years of adoption (Fernandez-Cornejo and Caswell, 2006; National Research Council, 2010).[14] However, by protecting the plant from certain pests, GE crops can prevent yield losses to pests, allowing the plant to approach its yield potential.

[13]Potential yield is defined as "the yield of an adapted cultivar when grown with the best management and without natural hazards such as hail, frost, or lodging, and without water, nutrient, or biotic stress limitations (water stress being eliminated by full irrigation or ample rainfall)" (Fischer and Edmeades, 2010). Farm level (actual or effective) yield is equal to potential yield minus the yield lost to pests or to other stresses.

[14]Since Bt and HT traits protect yield rather than increase potential yield, it is possible that in some cases the Bt and HT traits are not introduced in the highest yielding germplasm. Over time, this so-called "yield drag" usually disappears (NRC, 2010, Ch 3). On the other hand, Shi et al. (2013) show that the opposite situation may arise if GE genes are added more frequently to "high quality" germplasm. They call this situation genetic selectivity bias.

Table 4

Summary of selected studies on the effects of genetically engineered crops on yields, pesticide use, and net returns

Crop/researchers/date of publication	Data source	Effects on		
		Yield	Pesticide use	Net returns
Herbicide-tolerant soybeans				
Delannay et al., 1995	Experiments	Same	na	na
Roberts et al., 1998	Experiments	Increase	Decrease	Increase
Arnold et al., 1998	Experiments	Increase	na	Increase
Marra et al., 1998	Survey	Increase	Decrease	Increase
Reddy and Whiting, 2000	Experiments	Same	na	Increase
Duffy, 2001	Survey	Small decrease	na	Same
Fernandez-Cornejo et al., 2002[1]	Survey	Small increase	Small increase	Same
McBride & El-Osta, 2002[2]	Survey	na	na	Same
Bradley et al., 2004	Experiments	Same	na	na
Marra et al., 2004	Survey	Same	na	Increase
Herbicide-tolerant cotton				
Vencill, 1996	Experiments	Same	na	na
Keeling et al., 1996	Experiments	Same	na	na
Goldman et al., 1998	Experiments	Same	na	na
Culpepper and York, 1998	Experiments	Same	Decrease	Same
Fernandez-Cornejo et al., 2000[1]	Survey	Increase	Same	Increase
Adhicari et al. 2000	Survey	na	na	Increase
Herbicide-tolerant corn				
Fernandez-Cornejo and Klotz-Ingram, 1998	Survey	Increase	Decrease	Same
Ferrell and Witt, 2002	Experiments	Same	na	Small increase
McBride & El-Osta, 2002[2]	Survey	na	na	Increase
Parker et al., 2006	Experiments	Same	na	na
Bt cotton				
Stark, 1997	Survey	Increase	Decrease	Increase
Gibson et al., 1997	Survey	Increase	na	Increase
ReJesus et al., 1997	Experiments	Same	na	Increase
Bryant et al., 19993	Experiments	Increase	na	Increase
Marra et al., 1998	Survey	Increase	Decrease	Increase
Fernandez-Cornejo et al., 2000[1]	Survey	Increase	Decrease	Increase
Falck-Zepeda et al., 2000[1]	Survey	Increase	na	Increase
Cattaneo et al., 2006	Survey	Increase	Decrease	na
Piggott and Marra, 2007	Experiments	Increase	na	Increase
Bt corn				
Rice and Pilcher, 1998[1]	Survey	Increase	Decrease	Depends on infestation

continued—

Table 4

Summary of selected studies on the effects of genetically engineered crops on yields, pesticide use, and net returns—continued

Crop/researchers/date of publication	Data source	Effects on		
		Yield	Pesticide use	Net returns
Marra et al., 1998	Survey	Increase	Decrease	Increase
Duffy, 2001[2]	Survey	Increase	Na	Same
Baute, Sears, and Schaafsma, 2002	Experiments	Increase	Na	Depends on infestation
McBride & El-Osta, 2002[4]	Survey	Na	Na	Decrease
Pilcher et al., 2002[5]	Survey	Increase	Decrease	Na
Dillehay et al., 2004[6]	Experiments	Increase	Na	Na
Mitchell et al., 2004[7]	Experiments	Increase	Na	Depends on infestation
Fernandez-Cornejo and Li, 2005[8]	Survey	Increase	Decrease	Na
Mungai et al., 2005[9]	Experiments	Increase	Na	Na
Fang et al., 2007[10]	Experiments	Increase	Na	Na

na = not analyzed in the study; [1]Results using 1997 data; [2]Results using 1998 data; [3]Results are for 1996 and 1998, results were different for 1997 when the pest pressure was low; [4]Results using 1998 data; [5]Results using 1996-1998 data; [6]Results using 2004-2006 data; [7]Results using data from 1997-1999 ; [8]Results using data from 2001; [9]Results using data from 2002-2003, [10]Results using data from 2002.

The profitability of GE seeds for individual farmers depends largely on the value of the yield losses mitigated and the associated pesticide and seed costs.[15] GE adoption tends to increase net returns if the value of yield losses mitigated plus the pesticide savings exceeds the additional GE seed costs.

Adoption of Bt crops increases yields by mitigating yield losses to pests. Bt crops are particularly effective at mitigating yield losses. For example, before Bt corn was commercially introduced in 1996, the European corn borer was only partially controlled using chemical insecticides (Fernandez-Cornejo and Caswell, 2006). Chemical use was not always profitable, and timely application was difficult. Many farmers accepted expected yield losses of 0.4 to 3.2 bushels from this pest rather than incur the expense and uncertainty of chemical control (Hyde et al., 1999). After the introduction of Bt corn, adopters who had previously controlled corn borer infestations using insecticides lowered their pesticide costs and increased their yields. Adopters who had not previously treated European corn borer infestations with insecticides achieved only yield gains (and may have incurred higher seed costs).

In addition to improvements in background germplasm, Bt corn yields have increased over time as new insect resistance traits have been incorporated into the seeds and multiple (stacked) traits have become available (Fernandez-Cornejo and Wechsler, 2012). For instance, upon commercial introduction in 1996, Bt corn seeds were only resistant to one type of pest: the European corn borer. Since then, resistance to corn rootworms (2003) and corn earworms (2010) has been introduced.

[15]In this report, net returns are defined as per-acre revenues minus per-acre variable costs. Revenues per acre are equal to crop yields times crop price. Per-acre variable input costs include pesticide, seed and labor costs. Seed costs paid by adopters of GE varieties include a technology fee. This measure of net returns is used because most of the financial impacts of adopting GE crops result from changes in crop yields, chemical costs, and increased seed costs. This measure is estimated using field-level data and captures the greatest influence that GE crop adoption would have on farm financial performance as it also filters out the impact of other farm activities—such as livestock production (Fernandez-Cornejo and McBride, 2002). The econometric estimation involves estimating a restricted profit function (Fernandez-Cornejo and Wechsler, 2012) together with the associated supply function and input demand functions (hired labor is also included and wages are used as the *numeraire*).

Most experimental field tests and farm surveys show that Bt crops produce higher yields than conventional crops (table 4). Intuitively, Bt adopters are more likely to obtain higher yields than nonadopters by controlling insects and thus reducing yield losses to pests. The yield gain of Bt crops has become larger in recent years as new Bt traits have been incorporated into the seeds and multiple (stacked) traits have become available. For example, ARMS data show that the yield gain by Bt corn adopters relative to conventional varieties increased from 12.5 bushels per acre in 2001 to 16 bushels in 2005 and 26 bushels in 2010 (table 5; Fernandez-Cornejo and Li, 2005).[16] The geographical distributions of Bt adoption rates and average corn yields for 2010 are shown in figures 6 and 8, respectively.

While mean comparisons are illustrative, definitive conclusions about relative yields are possible only if the data are generated under experimental settings where factors other than adoption are controlled for by making them as similar as possible (Fernandez-Cornejo and McBride, 2002; NRC, 2010).[17] This is not the case with survey data.[18] Bt use is not random. Surveyed farmers are not randomly assigned to a treatment group (adopters) and a control group (nonadopters). Consequently, adopters and nonadopters may be systematically different from one another (for example, in terms of management ability). If these differences affect both farm performance and Bt adoption, they will confound the analysis (Fernandez-Cornejo and McBride, 2002; Fernandez-Cornejo et al., 2002). This self-selection[19] biases the statistical results unless it is corrected (Greene, 1997). Fernandez-

Table 5

Bt corn adopters and non-adopters, 2005 and 2010 (Samnple means of selected variables)

Variable	Unit	Bt	Non-Bt	Difference	Significance
2005					
Yield	Bushels/acre	155.1	138.6	16.6	***
Insecticide use	Pounds Ai/acre	0.05	0.09	-0.04	1
Corn price	Dollars/bushel	1.95	2.01	-0.06	NS
2010					
Yield	Bushels/acre	159.2	132.7	26.5	***
Insecticide use	Pounds Ai/acre	0.02	0.02	0.00	NS
Corn price	Dollars/bushel	5.39	5.40	-0.01	NS

*, **, and *** Indicates statistical significance at 10, 5, and 1 percent level, respectively.
NS = Not significant. [1]Significant at the 5-percent level when using standard procedures but not significant (p value 0.15) when using the delete-a-group jacknife procedure to estimate variances (Kott, 1998).
Source: USDA Economic Research Service using data from 2005 and 2010 Agricultural Resource Management Survey corn surveys.

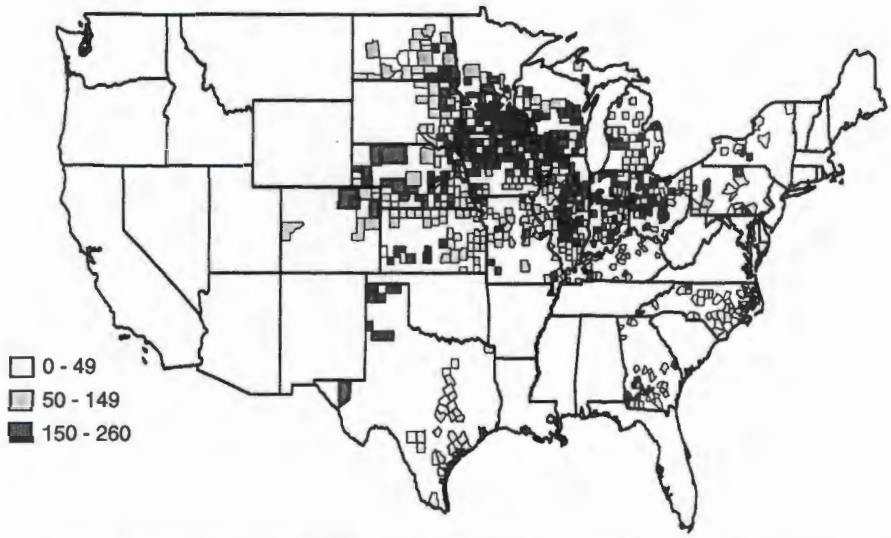
[16]The difference in means of corn yields between adopters and nonadopters is statistically significant for 2005 and 2010 using either the delete-a-group jackknife procedure (Kott, 1998) or the standard statistical test.

[17]The panel members who wrote the NRC report were Y. Carriere, W. Cox, D. Ervin, J. Fernandez-Cornejo, R. Jussaume Jr., M. Marra, M. Owen, P. Raven, L. Wolfenbarger and D. Zilberman.

[18]Marra et al. (2002a) provides an extensive discussion of the various types of biases that can arise when comparing means not only in farm (and field) surveys but in experimental settings as well (see box 3 for a discussion of the bias that may be caused by the halo effect).

[19]Self-selection is a type of endogeneity (Maddala, 1983; Greene, 1997). Endogeneity arises when there is a correlation between the explanatory variable and the model's residuals. If endogeneity is not accounted for (for instance, through the use of instrumental variable techniques), the results of the analysis will be biased. A common approach used to control for self-selection is sometimes called an instrumental variables approach. The model includes two stages. The first stage, which is referred to as the *adoption decision model*, is used to estimate the predicted values of the probability of adoption using a probit model. The second stage, or *impact model*, uses the predictions estimated in the first stage to estimate the impact of adopting Bt seeds on yields, seed demand, insecticide demand, and net returns.

Figure 8
Average yields (in bushels per acre) for U.S. corn farmers in 2010



Source: USDA, Economic Research Service using data from 2010 Agricultural Resource Management Survey (ARMS) Phase II corn survey.

Cornejo and Wechsler (2012) specified an econometric model to estimate the impact of adoption that accounts for self-selection. Using this model, they found that a 10-percent increase in the probability of adopting Bt corn was associated with a 1.7-percent increase in yields in 2005, and in a new ERS analysis using 2010 survey data, they found a 2.3-percent increase in yields (table 6). Using a similar econometric method to analyze cotton data, ERS researchers found that a 10-percent increase in the probability of adopting Bt cotton was associated with a 2.1-percent increase in yields in 1997 (Fernandez-Cornejo and McBride, 2002).

The effect of HT seeds on yields is mixed. The evidence on the impact of HT seeds on soybean, corn, and cotton yields is mixed (table 4). Several researchers found no significant difference between the yields of adopters and nonadopters of HT; some found that HT adopters had higher yields, while others found that adopters had lower yields. For instance, an ERS study found that a 10-percent increase in the adoption of HT cotton led to a 1.7-percent increase in cotton yields. HT soybean adoption was associated with a statistically significant, but small, increase in yields: a 10-percent increase in the probability of adopting HT soybeans was associated with a 0.3-percent increase in yields (Fernandez-Cornejo and McBride, 2002).

ARMS results show that HT soybean yields were 5 bushels per acre (3 percent) higher than conventional soybean yields in 2006 (but only significantly different at the 10-percent level) (table 7). In the case of corn, ARMS results show that HT corn yields were similar to those of conventional corn in 2010. However, unlike soybeans, the majority of corn (and cotton) producers in recent years use seed with stacked traits (figs. 9 and 10). Multiple stacked traits make evaluating the effect of individual GE traits on yields and profitability more complicated.

Stacked-trait seeds tend to have higher yields. An analysis of ARMS corn data indicates that stacked seeds (seeds with several GE traits) have higher yields than conventional seeds or seeds with only one GE trait. For example, 2010 ARMS data show that conventional corn seeds had an average

Table 6
The Impact of adopting Bt corn: Elasticities 2005, 2010[1]

	Elasticity with respect to the probability of adoption	
Variable	2005	2010
Net returns	0.17	0.23
Yield	0.17	0.23
Seed	0.1	0.21
Insecticide	NS	NS

[1]Elasticity measures the responsiveness of a variable (e.g., s, yield) to a change in another (e.g., adoption rate). It is unit free and always expressed in percentage terms.
Bt crops have insect-resistant traits
NS = Not significant.

Sources: 2005: Fernandez-Cornejo and Wechsler (2012). 2010: New analysis by Economic Research Service. (Model results using 2010 ARMS corn data. Model specification similar to that used by Fernandez-Cornejo and Wechsler, 2012).

Table 7
HT soybean adopters and non-adopters, 2006

Variable	Units	HT adopters	Non-adopters	Difference	Significance
Yield	Per acre yields, in bushels	45.6	40.6	5.0	*
Total herbicide use	Pounds AI per acre	1.36	1.05	0.31	NS
Glyphosate use	Pounds per acre	1.23	0.38	0.85	***
Other herbicides use	Pounds per acre	0.13	0.66	-0.53	**[1]

*, **, and *** Indicates statistical significance at 10-, 5-, and 1-percent level, respectively.
NS = Not significant.
[1]Significant at the 5-percent level when using standard procedures but not significant (p value = 0.14) when using the jacknife procedure to estimate variances (Kott, 1998).
HT crops have herbicide tolerance traits.

Source: Economic Research Service using data from 2006 Agricultural Resource Management Survey soybean survey.

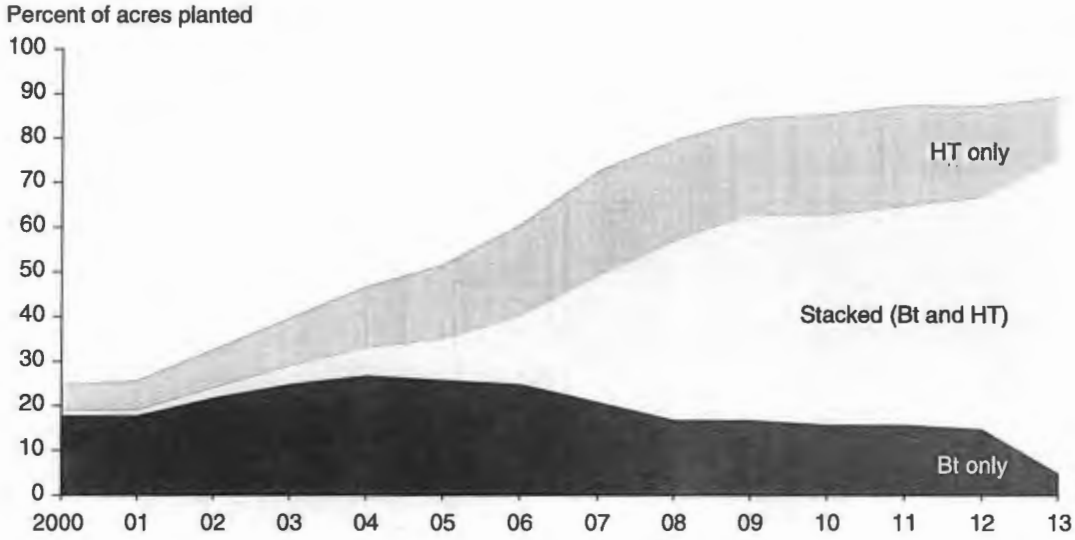
yield of 134 bushels per acre in 2010. By contrast, seeds with two types of herbicide tolerance (glyphosate and glufosinate) and three types of insect resistance (corn borer, corn rootworm, and corn earworm) had an average yield of 171 bushels per acre. These results are consistent with findings by Nolan and Santos (2012), who analyzed a rich dataset of experimental hybrid trials collected by the extension services of 10 universities in major corn-producing States from 1997 to 2009.

Not surprisingly, adoption rates of stacked-seed varieties have increased quickly (figs. 9 and 10). Stacked corn seeds grew from 1 percent of the corn acres in 2000 to 9 percent in 2005 and 71 percent in 2013, while stacked cotton seeds grew from 20 percent to 34 percent in 2005, and 67 percent in 2013 (figs. 9-10). The most widely adopted GE corn varieties have both Bt and HT traits (table 8). Varieties with three or four traits are now common.

GE seed prices are influenced by stacking and many other factors. The market price of seed incorporates the costs associated with seed development, production, marketing, and distribution (Fernandez-Cornejo, 2004). The price must reflect farmers' willingness to pay while ensuring a profit margin after costs. Furthermore, the price depends on the competitiveness of the particular seed market, and the pricing behavior of those firms that hold large shares of the market (NRC, 2010).

Figure 9

Adoption of genetically engineered corn: growth of stacked traits, 2000-2013

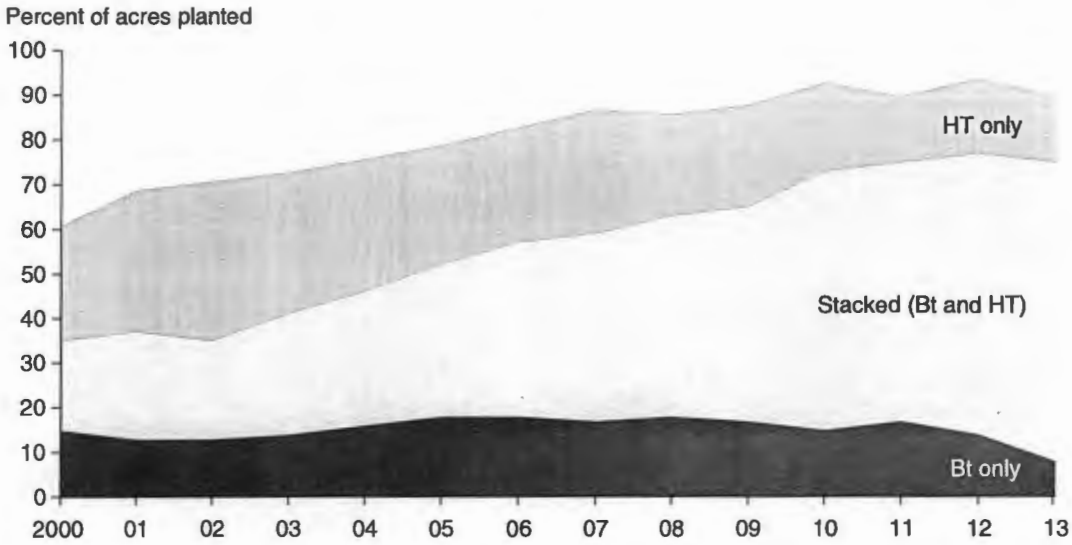


Bt crops have insect-resistant traits; HT crops have herbicide tolerance traits.

Source: U.S. Department of Agriculture (USDA), Economic Research Service (ERS). 2013. *Adoption of Genetically Engineered Crops in the United States,* data product.

Figure 10

Adoption of genetically engineered cotton: growth of stacked traits, 2000-2013



Bt crops have insect-resistant traits; HT crops have herbicide tolerance traits.

Source: U.S. Department of Agriculture (USDA), Economic Research Service (ERS). 2013. *Adoption of Genetically Engineered Crops in the United States,* data product.

In recent decades, private sector R&D costs have been rising with the application of new technologies, and much of the increase in seed prices has been associated with this trend (Krull et al., 1998). R&D costs vary among the different seed markets. For example, the corn seed market depends extensively on private sector R&D and passes these costs on to farmers. The wheat seed market

Table 8

Adoption of genetically engineered varieties by U.S. corn producers, 2010

	GE traits (percent adopters)			
Seed Type	Bt only	HT only	Bt/HT	No GE
1. Genetically modified **herbicide resistant** seed variety (*e.g. LIBERTYLINK; ROUNDUP READY CORN*)		21.36		
2. Non-genetically modified **herbicide resistant** seed variety (*e.g. IMI-CORN*)				3.48
3. Genetically-modified **Bt** variety for insect resistance to control the European Corn Borer (**Bt-ECB**) (*e.g. YIELDGARD, YIELDGARD CORN BORER, HERCULEX I, NATUREGARD, KNOCKOUT*)	7.12			
4. Genetically modified **Bt** variety for insect resistance to control the corn rootworm (**Bt-CRW**) (*e.g. YIELDGARD ROOTWORM, HERCULEX RW*)	3.06			
5. **Stacked** gene (trait) variety with both genetically modified **Bt-ECB** and **Bt-CRW** (*e.g. YIELDGARD PLUS, HERCULEX XTRA*)	3.81			
6. **Stacked** gene variety with **two** genetically modified herbicide resistant traits (e.g. LIBERTYLINK + ROUNDUP READY)		3.73		
7. **Stacked** gene variety with both genetically modified **Bt-ECB** and **herbicide resistant** (e.*g. YIELDGARD + ROUNDUP READY, YIELDGARD CORN BORER WITH ROUNDUP READY CORN 2, HERCULEX I + LIBERTYLINK*)			9.77	
8. **Stacked** gene variety with both genetically modified **Bt-CRW** and **herbicide resistant** (e.*g. YIELDGARD ROOTWORM WITH ROUNDUP READY CORN 2, HERCULEX CW + ROUNDUP READY CORN*)			8.03	
9. **Triple stacked** gene variety with genetically modified **Bt-ECB** and **Bt-CRW** plus **herbicide resistant** traits (*e.g. YIELDGARD PLUS WITH ROUNDUP READY CORN 2, HERCULEX XTRA + LIBERTYLINK*)			25.91	
10. **Stacked** gene varieties that, in addition to the ECB and the rootworm, can control the corn earworm			5.71	
11. Multiple (more than three) **trait** stacked variety with several Bt traits and two herbicide resistant traits—glyphosate (Roundup) and glufosinate (Liberty)			1.24	
12. None of the above				6.79
Total	13.99	25.08	50.66	10.26

Source: USDA Economic Research Service using data from 2010 Agricultural Resource Management Survey corn survey.

depends largely on public sector research, which is largely cost free for farmers. There is no GE wheat commercially available.[20]

The real price index for seed rose nearly 30 percent faster than the average index of prices paid by U.S. farmers over 1996-2007 (NRC, 2010). The price of GE soybean and corn seeds grew by about

[20]Monsanto discontinued breeding and field level research on its GE Roundup Ready wheat in 2004.

50 percent in real terms (adjusted for inflation) between 2001 and 2010 (fig. 11). The price of GE cotton seed grew even faster (NRC, 2010).

The increase in GE seed prices can be attributed in part to increasing price premiums over conventional seeds (which include technical fees) associated with the rising share of GE seeds with more than one trait and/or more than one mode of action for particular target pests (NRC, 2010). Another factor contributing to the increase in GE seed prices is the improvement in seed genetics (germplasm) (NRC, 2010). The rapid adoption of GE crops indicates that many farmers are willing to pay higher seed prices because of improved seed performance and the additional pest management traits embedded in the GE seed.

Various studies of stacked GE seed varieties have found that stacked seeds are priced less than the sum of their component values (Stiegert et al., 2010). Shi et al. (2008, 2010) note that sub-additive pricing is consistent with "the presence of economies of scope in seed production." Moreover, these scope economies are consistent with "synergies in R&D investment (treated as a fixed cost)" across stacked seeds that can contribute to reducing total cost (Shi et al., 2010). Shi et al. (2009) found that while increased concentration in the seed industry has contributed to higher seed prices, complementarity effects in production and distribution mitigate these effects. Kalaitzandonakes et al. (2010-11) conclude that, while estimation of market power and associated price markups is not straightforward, the U.S. seed industry show both "moderate market power" and dynamic market efficiency (as indicated by the balance between firm profits and investments in product quality and innovation) over their period of analysis (1997-2008).

Adoption, Net Returns, and Farm Household Income

The impacts of GE crop adoption vary by crop and technology. Most studies show that adoption of Bt cotton and Bt corn is associated with increased net returns (table 4). However, some studies of Bt corn show that profitability is strongly dependent on pest infestation levels.[21] The impact of HT seeds (for corn, cotton, and soybeans) on net returns depends on many factors.

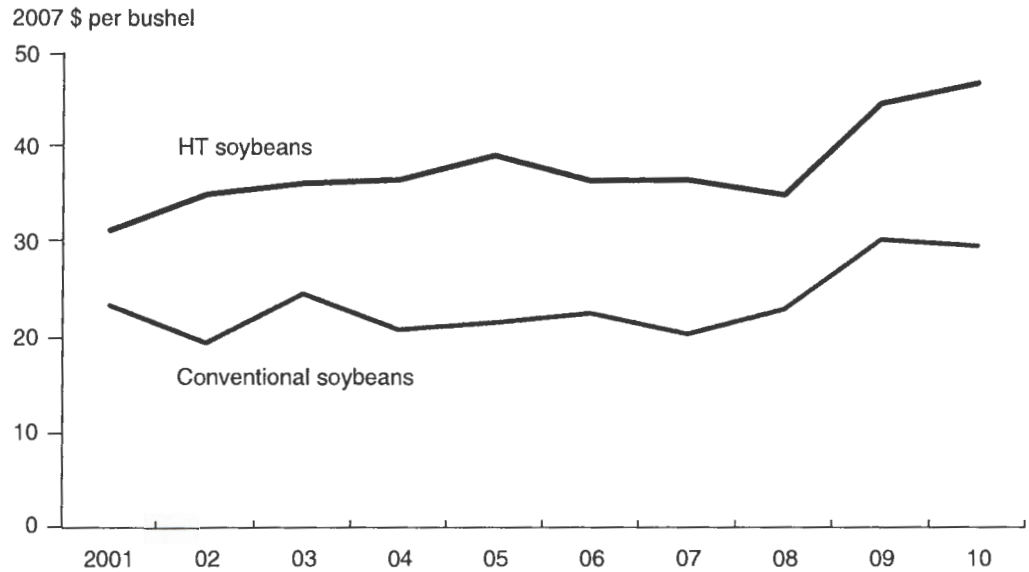
Planting Bt cotton and Bt corn is often more profitable than planting conventional seeds. ERS researchers found that adoption of Bt cotton was positively associated with net producer returns in 1997 (Fernandez-Cornejo and McBride, 2002). Using 2005 ARMS data, Fernandez-Cornejo and Wechsler (2012) found that a 10-percent increase in the probability of adopting Bt corn was associated with a 1.7-percent increase in net returns. In a new ERS analysis using 2010 ARMS data, we find that a 10-percent increase in the probability of adopting Bt corn was associated with 2.3-percent increase in net returns (table 6). Thus, there is essentially no change compared to earlier findings that planting Bt cotton and Bt corn is more profitable, as measured by net returns, than planting conventional seeds.

The effect of HT seeds on net returns depends on many factors. A primary advantage of herbicide-tolerant crops over traditional crops is cost savings (Fernandez-Cornejo and McBride, 2002). Producers who plant HT crops expect to achieve at least the same output while lowering weed

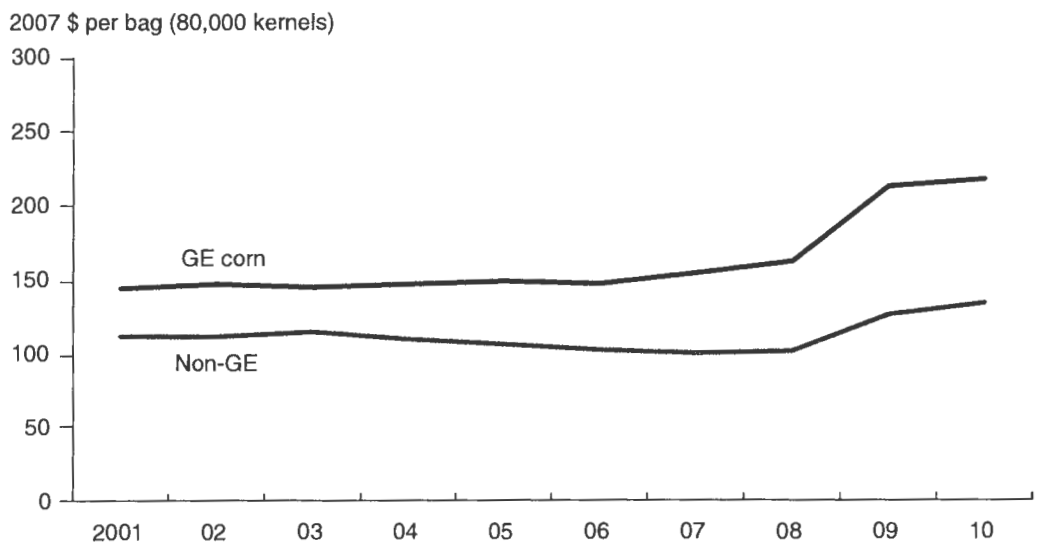
[21]Because pest pressure varies from one region to another, the economic benefits of Bt corn and consequently the rates of adoption vary regionally (fig. 6). Additionally, farmers must decide whether or not to use Bt corn before they know the severity of pest infestations, corn prices, or the price of insecticides. "Overadoption" may result from incorrect predictions (Fernandez-Cornejo and McBride, 2002). Alternately, farmers may be willing to adopt Bt seeds in order to reduce the risks associated with infestation levels that are higher than expected.

Figure 11

Prices of genetically engineered (GE) seed are higher than those of non-GE seed, soybeans



Prices of genetically engineered (GE) seed are higher than those of non-GE seed, corn



HT crops have herbicide tolerance traits.

Source: USDA Economic Research Service using data from USDA National Agricultural Statistics Service *Agricultural Prices*, various years.

control costs for chemicals and for mechanical methods, and minimizing the need for scouting. In return, producers pay more for HT seeds.

An additional economic effect is that the substitution of glyphosate, used in most herbicide-tolerant programs, for other herbicides decreases the demand for (and thus the price of) other herbicides

(Fernandez-Cornejo and McBride, 2002). Thus, the introduction of HT seeds may have lowered pesticide costs for both HT seed adopters and nonadopters.

Finally, HT seed-based production programs allow growers to use one product to control a wide range of both broadleaf and grass weeds instead of using several herbicides to achieve adequate weed control. Herbicide-tolerant crops also complement ongoing trends toward post-emergence weed control, the adoption of conservation tillage practices, and the use of narrow row spacing. The simplicity and flexibility of weed control programs for HT seeds require less management attention, freeing valuable management time for other activities (Fernandez-Cornejo and McBride, 2002).

HT seed has a mixed effect on net returns. The evidence on the impact of HT seeds (for corn, cotton, and soybeans) on net returns is mixed (table 4). Several researchers (Fernandez-Cornejo and McBride, 2002; Bernard et al., 2004; Marra et al., 2002) found that the adoption of herbicide-tolerant cotton has a positive impact on net returns. For example, Fernandez-Cornejo and McBride (2002) found that the elasticity of net returns with respect to the probability of adoption of herbicide-tolerant cotton was +0.18.[22] Bernard et al. (2004) found that adopting HT soybeans improved profits on Delaware farms. However, Fernandez-Cornejo et al. (2002) and McBride and El-Osta (2002) found no significant difference between the net returns of adopters and nonadopters of HT soybeans. Bullock and Nitsi (2001) found that HT soybean farmers are less profitable than their conventional counterparts. Overall, the empirical evidence on the impact of adopting herbicide-tolerant soybeans on net returns is inconclusive (NRC, 2010).[23]

The fact that several researchers found no significant differences between the net returns of adopters and nonadopters of HT crops (particularly HT soybeans) despite the rapid adoption of these crops suggests that many adopters may derive nonmonetary benefits from HT adoption. In particular, weed control for HT soybeans may be simpler, freeing up management time for leisure, enterprise growth, or off-farm income-generating activities.

HT crop adoption increases farm household income and has non-pecuniary benefits. ERS research shows that HT adoption is associated with higher off-farm household income for U.S. soybean farmers, most likely because time savings are used to generate income via off-farm employment (Fernandez-Cornejo et al., 2005). ERS researchers found that a 10-percent increase in the probability of adopting HT soybeans is associated with a 16-percent increase in off-farm household income. Household income from onfarm sources is not significantly associated with adoption of HT technology (Fernandez-Cornejo et al, 2007). These findings corroborate the notion that technology adoption is influenced by (or influences) the tradeoff between household/operator time spent in onfarm and off-farm activities. More recently, Gardner et al. (2009) confirm that genetically engineered crops lead to household labor savings in U.S. crop (corn and cotton) production. Using corn and soybean data, Marra and Piggott (2006) demonstrate that there are non-pecuniary benefits to GE crop adoption and show that farmers adopting GE crops place a monetary value on the convenience, flexibility, and increased worker safety associated with growing HT crops.

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[22]Elasticity measures the responsiveness of a variable (e.g., net returns) to a change in another (e.g., adoption rate). It is unit free and is expressed in percentage terms.

[23]Given the high rates of adoption of HT soybeans (more than 90 percent in recent years), econometric studies using recent data are problematic because of the small size of the sample of nonadopters and the likelihood that there may be other factors influencing the decision not to adopt (e.g., organic farming) of that small group. This may lead to a stronger selection bias compared to studies using data from earlier years.

Adoption and Pesticide Use

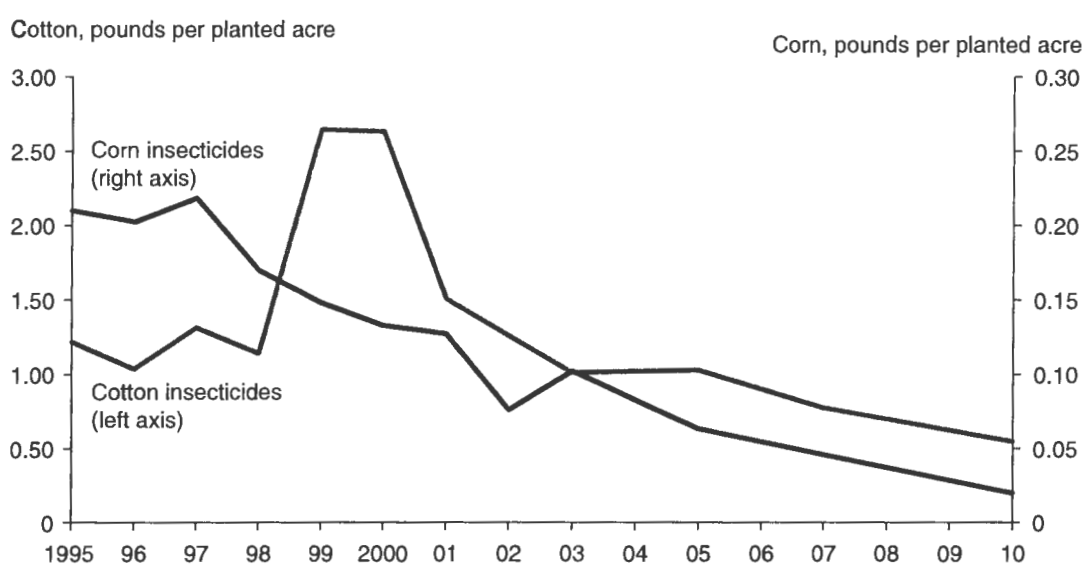
Many studies based on field tests and farm surveys have examined the extent to which GE crop adoption affects pesticide (insecticide and herbicide) use, and most results show a reduction in pesticide use (table 4). A National Research Council study (2010) concurred that GE crops lead to reduced pesticide use and /or lower toxicity compared to conventional crops.

Insecticide use decreases with the adoption of Bt crops. Generally, Bt adoption is associated with lower insecticide use (table 4). Pounds of insecticide (per planted acre) applied to corn and cotton crops have declined over the course of the last 15 years (fig. 12). (Results for cotton in 1999-2001 were distorted because of the high application rates of the insecticide Malathion during the boll weevil eradication program.)

Insecticide use on corn farms declined most years and had an overall drop from 0.21 pound per corn planted acre of corn in 1995 (the year before Bt corn was commercially introduced) to 0.06 in 2005 and 0.02 pound in 2010 (fig. 12). Insecticide use has declined for both Bt adopters and nonadopters in recent years. According to ARMS data, only 9 percent of all U.S. corn farmers applied insecticides in 2010.

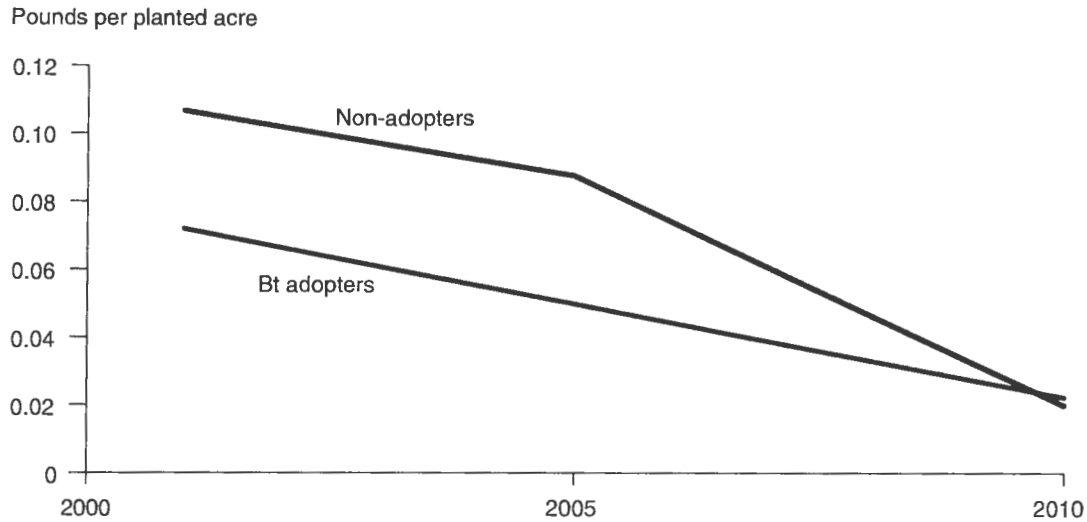
Econometric studies by ERS researchers have also found that, except for recent years, Bt crop adoption led to decreases in insecticide use, controlling for other factors. For example, Fernandez-Cornejo et al. (2003) show that the adoption of Bt cotton in the Southeast region (which had higher rates of Bt adoption) was associated with lower insecticide use on cotton in 1997. After controlling for other factors, a 10-percent increase in Bt corn adoption was associated with a decrease in insecticide use of 4.1 percent in 2001 (Fernandez-Cornejo and Li, 2005). However, Bt corn adoption was not significantly related to insecticide use in more recent years using 2005 data (Fernandez-Cornejo and Wechsler, 2012), as well as in a new ERS analysis using 2010 survey data (table 6).

Figure 12
Insecticide use in corn and cotton production, 1995-2010



Source: USDA Economic Research Service using data from USDA National Agricultural Statistics Service Agricultural Chemical Usage reports.

Figure 13
Insecticide use in corn farms: adopters and non-adopters of Bt corn, 2001-2010



Bt crops have insect-resistant traits.
Source: USDA Economic Research Service using data from 2001, 2005, and 2010 ARMS Phase II corn surveys.

Taken together, these results suggest that insect infestation levels on corn were lower in recent years than in earlier years and are consistent with findings by Hutchinson et al. (2010) that European corn borer populations have steadily declined over the last decade. Moreover, several researchers have shown that areawide suppression of certain insects such as the European corn borer and the pink bollworm are associated with the use of Bt corn and Bt cotton, respectively (see box, "Bt Crop Adoption and Areawide Pest Suppression").

Adoption of HT crops has mixed impact on herbicide use. Herbicide use on cotton and soybean acres (measured in pounds per planted acre) declined slightly in the first years following introduction of HT seeds in 1996, but increased modestly in later years (fig. 14a). Herbicide use on soybean farms has been mostly constant since 1996, but increased slightly starting in 2002 and peaked in 2006. Herbicide use on corn fell from about 2.6 pounds per acre in the early years of HT corn adoption to less than 2 pounds per acre in 2002 but increased moderately in recent years. Herbicide use on corn by HT adopters increased from around 1.5 pounds per planted acre in both 2001 and 2005 to more than 2.0 pounds per planted acre in 2010, whereas herbicide use by nonadopters did not change much (fig. 14b). HT adoption likely reduced herbicide use initially, but herbicide resistance among weed populations may have induced farmers to raise application rates in recent years, thus offsetting some of the economic and environmental advantages of HT corn adoption regarding herbicide use.[24]

The main effect of HT crop adoption on herbicide use is the substitution of glyphosate for more toxic herbicides. Despite the mixed but relatively minor effect HT crop adoption has had on overall herbicide usage, most researchers agree (NRC, 2010) that the main effect of HT crop adoption is the substitution of glyphosate for more traditional herbicides. Because glyphosate is significantly

[24]Adoption of conservation tillage by HT adopters may have also confounded these comparisons.

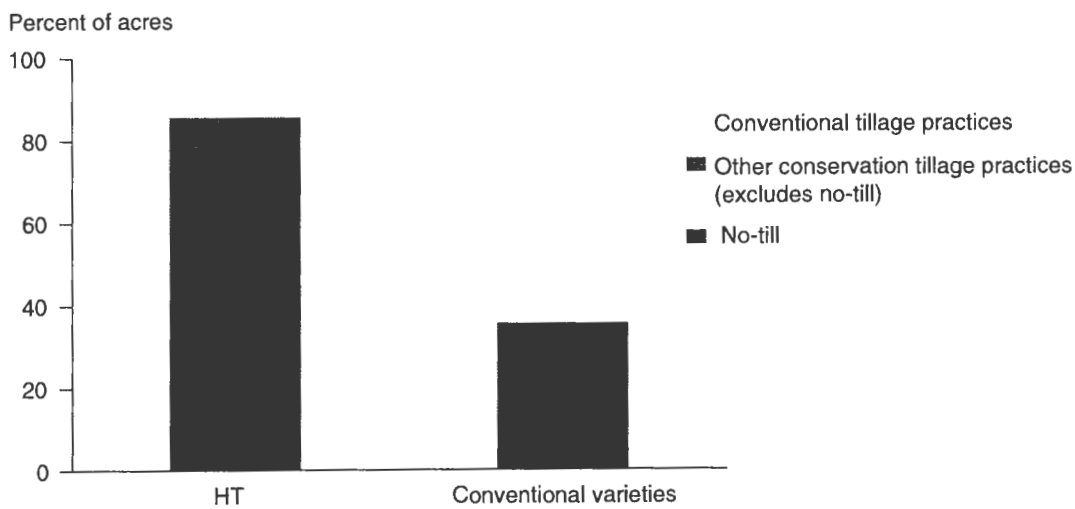
wind and water, increases water retention, and reduces soil degradation and water/chemical runoff. In addition, conservation tillage reduces the carbon footprint of agriculture.

Adopters of HT crops practice conservation tillage more than growers of conventional varieties. Since the 1980s, the adoption of conservation tillage practices by U.S. farmers has been facilitated by the availability of post-emergent herbicides that can be applied over a crop during the growing season. Post-emergent herbicides are especially beneficial in no-till production systems because these herbicides control weeds without tilling the soil. HT crops have helped spread no-till farming further since they often allow a more effective system than just using other post-emergent herbicides (Fernandez-Cornejo and Caswell, 2006).

According to USDA survey data, 60 percent of HT soybean planted acres used conservation tillage practices in 1997 versus 40 percent of conventional soybean acres (Fernandez-Cornejo and Caswell, 2006). By 2006, approximately 86 percent of HT soybean planted acres were under conservation tillage compared to only 36 percent of conventional soybean acres (fig. 15).

Differences in the use of no-till specifically are just as pronounced. While approximately 45 percent of HT soybean acres were cultivated using no-till technologies in 2006, only 5 percent of the acres planted with conventional seeds were cultivated using no-till techniques.[27] Cotton and corn data exhibit similar though less pronounced patterns. Thirty-two percent of HT cotton acres were planted using conservation tillage in 2007, compared to 17 percent of conventional cotton acres (fig. 16). Thirty-three percent of HT corn acres were planted using no-till in 2005, versus 19 percent of conventional corn acres (fig. 17).

Figure 15
Adopters of herbicide-tolerant crops used conservation tillage more than did growers of conventional varieties: soybeans, 2006



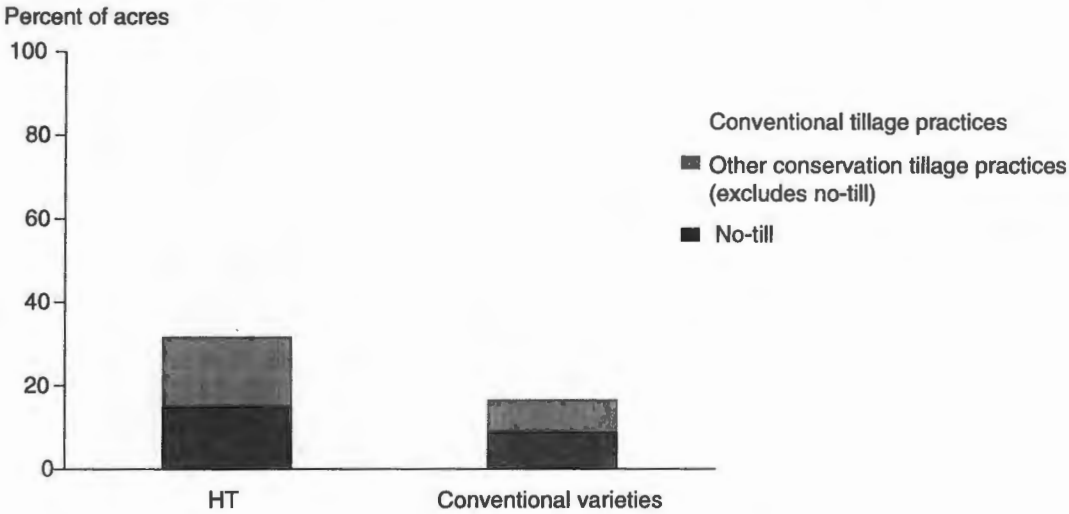
Conservation tillage includes no-till, ridge-till and mulch-till.
Source: USDA Economic Research Service using data from 2006 ARMS Phase II soybean survey.

[27]No-till systems are often considered the most effective of all conservation tillage systems. They leave 100 percent of crop residues on the soil surface and the soil is undisturbed from harvest to planting, resulting in the highest percentage of surface being covered by crop residues, minimizing soil loss and water runoff (Janssen and Hill, 1994).

These trends suggest that HT crop adoption may encourage soil conservation practices. In addition, a review of several econometric studies point to a two-way causal relationship between the adoption of HT crops and conservation tillage (NRC, 2010). This implies that the adoption of herbicide-tolerant crops indirectly benefits the environment.

Figure 16

Adopters of herbicide-tolerant crops used conservation tillage more than did growers of conventional varieties: cotton, 2007

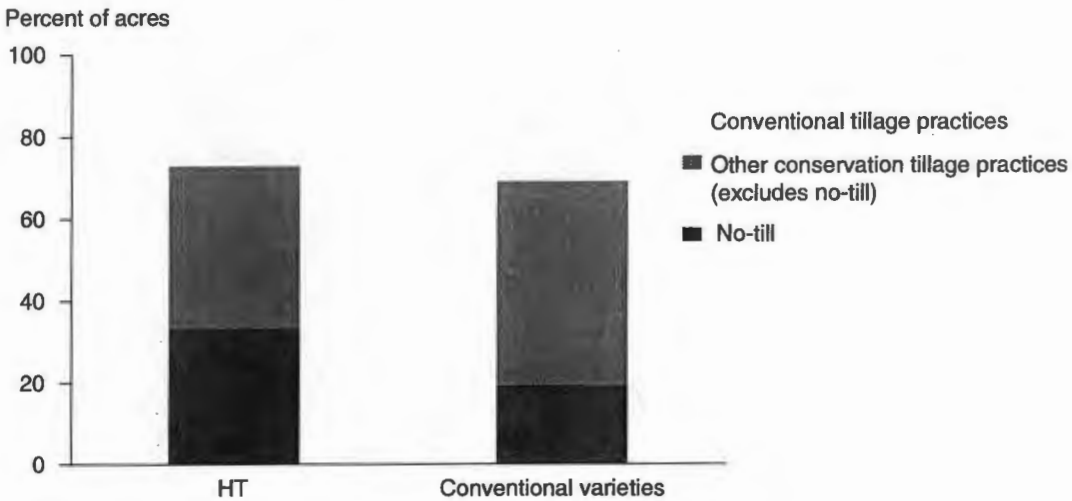


Conservation tillage includes no-till, ridge-till and mulch-till.

Source: USDA Economic Research Service using data from 2007 ARMS Phase II cotton survey.

Figure 17

Adopters of herbicide-tolerant crops used conservation tillage more than did growers of conventional varieties: corn, 2005



Conservation tillage includes no-till, ridge-till and mulch-till.

Source: USDA Economic Research Service using data from 2005 ARMS Phase II corn survey.

Pest Resistance Management and GE Crops

Pesticide resistance evolution occurs when pesticide use favors the survival of pests naturally resistant to the pesticide. Over time, these resistant pests become predominant in the pest population (see box, "Economics of Resistance Management"). Developers of Bt crops and other researchers recognized early on that insect resistance to Bt toxins could develop. Measures to delay the onset of such resistance (such as refuges) were taken and, so far, the emergence of insect resistance to Bt crops has been low and of "little economic and agronomic significance" (NRC, 2010), but there are some indications that insect resistance is developing to some Bt traits in some areas.[28] Also, since many users of HT crops rely solely on glyphosate to control weeds, resistance to this herbicide was anticipated by some researchers. Thus far, overreliance on glyphosate and a reduction in the diversity of weed management practices adopted by crop producers have contributed to the evolution of glyphosate resistance in 14 weed species and biotypes in the United States.

Insect Resistance to Bt Crops

Prior to the availability of Bt crops, entomologists and other scientists successfully argued that mandatory refuge requirements—planting sufficient acres of the non-Bt crop near the Bt crop—were needed to reduce the rate at which targeted insect pests evolved resistance. Such refuges slow the rate at which Bt resistance evolves by allowing target insects that are susceptible to the Bt toxin to survive and reproduce. To be effective, the refuge must be positioned appropriately and be large enough to ensure that insects that survive on the Bt acres mate with insects that survive on the non-Bt acres. Such interbreeding increases the chances that their progeny are susceptible, having inherited Bt resistance as a recessive trait.[29]

The U.S. Environmental Protection Agency (EPA) instituted mandatory refuge requirements as a condition of the registration of Bt corn and Bt cotton varieties for commercial use in the United States. This was the first time regulations were used to manage resistance to a pest control technology. Bt crop growers were required to sign a contract with their technology provider to comply with minimum refuge requirements, and technology providers were required to monitor and enforce grower compliance. An analysis of more than a decade of monitoring data suggests that the minimum refuge requirement, as well as natural refuges that also serve as hosts for target insect pests, has helped delay the evolution of Bt resistance (Tabashnik et al., 2008).

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[28]There is some indication of emergence of Bt-resistant corn rootworm in some parts of the Corn Belt http://www.bloomberg.com/news/2012-09-04/-mounting-evidence-of-bug-resistant-corn-seen-by-epa.html. http://bulletin.ipm.illinois.edu/article.php?id=1704. There is also anecdotal evidence that resistance is a contributing factor to increasing corn insecticide sales in 2012 and 2013 (I. Berry; *WSJ*, May 21, 2013). Tabashnik et al. (2013) recently analyzed 77 studies carried out in 5 continents from 1996 to 2012. They find that "although most pest populations remained susceptible, reduced efficacy of Bt crops caused by field-evolved resistance has been reported now for some populations of 5 of 13 major pest species examined, compared with resistant populations of only one pest species in 2005." They conclude that "the increase in documented cases of resistance likely reflects increases in the area planted to Bt crops, the cumulative duration of pest exposure to Bt crops, the number of pest populations exposed and improved monitoring efforts." They also conclude that while "regulations in the United States and elsewhere mandate refuges of non-Bt host plants for some Bt crops, farmer compliance is not uniformly high and the required refuge percentages may not always be large enough to achieve the desired delays in evolution of resistance. Both in theory and practice, using Bt crops in combination with other tactics as part of integrated pest management may be especially effective for delaying pest resistance."

[29]A dominant trait will be expressed in progeny if at least one of the parents has the gene for that trait. A recessive trait will be inherited if both parents have the gene for that trait. (Hedrick, 2000).

Economics of Resistance Management

When a pest population is confined to an individual farming operation, many of the benefits and costs associated with the farmer's pest control decisions accrue to and are borne by the farmer. In this hypothetical scenario, economic theory suggests that the pest population will be maintained at an economically efficient or socially optimal level.[1] However, when the pest moves from farm to farm, the pest control decisions made by any given farmer will affect the net returns accruing to that farmer, as well as those accruing to nearby farmers, although to a lesser extent. Because the effects of any farmer's control decisions on the regional pest population are practically negligible and because the benefits and costs associated with those effects are not borne by any given farmer (are not fully internalized), those effects might not be accounted for in the farmer's control decision. Because regional pest population dynamics are determined collectively by the decisions made by each farmer in the region, however, economic theory suggests that the pest population will not be maintained at a socially optimal level (Feder and Regev 1975).

This situation is referred to in the economics literature as a stock externality, an economic environment in which an individual ignores the impact of a decision that affects the level of a resource that is used by others (Gordon, 1954). In the presence of a stock externality, the resource might not be managed in a socially optimal manner. When the resource is a mobile pest population, Feder and Regev (1975) show how the introduction of a marginal user cost on pesticides, via a tax or a subsidy depending on the characteristics of the problem, can improve social welfare by ensuring that all of the net returns to pesticide use accrue to each user. The marginal user cost for a pesticide is the marginal expected present value of economic and environmental costs associated with the use of the pesticide, including impacts on regional pest population dynamics, impacts on the regional population dynamics of beneficial organisms that prey on the pest, and the evolution of resistance in the regional pest population to the pesticide, as well as the health effects associated with the accumulation of toxic pesticide residues and water/air pollution.

Pesticide resistance evolution is a process of artificial selection in which pesticide use favors the survival of particular insects and weeds and other pests resistant to the pesticide so that the frequency of resistant individuals in the population increases over time. In the presence of a mobile pest, farmers might not account for the effects of their pesticide use decisions on the evolution of resistance nor for the effects on regional pest population dynamics (Miranowski and Carlson, 1986). Hueth and Regev (1974) suggest that the institution of a tax equal to the marginal user cost could improve social welfare by ensuring that the costs associated with resistance are incorporated by farmers. Regev et al. (1983) examine such a tax in another theoretical analysis; however, noting the difficulty of applying the tax in practice, they suggest pesticide-use restrictions as an alternative.

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[1]For the purposes of this discussion, we are ignoring the costs associated with the accumulation of toxic pesticide residues, leaching of pesticides into surface and groundwater resources, and pesticide drift.

Refuge requirements depend on economic factors. Hurley et al. (2001) and Livingston et al. (2004) examine the characteristics of economically efficient refuge requirements for U.S. corn and cotton producers, respectively, for the single-toxin Bt corn and Bt cotton varieties. Both studies demonstrate that economic returns might be improved over the long run if corn and cotton producers comply with refuge requirements because of forestalling the onset of Bt resistance. The size of the economically efficient refuge requirement, however, was shown to depend on the length of the time horizon, the discount rate, and resistance evolution to conventional insecticides used to control target insect pests in the refuge acres. The refuge's ideal size was also shown to be extremely sensitive to how dominant the inherited Bt resistance trait is. Larger refuges are required to maintain susceptibility to Bt in target pest populations for longer time periods and when Bt resistance is inherited as a more dominant genetic trait by the target insect species.

Livingston et al. (2007) provide empirical support for the relaxation of mandatory refuge requirements for farmers who plant cotton varieties that express multiple Bt toxins in areas that have sufficient sources of unstructured refuge.[30] These varieties control the target pest species much more effectively than single-toxin varieties. Also, most U.S. cotton is grown in areas with sufficient sources of unstructured refuge—including both cultivated and uncultivated crops and plants that serve as alternative hosts for the target insect pest species, particularly the cotton bollworm and the tobacco budworm—effectively eliminating the need for a structured (or minimum) refuge requirement. Cotton growers in Arizona, California, New Mexico, and west Texas are still required to plant minimum, structured refuges.

Refuge requirements are reduced for multiple-toxin Bt cotton varieties in some areas. EPA has eliminated the minimum refuge requirement for certain Bt cotton varieties that express multiple toxins in areas that appear to have sufficient unstructured refuge, but not for Bt corn varieties that express multiple toxins. The latter are less toxic to an important target pest known as the western corn rootworm, which might inherit Bt resistance as a partially dominant trait. Recently, western corn rootworm larvae were collected from Iowa Bt cornfields that showed evidence of root damage, and laboratory assays later confirmed that their progeny were less susceptible to Bt toxins (Gassmann et al., 2011). This has raised concerns about regulatory compliance and a continued need for minimum refuge requirements for Bt corn growers.

Evolution of Glyphosate Resistance in Weeds

The herbicide glyphosate is more environmentally benign than the herbicides that it replaces. Glyphosate controls a wide array of weeds and is used on most of the HT corn, soybeans, and cotton grown in the United States. Glyphosate has been the most heavily used pesticide in the United States since 2001 (Grube et al., 2011), due in part to the popularity of HT crops and the steady decline in its price following the expiration of glyphosate's patent in 2000 (Duke and Powles, 2008).[31]

Because the pollen and seeds of many different weed species can disperse between farms in the atmosphere and in conjunction with the movement of animals and farm equipment, economic incentives for adopting best management practices (BMPs) that maintain the effectiveness of glyphosate

[30]According to Andow et al. (2008), "a structured refuge is one that is planted near Bt cotton deliberately and an unstructured refuge relies on the other crops already grown as part of the local cropping system and where Bt is not used."

[31]Impending expiration of glyphosate patent protection in 2000 and the availability of generic glyphosate herbicides have led to a decrease in its price since 1998.

over time are reduced (Miranowski and Carlson, 1986).[32] The economic and biological impacts associated with any farmer's pesticide-use decisions will accrue not only to that farmer, but to other nearby farmers as well. Unless resistance management is coordinated across farms, economic incentives for farmers to account for the effects of their decisions on resistance are reduced, even on their own farms. This is because the effectiveness and longrun economic benefits of using BMPs to manage resistance depend on the level of adoption by nearby farmers, while the short-run costs of BMP adoption are borne solely by the adopters.[33] In this setting, resistance can evolve at an economically inefficient rate because market-based economic incentives are insufficient to promote an efficient level of BMP adoption (Hueth and Regev, 1974; Feder and Regev, 1975).

This reduction in economic incentives to adopt BMPs and the economic and environmental benefits associated with the HT crop-glyphosate combination have contributed to an overreliance on glyphosate and a concomitant reduction in the diversity of weed management practices by U.S. crop producers. This, in turn, has contributed to the evolution of glyphosate resistance in some weed species and a shift in weed composition in fields, favoring weeds that are naturally resistant to glyphosate. This leads to higher management costs, reduced yields and profits, and increased use of less environmentally benign herbicides. Glyphosate resistance is currently documented in 14 U.S. weed species (Heap, 2012), and the potential exists for much more acreage to be affected (Frisvold et al., 2009; Shaw et al., 2011).[34]

Because no new major herbicide chemistry has been made commercially available in the last 20 years, and because few new ones are expected to be available soon (Harker et al., 2012), many plant scientists believe that slowing the rate of glyphosate resistance and the spread of glyphosate-resistant (GR) weeds are among the most important problems facing U.S. crop producers (NRC, 2010, 2012). In addition, private and public programs seeking to promote the adoption of BMPs are in their infancy and do not address the reduced incentives to adopt BMPs caused by the ability of weed seeds to disperse between farms—the programs do not discourage the use of weed management practices that contribute to resistance.

Best management practices (BMP) may help sustain the efficacy of HT crops. Because weeds tend to inherit resistance to glyphosate as a dominant trait, the mandatory refuge requirement, which has been successful in sustaining the efficacy of Bt crops, might not be a viable option for HT crops (NRC, 2010). Depending on the weed, several BMPs, which are relatively difficult to monitor and enforce, might be required. These include using at least one other herbicide (particularly a residual herbicide that takes longer to decompose and thus stays in the soil longer), rotating crops, increasing the intensity of tillage, cleaning equipment between use in different fields to prevent the spread of weed seeds and pollen, and optimizing application by using the application rate recommended on the herbicide label and applying herbicides at the appropriate time and uniformly throughout the field. Some of these practices have been associated with increased weed management costs (Hurley et al., 2009), and many farmers, perhaps due partly to the incentive problems described above, are

[32]Dauer et al. (2009) provide empirical evidence that horseweeds, one of the more important glyphosate-resistant weed species, can disperse between farms.

[33]BMPs include applying multiple herbicides with different modes of action at the recommended rates and developmental stages for the target weeds in the field, increasing the intensity of tillage to reduce the fraction of seeds that germinate, planting weed-free crop seed, scouting fields routinely, cleaning equipment to reduce the rate of introducing weeds to other fields, and preventing weed introductions by maintaining field borders (Norsworthy et al., 2012).

[34]Glyphosate resistance in weed species and biotypes in the United States is also due to glyphosate use in tree orchards, on roadsides, and on non-HT crops, where it is used before crops are planted and after they are harvested.

only adopting BMPs in the presence of glyphosate-resistant weeds, as opposed to adopting preventative approaches.[35]

Another approach currently being promoted by technology providers is the use of HT crops that are tolerant to two herbicides. However, the commercial availability of these types of crops does not address the incentive problem caused by the ability of weeds to disperse between farms. At least one HT crop provider is issuing rebates to growers who plant specific HT crop varieties, use glyphosate herbicides manufactured by that HT crop technology provider, and agree to use pre-emergent, residual herbicides.[36] The rebate program promotes the use of glyphosate in combination with other herbicides, which mitigates resistance; however, the program does not fully address the reduced incentive to adopt BMPs caused by the ability of weed seeds and pollen to disperse between farms.

USDA's NRCS recently initiated the Integrated Pest Management (IPM) Herbicide Resistance Weed Conservation Plan, which specifies guidelines for monitoring, recordkeeping, IPM, and conservation that satisfy criteria for soil, water, and air quality. Under the program, USDA pays farmers 75 percent of the cost of developing activity plans, which contain the minimum components needed to apply for cost-sharing assistance under the Environmental Quality Incentives Program (EQIP). This program can help promote the adoption of BMPs. However, in the absence of widespread adoption of BMPs, farmer participation might be insufficient to manage the evolution of glyphosate resistance in a manner that is optimal for crop producers.

[35]Many farmers incorrectly assume there is no need to adopt BMPs because new herbicides will be available in the future (Norsworthy et al. 2012). In addition, the benefits of using BMPs occur in the future and are uncertain, as opposed to the certain increase in production costs.

[36]More information about this program is available at https://www.roundupreadyplus.com/Pages/Home.aspx.

Consumer Demand for GE Products

The successful marketing of crops produced via genetic engineering is contingent on consumer acceptance of these products (or products containing GE ingredients). Some consumers, including those in the European Union, have indicated a reluctance to consume GE products. In other countries, including the United States, expression of consumer concern is less widespread. Researchers studying markets in high-income nations often find that consumers are willing to pay a premium for non-GE products,[37] but recent studies have found that some consumers in developing countries, and others interested in second-generation traits like enhanced nutrition content, are more willing to consider GE foods. Information and types of GE technology may also affect consumer response to GE foods. In some countries, retailers have developed particular policies for GE ingredients in the foods they sell under their own brand names.

Willingness-to-Pay for GE and Non-GE Foods

Researchers have used a variety of methodologies to determine how much consumers are willing to pay for GE foods and how much they are willing to pay to avoid them (table 9). Some studies use the contingent valuation method, in which consumers are asked how much they would pay for non-GE foods. Other studies use experimental auctions, in which participants bid with actual money.

Consumers' responses on a survey, however, may differ from what they are actually willing to spend while shopping (Lusk, 2003). Meta-analyses of surveys indicate that when consumers are asked how much they value a good hypothetically, the values differ from what they actually will pay in a market setting, with the size of the difference dependent on such factors as whether consumers are asked how much they are willing to accept or willing to pay, the magnitude of the hypothetical price, the type of auction used or choices offered, and the type of good being evaluated (Murphy et al., 2005; List and Gallet, 2001). Murphy et al. (2005) found that models where respondents were asked to choose among alternatives, as opposed to developing their own, were associated with less hypothetical bias. On average, consumers tend to overstate what they would pay for goods, although in a significant minority of cases, they understated what they would pay. The willingness-to-pay values therefore may only approximate what consumers will actually pay.

Mather et al. (2011), combining surveys with market methodology, found that when consumers in five EU countries plus New Zealand were surveyed, they selected organic over conventional or GE fruit.[38] However, when actual fruit stalls were set up offering three different varieties of fruit, consumers in Sweden, New Zealand, and Germany bought more of the GE varieties, also labeled "spray-free," but only when they were offered at a 15-percent discount.

Consumer Acceptance of GE Foods in High- and Low-Income Countries

Research on consumer acceptance of GE foods in high-income countries such as the United States, UK, and Canada finds that consumers are willing to pay a premium for non-GE foods

[37]Non-GE foods can be more expensive if they cost more to produce, or if marketing streams must be kept separate.

[38]Consumers who asked about the GE fruit were told that it contained genes that caused it to produce a natural insecticide. GE fruit is not commercially available in these countries, and consumers who expressed surprise about this were told the fruit may have come from an experimental orchard (Mather et al., 2011).

Table 9

Studies in which consumers were willing to pay a premium for non-GE food

Country	Good	Study	Willingness to pay premium [1]
United States	Potatoes and corn	Bernard and Bernard, 2010	In experimental nth price auction, found positive premium for non-GE food
United States	Various	Huffman, 2010	In experimental nth price auction, found 15-percent discount for GE food, but difference was only statistically significant for one of three foods
United States	Tomatoes	Bukenya and Wright,2007	Surveyed Alabama consumers willing to pay a $0.39 or 19-21 percent premium for non-GE tomatoes
United States	Vegetable oil, tortilla chips, and potatoes	Huffman et al., 2007	Found consumers willing to pay 14 percent less for GE foods
United States	Vegetable oil	Tegene et al., 2003	In experimental auctions, consumers willing to pay 14 percent more for non-GE food
United States	Potatoes	Loureiro and Hine, 2002	Customers willing to pay 5 percent more for non-GE food
United Kingdom	All foods	Burton et al.,2001	Customers indicated willingness to increase food budgets by 26-129 percent to avoid GE foods
United States, France, Germany, United Kingdom	Beef fed with GE feed	Lusk et al., 2003	U.S. consumers willing to pay $2.83 and $3.31 per lb. to avoid biotech; European consumers $4.86 to $11.01
United States, United Kingdom	Breakfast cereal	Moon and Balasubramanian, 2001	Found 56 percent of UK consumers willing to pay a premium to avoid GE food, compared to 37 percent of U.S. consumers.
United Kingdom	Various	Moon et al., 2007	Found that consumers were willing to pay a 20-percent premium for non-GE products and willing to accept a discount of 23 percent for GE foods
UK, Belgium, France, Germany, New Zealand, Sweden	Fruit	Mather et al., 2011	Found that surveyed consumers offered organic, conventional, or GM fruit stated that they wanted organic, but the same consumers at roadside stalls bought GM (labeled spray-free and offered at a 15-percent discount) 15-43 percent of the time
Germany	Canola	Hartl and Herrmann, 2009	In an online survey, found that the GE version must be discounted by over 100 percent
Romania	Potatoes, Sunflower oil	Curtis and Moeltner, 2007	Found that so few of surveyed Romanians were willing to purchase GE foods that a premium could not be calculated
Sweden	Beef, chicken	Carlsson et al., 2007	Found that consumers were willing to pay 30 SEK/kg extra for chicken and 32.5 SEK/kg for beef fed feed not produced using GE ingredients

continued—

Table 9
Studies in which consumers were willing to pay a premium for non-GE food—continued

Country	Good	Study	Willingness to pay premium [1]
Norway, United States, Japan, Taiwan	Vegetable oil	Chern et al., 2002	For non-GE vegetable oil, Norwegian students were willing to pay $1.51 (55-69 percent premium) per liter. U.S. students were willing to pay $1.13 (50-62 percent premium), Japanese students were willing to pay $0.88 (33-40 percent premium), and Taiwanese students were willing to pay $0.45 (17-21 percent premium)
Norway	Bread	Grimsrud, et al., 2004	Consumers required discounts of 37 to 63 percent to buy GE bread; one-fourth were willing to buy with no discount
Australia	Beer	Burton and Pearse, 2002	Younger Australian consumers would pay $A 0.72 less and older consumers $A 0.40 less for beer made with GE barley
Canada	Canola	Volinskiy et al, 2009	In a shopping experiment, found that consumers would pay Canadian $0.45 (20-30 percent) premium for non-GE canola
Canada		West et al., 2002	83 percent of consumers ascribed a lower value to several GE food products
China	Vegetable oil	Hu et al., 2006	Consumers would consume GE product with a 14-percent discount after hearing basic or positive information, and a 66-percent discount after hearing negative information
China	Soybean oil and rice	Lin et al., 2006	Consumers on average would pay a 52-percent premium for non-biotech foods
France	Biscuits	Noussair, et al., 2004	35 percent of consumers were unwilling to purchase GE foods, and 42 percent were willing to purchase them if they were less expensive
United States	Various	Rousu et al., 2004	Consumers reduced their demand by an average of 7-13 percent for each food product having 1-percent and 5-percent tolerance levels for GE material relative to food not produced using GE ingredients

[1] Lusk et al., 2005 contains a more exhaustive review of the literature prior to 2005.

(Bernard and Bernard, 2010; Huffman, 2010; Hartl and Herrmann, 2009; Volinskiy et al., 2009; Bukenya and Wright, 2007; Moon et al. 2007; Huffman et al., 2007; Carlsson et al., 2007; Tegene et al., 2003; Loureiro and Hine, 2002; Burton et al., 2001; Lusk et al., 2003; Moon and Balasubramanian, 2001). Other research studies have identified concerns about GE foods (Bernard et al., 2007; Komirenko et al., 2010).

Lusk et al. (2005) found that much of the variation in premia for non-GE foods across studies can be explained by a number of factors, including whether the study was done in Europe, whether the research surveyed shoppers, whether the survey took place in person, whether the consumers were asked to give hypothetical values for willingness-to-pay, whether they were asked for values for GE or non-GE foods, what type of product was considered, and whether consumers were told the product would provide them with a direct benefit.

More recent research on consumer willingness-to-pay for GE foods has focused on consumers in developing countries and has yielded different results than in wealthier nations (table 10). Several authors found that consumers are willing to pay a slight premium for GE foods in India (Krishna and Qaim, 2008; Anand et al., 2007), Kenya (Kimenju and De Groote, 2008), and China (Li et al., 2002). The few studies that have considered second generation attributes like nutrition have also found willingness-to-pay a premium for GE foods in India and Brazil (Anand et al., 2007; Gonzalez et al., 2009a). However, these findings are not universal across all developing countries. Hu et al. (2006) found that, on average, consumers in Nanjing would consume GE vegetable oil at a discount of 14 percent if presented with basic information or positive information and would require a discount of 66 percent if presented with negative information. Lin et al. (2006) also found that Chinese consumers would pay an average premium of 52 percent for non-GE foods. In addition, in Romania, a lower income country that is also in the EU, Curtis and Moeltner (2007) could not calculate a premium for non-GE goods over GE goods since too few in their survey of Romanians were willing to purchase GE goods. A cluster analysis of Brazilian stakeholders in the debate over

Table 10

Studies in which consumers were willing to pay a premium for genetically engineered (GE) food or GE food with enhanced characteristics

Country	Good	Study	Willingness to pay premium [1]
United States	Good	Huffman, 2010	Found that consumers would pay a 19- to 26-percent [2] premium for a product with intragenic addition of vitamins over a plain labeled product
United States	Golden Rice	Lusk, 2003	Customers willing to pay $0.93 for GE "golden rice" with added vitamin A, $0.65-0.75 for regular rice
Germany	Canola	Hartl and Herrmann, 2009	In an online survey, also found that consumers were willing to pay 1.37 Euros/ half-liter extra for GE oil with Omega3's and 0.80 euros per half-liter for GE oil with cholesterol-reducing compounds, which reduced but didn't eliminate the GE discount
Italy		Bocatelli and Moro, 2001	Consumers willing to pay a positive amount for GE attributes; 66 percent did not require a premium to consume GE foods
China	Rice	Li et al., 2002	80 percent of consumers did not require a premium to purchase GE rice and on average were willing to pay a 38-percent premium for GE rice and a 16-percent premium for GE soy oil
Brazil	Vitamin A fortified cassava	Gonzalez et al., 2009	Found surveyed consumers willing to pay 64-70 percent more for GE Vitamin-A fortified cassava
India	Bt vegetables	Krishna and Qaim, 2008	Found surveyed consumers willing to pay 1.5 percent premium for GE Bt (pest resistant) vegetables
India	Wheat	Anand et al., 2007	Found that if given no info, consumers will pay a 7-percent premium for GE foods; positive info leads to a 10-percent premium, negative info leads to a negative 139-percent premium (discount) for GE foods, and positive info on heart-healthy characteristics leads to a 23-percent premium for GE foods
Kenya	Maize meal	Kimenju and De Groote, 2008	Consumers surveyed in 2003 would pay a 13.8-percent premium for GE food

[1] Lusk et al., 2005 contains a more exhaustive review of the literature prior to 2005.
[2] Across all information treatments.

GE foods found that while many respondents perceived little or no risk from GE foods, some were skeptical of the benefits (Gonzalez et al., 2009b).

Some studies found that consumers, on average, would pay a premium for the non-GE version of the product while some would be willing to purchase GE foods without a premium (Lin et al., 2006). Bukenya and Wright (2007) found that younger consumers were willing to pay a premium for GE versions of the product.

More research is beginning to focus on second-generation attributes. Many of the currently marketed varieties of GE foods come from crops that have been engineered to decrease yield losses to pests and/or reduce costs of production (first generation). Second-generation attributes refer to genetically engineered characteristics of the foods themselves, such as extra vitamins that might make the food more attractive to consumers. Lusk et al. (2005) examined the literature up until 2005 and found that benefits to the consumer were significant in explaining the size of the premium consumers would pay for a non-GE food. Huffman (2010) found that U.S. consumers were willing to pay a premium for vitamin-enhanced GE food, as did Lusk (2003). Gonzalez et al. (2009) and Anand et al. (2007) found the same thing for consumers in Brazil and India. With an online survey of German consumers, Hartl and Herrmann (2009) found that GE enhancement of the Omega-3 content of foods or the addition of cholesterol-fighting compounds reduced the discount that GE foods had to offer relative to non-GE products. Boccaletti and Moro (2000) found that a sample of Italian consumers were willing to pay more for GE foods with improved nutritional qualities and lower pesticide use.

A new area of research has been the contrast between intragenic and transgenic goods. Intragenic goods are created by transferring genes from a plant of the same species, but of a different variety, as opposed to transferring a gene from another species or type of plant. Huffman (2010), using experimental auctions, found that consumers discounted GE foods, but were willing to pay a premium for intragenic foods that had enhanced vitamin content versus a plain-labeled product. The difference between the premia for intragenic- and transgenic-enhanced vitamins, however, was not statistically significant unless pro-biotech information was given to consumers. A survey of stakeholders in the potato industry (Toevs et al., 2011) found that certain categories of stakeholders (women, Canadians) were optimistic about intragenic potato varieties. More research remains to be done to determine whether consumers as a whole will find intragenic foods more acceptable than transgenic foods.

Effect of Information on the Desire of Consumers To Purchase GE Foods

Several studies have also considered the impact of information on the desire of consumers to purchase GE foods, and the results have varied. Huffman (2010), Huffman et al. (2007), Hu et al. (2006), and Tegene et al. (2003) found that positive information regarding biotechnology increased the willingness-to-pay for GE foods, while negative information reduced it. Onyango et al. (2004) found that those given both positive and negative information were less willing to buy GE foods than those given only positive information. Martinez-Poveda et al. (2009) found that previous knowledge of GE technology reduces the effects of negative information on the perception of GE foods, but could increase concern for health. Boccaletti and Moro (2000) found that previous knowledge increased the willingness-to-pay for positive GE attributes, while Lusk (2003) found that lack of previous knowledge increased willingness-to-pay.

Other studies have found that consumers value certain types of information. Hu et al. (2009) argued that those choosing to access information about GE foods may be different types of consumers than those who don't access information about GE foods. They found that consumers who voluntarily access *general* information on GE foods are more likely to buy them, while those who access *environmental* information related to GE foods are less likely to buy them. Rousu and Lusk (2009) found that providing consumers with information on the environment was more likely to change consumer purchasing behavior with respect to GE foods, while information on the beneficial impact of GE foods in developing countries created more value for the consumer.

Evidence From Retail Settings

Market settings offer examples of retailers' efforts to consider consumer preferences for GE foods. Some retailers do not have policies that explicitly address GE foods. Other retailers, mostly in the EU, have explicit policies stating that GE ingredients will not be used in their brand name food products.[39] Some companies have even introduced lines of meat and eggs from animals not fed on GE feed (Agriculture and Agri-food Canada, 2007; ASDA, 2011; Carrefour, 2011b; ECCC, 2008; Tesco, 2011; SHAFE, 2011).

Lusk et al. (2005) found that consumers in Europe were willing to pay more for non-GE foods than consumers in other regions. Thus, we might expect to see more responsiveness on the part of European retailers, and indeed some of them have developed auditing procedures for their suppliers (Tesco, 2011). Store visits by researchers in 10 EU countries found few (between 1 and 27) products with GE ingredients in grocery stores in 7 of the countries (King's College, 2008). The results of Mather et al. (2011) suggest that there may be circumstances under which consumers in a few EU countries would purchase GE foods.

A market exists for non-GE products in the United States, as some U.S. retailers do offer non-GE products, and U.S. consumers wishing to avoid GE ingredients may also purchase organic products. However, the share of this market in the United States is still small compared to the widespread marketing of non-GE goods in the EU. For example, the four largest retail chains in the UK[40] all indicate on their websites that their own-brand products do not include biotech ingredients (Tesco website, 2011; ASDA website, 2011; Sainsbury's website, 2013; Wm Morrison website, 2013). They also have tried developing brands of meat from animals fed non-GE feed, but some of the chains have been unable to source enough feed to maintain production (Tesco Food News, 2013; Wm Morrison website, 2013). In contrast, of the four largest U.S. grocery retail chains,[41] two make no mention of GE foods on their websites or corporate responsibility reports, one indicates that non-GE ingredients are not yet defined, and one will make one of its inhouse product lines non-GE in the coming year (Walmart, 2013a; Walmart, 2013b; Kroger, 2013a, Kroger, 2013b; Publix website, 2013; Safeway/Vons website, 2013). Thus, U.S. supermarkets do not perceive the same advantage from marketing non-GE goods that the UK retailers do.

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[39]The supermarket chain Whole Foods has announced a labeling policy that will be implemented by 2018 to indicate if their products contain GE ingredients (http://media.wholefoodsmarket.com/news/whole-foods-market-commits-to-full-gmo-transparency). ERS researchers discuss the economic issues related to food labeling, including GE foods (Golan et al., 2001).

[40]Tesco, ASDA, Sainsbury's, and William Morrison.

[41]WalMart, Kroger, Safeway, and Publix.

Further evidence comes from new product introductions in the United States. Of the 7,637 new food or food supplement products introduced between February 12, 2010, and February 11, 2011, as documented by the Datamonitor database, 2.6 percent advertise[42] that they do not include GE ingredients, 8 percent advertise that they are organic, and another 2.8 percent indicate that they at least have some organic or non-GE ingredients (Datamonitor, 2010-2011). Organic acreage of corn and soy, two potential sources of verified non-GE ingredients for U.S. food producers, remain a small share of the total acreage, with organic soy constituting 0.17 percent of total U.S. production and organic corn constituting 0.26 percent of total U.S. production in 2011 (USDA-ERS, 2013).

Whether patterns of consumer approval have changed over time is not clear. International Food Information Council (FIC) polls seem to indicate that the percentage with favorable opinions of GE foods in the United States fell between 2003 and 2008, but it has recently risen somewhat. In terms of the more rigorous studies cited in this report, even in the United States and in the United Kingdom, for which we cite several studies from different time periods, the temporal patterns are not clear enough to draw definite conclusions.

[42]Via labels or promotional material. The current website was sometimes consulted if the claim was ambiguous.

Conclusion

A large majority of U.S. farmers have adopted GE seeds for corn, soybeans, and cotton since their commercial introduction over 15 years ago. Despite the higher prices of GE seeds compared to conventional seed, farmers realize economic benefits from growing GE crops through higher crop yields, and/or lower pesticide costs, and management time savings.

Farmers will continue to use GE seeds as long as these seeds benefit them. However, it is not clear that first-generation GE seeds will benefit farmers indefinitely. With the help of refuges, the emergence of insect resistance to Bt crops has been low and of little economic significance over the first 15 years, but there are some indications that insect resistance is developing to some Bt traits in some areas and resistance to the herbicide glyphosate has already evolved in certain weed populations. Best management practices can help delay the evolution of resistance and sustain the efficacy of HT crops.

An important issue beyond the scope of this report is the coexistence of crop production systems. According to the USDA Advisory Committee on Biotechnology and 21st Century Agriculture—AC21 (2012), coexistence is defined as the "concurrent cultivation of crops produced through diverse agricultural systems including traditionally produced, organic, identity preserved, and genetically engineered crops." USDA supports all these crop production systems and wants each to be "as successful as possible providing products to markets in the United States and abroad."[43] ERS is collecting data and conducting a study on several aspects of the economics of coexistence of organic, non-GE, and GE crops.

[43]http://www.aphis.usda.gov/newsroom/2013/09/ac21.shtml)

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PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS
Subpart B—Food Additive Listing

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§573.225 1,3-Butylene glycol.

The food additive 1,3-butylene glycol (1,3-butanediol) may be safely used in accordance with the following prescribed conditions:

(a) It complies with the specifications in §173.220(a) of this chapter.

(b) It is intended for use in swine feed as a source of energy.

(c) It is to be thoroughly mixed into feed at levels not to exceed 9 percent of the dry matter of the total ration.

(d) 1,3-Butylene glycol should be mixed in feed with equipment adapted for the addition of liquids, and the feed should be mixed not less than 5 minutes after its addition.

[53 FR 40061, Oct. 13, 1988]

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§573.360 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraace- tate) may be safely used in animal feeds, in accordance with the following prescribed conditions:

(a) The food additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate ($C_{10}H_{14}O_8N_2Na_2 \cdot 2H_2O$).

(b) It is used to solubilize trace minerals in aqueous solutions, which are then added to animal feeds.

(c) It is used or intended for use in an amount not to exceed 240 parts per million of the additive in finished feed.

(d) To assure safe use of the additive the label and labeling shall bear:

(1) The name of the additive; and

(2) Adequate mixing directions to ensure that the chelated trace-mineral mix is uniformly blended throughout the feed.

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§573.460 Formaldehyde.

The food additive formaldehyde may be safely used in the manufacture of animal feeds in accordance with the following conditions:

(a) The additive is used, or intended for use, to improve the handling characteristics of fat by producing a dry, free-flowing product, as follows:

(1) For animal fat in combination with certain oilseed meals, as a component of dry, nonpelletted feeds for beef and nonlactating dairy cattle.

(i) An aqueous blend of soybean and sunflower meals in a ratio of 3:1, respectively, is mixed with animal fat such that the oilseed meals and animal fat are in a ratio of 3:2. The feed ingredients are those defined by the "Official Publication" of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 303, 308, and 309, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., P.O. Box 478, Oxford, IN 47971, or you may examine a copy at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) Formaldehyde (37 percent solution) is added to the mixture at a level of 4 percent of the dry matter weight of the oilseed meals and animal fat. This mixture, upon drying, contains not more than 1 percent formaldehyde and not more than 12 percent moisture.

(iii) To assure the safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the act), the label and labeling of the dried mixture shall bear:

(A) The name of the additive.

(B) Adequate directions for use providing that the feed as consumed does not contain more than 25 percent of the mixture.

(2) For soybean and canola seeds and/or meals to which there may be added vegetable oil as

a component of dry, nonpelleted feeds for beef and dairy cattle, including lactating dairy cattle.

(i) An aqueous blend of oilseed and/or meals, with or without added vegetable oil, in a ratio such that, on a dry matter basis, the final protein level will be 25 to 35 percent and the fat content will be 20 to 45 percent. The feed ingredients are those defined by the "Official Publication" of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 301, 307, 308, and 309, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., P.O. Box 478, Oxford, IN 47971, or you may examine a copy at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers lane, rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) Formaldehyde (37 percent solution) is added to the mixture at a level of 2.7 percent of the dry matter weight basis of the oilseeds and/or meals and the vegetable oil. This mixture, upon drying, contains not more than 0.5 percent formaldehyde and not more than 12 percent moisture.

(iii) To assure the safe use of the additive, in addition to the other information required by the act, the label and labeling of the dried mixture shall bear:

(A) The name of the additive.

(B) The statement, "This supplement is not to exceed 12.5% of the total ration. Dietary calcium and magnesium levels should be considered when supplementing the diet with fat."

(C) The minimum and maximum levels of crude fat must be guaranteed and must be between -5 percent and +5 percent of the analyzed fat content for each batch.

(b)(1) The food additive is formaldehyde (CAS No. 50-00-0; 37 percent aqueous solution). It is used at a rate of 5.4 pounds (2.5 kilograms) per ton of animal feed or feed ingredient. It is an antimicrobial agent used to maintain complete animal feeds or feed ingredients *Salmonella* negative for up to 21 days.

(2) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:

(i) The name of the additive.

(ii) A statement that formaldehyde solution which has been stored below 40 °F or allowed to freeze should not be applied to complete animal feeds or feed ingredients.

(iii) Adequate directions for use including a statement that formaldehyde should be uniformly sprayed on and thoroughly mixed into the complete animal feeds or feed ingredients and that the complete animal feeds or feed ingredients so treated shall be labeled as containing formaldehyde. The label must prominently display the statement: "Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days."

(iv) The labeling for feed or feed ingredients to which formaldehyde has been added under the provisions of paragraph (b)(1) of this section is required to carry the following statement: "Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days."

(3) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:

(i) Appropriate warnings and safety precautions concerning formaldehyde.

(ii) Statements identifying formaldehyde as a poison with potentials for adverse respiratory effects.

(iii) Information about emergency aid in case of accidental inhalation.

(iv) Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(v) Contact address and phone number for reporting adverse reactions or to request a copy of the Materials Safety Data Sheet (MSDS).

[41 FR 38652, Sept. 10, 1976, as amended at 54 FR 18281, Apr. 28, 1989; 61 FR 15704, Apr. 9, 1996; 63 FR 53580, Oct. 6, 1998; 68 FR 65633, Nov. 21, 2003]

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TITLE 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 582—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A—GENERAL PROVISIONS

§582.1	Substances that are generally recognized as safe.
§582.10	Spices and other natural seasonings and flavorings.
§582.20	Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).
§582.30	Natural substances used in conjunction with spices and other natural seasonings and flavorings.
§582.40	Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.
§582.50	Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.
§582.60	Synthetic flavoring substances and adjuvants.
§582.80	Trace minerals added to animal feeds.
§582.99	Adjuvants for pesticide chemicals.

Subpart B—GENERAL PURPOSE FOOD ADDITIVES

§582.1005 Acetic acid.

§582.1009 Adipic acid.

§582.1033 Citric acid.

§582.1057 Hydrochloric acid.

§582.1061 Lactic acid.

§582.1069 Malic acid.

§582.1073 Phosphoric acid.

§582.1077 Potassium acid tartrate.

§582.1087 Sodium acid pyrophosphate.

§582.1091 Succinic acid.

§582.1095 Sulfuric acid.

§582.1099 Tartaric acid.

§582.1125 Aluminum sulfate.

§582.1127 Aluminum ammonium sulfate.

§582.1129 Aluminum potassium sulfate.

§582.1131 Aluminum sodium sulfate.

§582.1135 Ammonium bicarbonate.

§582.1137 Ammonium carbonate.

§582.1139 Ammonium hydroxide.

§582.1141 Ammonium phosphate.

§582.1143 Ammonium sulfate.

§582.1155 Bentonite.

§582.1165 Butane.

§582.1191 Calcium carbonate.

§582.1193 Calcium chloride.

§582.1195 Calcium citrate.

§582.1199 Calcium gluconate.

§582.1205 Calcium hydroxide.

§582.1207 Calcium lactate.
§582.1210 Calcium oxide.
§582.1217 Calcium phosphate.
§582.1235 Caramel.
§582.1240 Carbon dioxide.
§582.1275 Dextrans.
§582.1320 Glycerin.
§582.1324 Glyceryl monostearate.
§582.1355 Helium.
§582.1366 Hydrogen peroxide.
§582.1400 Lecithin.
§582.1425 Magnesium carbonate.
§582.1428 Magnesium hydroxide.
§582.1431 Magnesium oxide.
§582.1480 Methylcellulose.
§582.1500 Monoammonium glutamate.
§582.1516 Monopotassium glutamate.
§582.1540 Nitrogen.
§582.1585 Papain.
§582.1613 Potassium bicarbonate.
§582.1619 Potassium carbonate.
§582.1625 Potassium citrate.
§582.1631 Potassium hydroxide.
§582.1643 Potassium sulfate.
§582.1655 Propane.
§582.1666 Propylene glycol.
§582.1685 Rennet.
§582.1711 Silica aerogel.
§582.1721 Sodium acetate.

§582.1736 Sodium bicarbonate.
§582.1742 Sodium carbonate.
§582.1745 Sodium carboxymethylcellulose.
§582.1748 Sodium caseinate.
§582.1751 Sodium citrate.
§582.1763 Sodium hydroxide.
§582.1775 Sodium pectinate.
§582.1778 Sodium phosphate.
§582.1781 Sodium aluminum phosphate.
§582.1792 Sodium sesquicarbonate.
§582.1804 Sodium potassium tartrate.
§582.1810 Sodium tripolyphosphate.
§582.1901 Triacetin.
§582.1973 Beeswax.
§582.1975 Bleached beeswax.
§582.1978 Carnauba wax.

Subpart C—ANTICAKING AGENTS

§582.2122 Aluminum calcium silicate.
§582.2227 Calcium silicate.
§582.2437 Magnesium silicate.
§582.2727 Sodium aluminosilicate.
§582.2729 Hydrated sodium calcium aluminosilicate.
§582.2906 Tricalcium silicate.

Subpart D—CHEMICAL PRESERVATIVES

§582.3013 Ascorbic acid.
§582.3021 Benzoic acid.
§582.3041 Erythorbic acid.

§582.3081	Propionic acid.
§582.3089	Sorbic acid.
§582.3109	Thiodipropionic acid.
§582.3149	Ascorbyl palmitate.
§582.3169	Butylated hydroxyanisole.
§582.3173	Butylated hydroxytoluene.
§582.3189	Calcium ascorbate.
§582.3221	Calcium propionate.
§582.3225	Calcium sorbate.
§582.3280	Dilauryl thiodipropionate.
§582.3336	Gum guaiac.
§582.3490	Methylparaben.
§582.3616	Potassium bisulfite.
§582.3637	Potassium metabisulfite.
§582.3640	Potassium sorbate.
§582.3660	Propyl gallate.
§582.3670	Propylparaben.
§582.3731	Sodium ascorbate.
§582.3733	Sodium benzoate.
§582.3739	Sodium bisulfite.
§582.3766	Sodium metabisulfite.
§582.3784	Sodium propionate.
§582.3795	Sodium sorbate.
§582.3798	Sodium sulfite.
§582.3845	Stannous chloride.
§582.3862	Sulfur dioxide.
§582.3890	Tocopherols.

Subpart E—EMULSIFYING AGENTS

§582.4101	Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
§582.4505	Mono- and diglycerides of edible fats or oils, or edible fat-forming acids.
§582.4521	Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids.
§582.4666	Propylene glycol.

Subpart F—NUTRIENTS AND/OR DIETARY SUPPLEMENTS

§582.5013	Ascorbic acid.
§582.5017	Aspartic acid.
§582.5049	Aminoacetic acid.
§582.5065	Linoleic acid.
§582.5118	Alanine.
§582.5145	Arginine.
§582.5159	Biotin.
§582.5191	Calcium carbonate.
§582.5195	Calcium citrate.
§582.5201	Calcium glycerophosphate.
§582.5210	Calcium oxide.
§582.5212	Calcium pantothenate.
§582.5217	Calcium phosphate.
§582.5223	Calcium pyrophosphate.
§582.5230	Calcium sulfate.
§582.5245	Carotene.
§582.5250	Choline bitartrate.
§582.5252	Choline chloride.
§582.5260	Copper gluconate.
§582.5271	Cysteine.

§582.5273 Cystine.

§582.5301 Ferric phosphate.

§582.5304 Ferric pyrophosphate.

§582.5306 Ferric sodium pyrophosphate.

§582.5308 Ferrous gluconate.

§582.5311 Ferrous lactate.

§582.5315 Ferrous sulfate.

§582.5361 Histidine.

§582.5370 Inositol.

§582.5375 Iron reduced.

§582.5381 Isoleucine.

§582.5406 Leucine.

§582.5411 Lysine.

§582.5431 Magnesium oxide.

§582.5434 Magnesium phosphate.

§582.5443 Magnesium sulfate.

§582.5446 Manganese chloride.

§582.5449 Manganese citrate.

§582.5452 Manganese gluconate.

§582.5455 Manganese glycerophosphate.

§582.5458 Manganese hypophosphite.

§582.5461 Manganese sulfate.

§582.5464 Manganous oxide.

§582.5470 Mannitol.

§582.5475 Methionine.

§582.5477 Methionine hydroxy analog and its calcium salts.

§582.5530 Niacin.

§582.5535 Niacinamide.

§582.5580 D-Pantothenyl alcohol.

§582.5590	Phenylalanine.
§582.5622	Potassium chloride.
§582.5628	Potassium glycerophosphate.
§582.5634	Potassium iodide.
§582.5650	Proline.
§582.5676	Pyridoxine hydrochloride.
§582.5695	Riboflavin.
§582.5697	Riboflavin-5-phosphate.
§582.5701	Serine.
§582.5772	Sodium pantothenate.
§582.5778	Sodium phosphate.
§582.5835	Sorbitol.
§582.5875	Thiamine hydrochloride.
§582.5878	Thiamine mononitrate.
§582.5881	Threonine.
§582.5890	Tocopherols.
§582.5892	*a*-Tocopherol acetate.
§582.5915	Tryptophane.
§582.5920	Tyrosine.
§582.5925	Valine.
§582.5930	Vitamin A.
§582.5933	Vitamin A acetate.
§582.5936	Vitamin A palmitate.
§582.5945	Vitamin B_{12}.
§582.5950	Vitamin D_2.
§582.5953	Vitamin D_3.
§582.5985	Zinc chloride.
§582.5988	Zinc gluconate.
§582.5991	Zinc oxide.

§582.5994 Zinc stearate.

§582.5997 Zinc sulfate.

Subpart G—SEQUESTRANTS

§582.6033 Citric acid.

§582.6085 Sodium acid phosphate.

§582.6099 Tartaric acid.

§582.6185 Calcium acetate.

§582.6193 Calcium chloride.

§582.6195 Calcium citrate.

§582.6197 Calcium diacetate.

§582.6199 Calcium gluconate.

§582.6203 Calcium hexametaphosphate.

§582.6215 Monobasic calcium phosphate.

§582.6219 Calcium phytate.

§582.6285 Dipotassium phosphate.

§582.6290 Disodium phosphate.

§582.6386 Isopropyl citrate.

§582.6511 Monoisopropyl citrate.

§582.6625 Potassium citrate.

§582.6751 Sodium citrate.

§582.6754 Sodium diacetate.

§582.6757 Sodium gluconate.

§582.6760 Sodium hexametaphosphate.

§582.6769 Sodium metaphosphate.

§582.6778 Sodium phosphate.

§582.6787 Sodium pyrophosphate.

§582.6789 Tetra sodium pyrophosphate.

§582.6801 Sodium tartrate.

§582.6804	Sodium potassium tartrate.
§582.6807	Sodium thiosulfate.
§582.6810	Sodium tripolyphosphate.
§582.6851	Stearyl citrate.

Subpart H—STABILIZERS

§582.7115	Agar-agar.
§582.7133	Ammonium alginate.
§582.7187	Calcium alginate.
§582.7255	Chondrus extract.
§582.7330	Gum arabic.
§582.7333	Gum ghatti.
§582.7339	Guar gum.
§582.7343	Locust bean gum.
§582.7349	Sterculia gum.
§582.7351	Gum tragacanth.
§582.7610	Potassium alginate.
§582.7724	Sodium alginate.

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2011

SUMMARY REPORT

On

Antimicrobials Sold or Distributed for Use in Food-Producing Animals

Food and Drug Administration
Department of Health and Human Services

Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA) (110 P.L. 316; 122 Stat. 3509) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) to require that sponsors of applications for new animal drugs containing an antimicrobial active ingredient submit an annual report to the Food and Drug Administration on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. This legislation was enacted to assist FDA in its continuing analysis of the interactions (including drug resistance), efficacy, and safety of antibiotics approved for use in both humans and food-producing animals (H. Rpt. 110-804).

Each report submitted to the FDA must specify: (1) the amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. Sponsors of antimicrobial drug products that are approved and labeled for more than one food-producing animal species are not required to report sales and distribution information for each individual animal species. Only total product sales information is required. Each year's report provides monthly sales and distribution data for the preceding calendar year. These reports are separate from periodic drug experience reports that are required under 21 CFR 514.80(b)(4).

Section 105 of ADUFA also directs the FDA to make annual summaries of the reported information publicly available. In accordance with statutory requirements designed to protect confidential business information, annual sales and distribution data are summarized by drug class and only those antimicrobial classes with three or more distinct sponsors of approved and actively marketed animal drug products are independently reported. Antimicrobial classes with fewer than three distinct sponsors are reported collectively as "Not Independently Reported" (NIR) if the product was marketed domestically or "Not Independently Reported Export" (NIRE) if the product was exported. The number of distinct sponsors in a particular antimicrobial class is determined by two criteria: (1) the sponsor must be named in 21 CFR 510.600 as the holder of an approved application for an animal drug product in that particular class on the last day of the annual reporting period, and (2) the sponsor must have actively sold or distributed such animal drug product at some point during that annual reporting period.

FDA's annual summary report for 2011 is presented in Table 1. The annual totals provided in Table 1 reflect all approved uses of all dosage forms (e.g., injectable, oral, medicated feed) of the identified classes of actively marketed drugs in food-producing animals. Table 2 lists the 17 antimicrobial drug classes represented in the report. As reference, this table also lists the specific drugs in each class for which there were actively marketed animal drug products. This summary report includes antimicrobial drugs that are specifically approved for antibacterial uses or are known to have antibacterial properties. Some antimicrobial drug products are approved and labeled for use in multiple species, including both food- and nonfood-producing animals, such as dogs and horses. For these products, sales and distribution data was not required to be reported to FDA by species.

Anti-fungal and anti-viral drugs are not included in this report because, with the exception of formalin and hydrogen peroxide water immersion products, there are currently no approved drug products actively marketed for these purposes in food-producing animals.

Table 1. Antimicrobial Drugs Approved for Use in Food-Producing Animals: 2011 Sales and Distribution Data Reported by Drug Class

	Antimicrobial Class	Annual Totals (kg[1])
Domestic	*Aminoglycosides*	214,895
	Cephalosporins[2]	26,611
	Ionophores	4,123,259
	Lincosamides[2]	190,101
	Macrolides	582,836
	Penicillins[2]	880,163
	Sulfas[2]	371,020
	Tetracyclines[2]	5,642,573
	NIR[2,3]	1,510,572
Export[4]	*Tetracyclines*[2]	15,321
	NIRE[2,5]	185,333

[1] kg = kilogram of active ingredient. Antimicrobials which were reported in International Units (IU) (e.g., Penicillins) were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

[2] Includes antimicrobial drug products which are approved and labeled for use in multiple species, including both food- and nonfood-producing animals, such as dogs and horses.

[3] NIR = Not Independently Reported. Antimicrobial classes for which there were less than three distinct sponsors actively marketing products domestically were not independently reported. These classes include: Aminocoumarins, Amphenicols, Diaminopyrimidines, Fluoroquinolones, Glycolipids, Pleuromutilins, Polypeptides, Quinoxalines, and Streptogramins

[4] Only includes exports of FDA-approved, US-labeled antimicrobial drugs approved for use in food-producing animals.

[5] NIRE = Not Independently Reported Export. Antimicrobial classes for which there were less than three distinct sponsors exporting products were not independently reported. These classes include: Aminocoumarins, Aminoglycosides, Amphenicols, Cephalosporins, Diaminopyrimidines, Fluoroquinolones, Glycolipids, Ionophores, Lincosamides, Macrolides, Penicillins, Pleuromutilins, Polypeptides, Sulfas, Quinoxalines, and Streptogramins.

Table 2. Marketed Antimicrobial Drugs and Drug Classes Approved for Use in Food-Producing Animals

Aminocoumarins Novobiocin **Aminoglycosides** Dihydrostreptomycin Gentamicin Neomycin Spectinomycin Streptomycin **Amphenicols** Florfenicol **Cephalosporins** Ceftiofur Cephapirin **Diaminopyrimidines** Ormetoprim **Fluoroquinolones** Danofloxacin Enrofloxacin **Glycolipids** Bambermycins **Ionophores** Laidlomycin Lasalocid Monensin Narasin Salinomycin **Lincosamides** Lincomycin Pirlimycin	**Macrolides** Erythromycin Gamithromycin Tilmicosin Tulathromycin Tylosin **Penicillins** Amoxicillin Ampicillin Cloxacillin Penicillin **Pleuromutilins** Tiamulin **Polypeptides** Bacitracin **Quinoxalines** Carbadox **Streptogramins** Virginiamycin **Sulfas** Sulfadimethoxine Sulfamerazine Sulfamethazine Sulfaquinoxaline **Tetracyclines** Chlortetracycline Oxytetracycline Tetracycline

Animal & Veterinary

Steroid Hormone Implants Used for Growth in Food-Producing Animals

Since the 1950s, the Food and Drug Administration (FDA) has approved a number of steroid hormone drugs for use in beef cattle and sheep, including natural estrogen, progesterone, testosterone, and their synthetic versions These drugs increase the animals' growth rate, the efficiency by which they convert the feed they eat into meat, and the leanness of their meat. The FDA approves these drugs only after extensive studies have shown that the food from the treated animals is safe for people to eat, and that the drugs do not harm the treated animal or the environment. The drugs also have to work as intended.

These steroid hormone drugs are formulated as pellets that are placed under the skin on the back side of the animal's ear. The pellets dissolve slowly under the skin and do not require removal. The ears of the treated animals are discarded at slaughter and not used for human food. Using scientific data, FDA establishes the acceptable safe limits for hormones in meat. A safe level for human consumption is a level of drug in the meat that would be expected to have no effect in humans based on extensive scientific study and review.

All approved implant products have a zero day withdrawal. This means that the meat from the animal is safe for humans to eat at any time after the animal is treated.

Naturally-Occurring Hormones

Some of the approved drugs are naturally produced throughout life in people and animals, such as estradiol (estrogen), progesterone, and testosterone. These natural hormones are necessary for normal development, growth, and reproduction. People are not at risk from eating food from animals treated with these drugs because the amount of additional hormone following drug treatment is very small compared with the amount of natural hormones that are normally found in the meat of untreated animals and that are naturally produced in the human body.

Synthetic Hormones

Some of the approved drugs are synthetic versions of the natural hormones, such as trenbolone acetate and zeranol. Just like the natural hormone implants, before FDA approved these drugs, FDA required extensive toxicological testing in animals to determine safe levels in the animal products that we eat (edible tissue). Furthermore, FDA required that the manufacturers demonstrate that the amount of hormone left in each edible tissue after treatment is below the appropriate safe level. As described above, a safe level is a level which would be expected to have no effect in humans.

No steroid hormones are approved for growth purposes in dairy cattle, veal calves, pigs, or poultry. All of the steroid hormone growth-promoting drugs are available for over-the-counter purchase in the U.S. and are generally given by the livestock producer at specific stages of the animals' growth.

Additional Information

Information about approved hormonal implant products can be found in the *Code of Federal Regulations* (CFR), Title 21, Parts 522 and 556. Copies of the CFR may be found at your local public or university library and are for sale from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. In addition, the *Code of Federal Regulations* may be found on the Internet:

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl[1]

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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

September 30, 2013

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Re: Docket No. FDA-2009-P-0594

Dear Ms. Tomaselli and Dr. Wallinga:

This letter responds to the Citizen Petition (FDA-2009-P-0594) you submitted to the Food and Drug Administration ("FDA" or "the Agency") on December 11, 2009, on behalf of the Center for Food Safety and the Institute for Agriculture and Trade Policy ("petition").

The petition requests that FDA: "immediately suspend the approval of all new animal drug applications (NADAs) for arsenic-containing compounds used as feed additives for food animals," specifically those for roxarsone, arsanilic acid, nitarsone, and carbarsone and combination drugs that include those four new animal drugs; publish a "Notice of Opportunity for an Evidentiary Hearing concerning 'new evidence'" related to such applications; issue, upon completion of the hearing, an "order withdrawing the approval of all NADAs for arsenic-containing compounds used as feed additives for animals"; and "[r]evoke all regulations associated with the approval of all NADAs for arsenic-containing compounds used as feed additives for animals . . . ." Petition at 2-3.

On June 3, 2010, FDA's Center for Veterinary Medicine (CVM or "the Center") issued an interim response to the petition explaining that more time was needed to issue a final response because of the complexity and the number of issues raised in the petition. On August 9, 2011, you sent a letter to Dr. Margaret Hamburg referencing a study FDA conducted on roxarsone and the voluntary suspension of the sale of that drug by its sponsor, and reiterating the requests in your petition.

FDA has carefully considered the issues raised in your petition, the comments submitted to the docket in association therewith, your August 9, 2011, letter to Dr. Hamburg, and other information before the Agency. As discussed further below, since you submitted your petition, the sponsors of roxarsone, carbarsone, and arsanilic acid have requested that FDA withdraw approval of the NADAs for those drugs. The Agency is in the process of formally withdrawing approval of those applications and amending the new animal drug regulations referencing those approvals. Your requests regarding roxarsone, carbarsone, and arsanilic acid are therefore moot. With respect to your requests regarding nitarsone, in accordance with 21 C.F.R. 10.30(e)(1)(ii), we are denying your petition. The reasons for this decision are discussed below.

BACKGROUND

A. Legal and Regulatory Framework

Under section 512(a)(1) of the Federal Food, Drug, and Cosmetic Act ("the FD&C Act"), any new animal drug shall be deemed unsafe, and as a result adulterated, unless it is approved, conditionally approved, or index-listed[1] by FDA. Under section 512(d)(1)(B) of the FD&C Act, FDA cannot approve an NADA if the evidence "do[es] not show that such drug is safe for use" under specified conditions. The determination of safety with respect to the target animal involves balancing risks against benefits for each specific use of a drug. *Cf. United States v. Rutherford*, 442 U.S. 544, 555 (1979). Moreover, FDA will not find a new animal drug intended for use in food-producing animals to be safe unless the sponsor demonstrates that there is a reasonable certainty of no harm to human health with respect to the food produced from treated animals under the intended conditions of use.

Once a drug is approved, the drug's sponsor may at any time voluntarily withdraw the drug from the market for any reason, including safety concerns. Section 512(e)(1) of the FD&C Act establishes grounds and procedures for FDA to withdraw approval of an NADA. One of these grounds provides that FDA "shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an [NADA] with respect to any new animal drug if [FDA] finds," among other things, that "new evidence . . . evaluated together with the evidence available to [FDA] when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved." Section 512(e)(1)(B) of the FD&C Act.[2]

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[1] The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index) is a list of new animal drugs generally intended for use in non-food producing minor species that have had their safety and effectiveness affirmed through an alternative FDA review process. They are often intended for use in species too rare or varied to be used in traditional safety and effectiveness studies. New animal drugs intended for use in early, non-food life stages of some food-producing minor species may be eligible for indexing under very limited circumstances. See Section 572 of the FD&C Act and 21 CFR 516 subpart C.

[2] Although your petition cites section 512(e)(1)(A)-(C), *see* p.24, your petition only contains arguments related to subsection (B).

FDA regulations in 21 CFR parts 12 and 514 describe the notice and hearing process required by section 512(e)(1) of the FD&C Act. First, FDA notifies in writing the person holding the approved application and affords an opportunity for a hearing on a proposal to withdraw that application's approval. 21 CFR 514.115(b). FDA publishes a notice of opportunity for a hearing in the Federal Register. 21 CFR 514.200(a). The sponsor then has 30 days to request a hearing, which the Commissioner will grant if, among other criteria, "genuine and substantial issues of fact" exist regarding whether withdrawal of approval is appropriate. 21 CFR 514.200(c). At the hearing, FDA has the initial burden of producing evidence that the drug at issue is not shown to be safe. *See Rhone-Poulenc, Inc. v. FDA*, 636 F.2d 750, 752 (D.C. Cir. 1980). If FDA meets that initial burden, the sponsor has the burden of showing that the drug is safe. *Id.* The matter is decided by an administrative law judge, 21 CFR 12.120(a)-(b) and 514.200(c), whose decision may be appealed to the Commissioner, 21 CFR 12.125(a).[3]

Section 512(e)(1) of the FD&C Act also provides for a special summary procedure that permits the Secretary to suspend approval of an NADA temporarily in advance of a hearing, and thereby remove the drug from the market, if the Secretary finds that the drug represents an "imminent hazard" to the health of man or the animals for which the drug is intended. FDA has interpreted the phrase "imminent hazard" in 21 CFR 2.5 to mean that such a hazard exits "when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held." After suspending approval, the Secretary must provide the sponsor with an expedited evidentiary hearing on whether the drug should be permanently removed from the market. Section 512(e)(1) of the FD&C Act. This special authority is vested solely in the Secretary (or in her absence the officer acting as Secretary), and may not be delegated. *Id.*

B. Arsenic-based Animal Drugs

Arsenic is an element that is present in the environment as a naturally-occurring substance or as a result of contamination from human activity. It is found in water, air, and soil in organic and inorganic form.

There are four FDA-approved arsenic-based animal drugs – roxarsone, arsanilic acid, nitarsone, and carbarsone – and a number of approved combination drug medicated feeds containing an approved arsenic-based new animal drug plus at least one approved non-arsenic-based new animal drug. The four arsenic-based animal drugs, which have been approved for several decades for use in animal feed for poultry and swine, all have as their active ingredient forms of organic arsenic, which is less toxic than inorganic arsenic and not known to be carcinogenic.

The scientific evidence at the time of the approval of all four arsenic-based animal drugs indicated that animals exposed to organic arsenic rapidly excrete the compound in its original form – as organic arsenic. FDA approved the products at doses and withdrawal times that, based on the available

[3] Alternatively, an NADA holder may request FDA withdraw approval of its NADA. Approval of an NADA "will be withdrawn on the basis of a request for its withdrawal submitted in writing by a person holding an approved [NADA] on the grounds that the drug subject to such application is no longer being marketed," so long as certain other criteria are met. 21 CFR 514.115(d).

information, allowed for the safe and effective use of the products when used according to label directions.

Below is summary information for each of the four approved arsenic-based animal drugs approved for use in medicated feed:

Roxarsone (3-nitro-4-hydroxyphenylarsonic acid)

- Drug form: Type A medicated article
- Trade names: 3-NITRO, Roxarsone
- Sponsor: Zoetis, Inc.
- Indications for Use: Chickens and turkeys (growing) - For increased rate of weight gain, improved feed efficiency and improved pigmentation. Swine (growing and finishing) - For increased rate of weight gain and improved feed efficiency.
- Marketing Status: Inactive, has not been marketed in U.S. since 2011

Carbarsone (p-ureidophenylarsonic acid)

- Drug form: Type A medicated article
- Trade name: CARB-O-SEP
- Sponsor: Zoetis, Inc.
- Indications for Use: As an aid in the prevention of blackhead in turkeys.
- Marketing Status: Inactive, has not been marketed in U.S. since at least 1996

Nitarsone (4-nitrophenylarsonic acid)

- Drug form: Type A medicated article
- Trade name: HISTOSTAT 50
- Sponsor: Zoetis, Inc.
- Indications for Use: As an aid in the prevention of blackhead[4] in chickens and turkeys
- Marketing Status: Active

Arsanilic acid (p-arsanilic acid)

- Drug form: Type A medicated article
- Trade name: PRO-GEN
- Sponsor: Fleming Labs, Inc.
- Indications for Use: Chickens and turkeys (growing) - For increased rate of weight gain, improved feed efficiency, and improved pigmentation. Swine (growing and finishing) - For increased rate of weight gain and improved feed efficiency.
- Marketing Status: Inactive, has not been marketed in U.S. since 2005

Currently, there are 101 approved NADAs for products containing one of the four arsenic-based animal drugs. Five NADAs are for single-ingredient Type A medicated articles used to manufacture single-ingredient medicated feeds (including two NADAs for roxarsone and one NADA each for carbarsone, nitarsone, and arsanilic acid). Five NADAs are for roxarsone tablets or concentrate solution used to make medicated drinking water. The remaining 91 NADAs are applications that permit the manufacture

[4] Blackhead is a form of histomoniasis caused by a protozoan which may be transmitted by a parasite.

of combination drug medicated feeds containing an approved arsenic-based new animal drug plus at least one approved non-arsenic-based new animal drug. There are 80 NADAs for combination drug medicated feeds containing roxarsone; 3 NADAs for combination drug medicated feeds containing arsanilic acid; 2 NADAs for combination drug medicated feeds containing nitarsone; and 6 NADAs for combination drug medicated feeds containing carbarsone. As discussed below, roxarsone, arsanilic acid, and carbarsone are not currently being marketed in the United States. Thus, none of the products, including drug combinations, containing roxarsone, arsanilic acid, and carbarsone, is currently marketed.

C. Recent FDA Activities Related to Safety of Arsenic-based Animal Drugs

Scientific reports over the last several years began to question whether organic arsenic could transform into inorganic arsenic in the environment or in the edible tissues of animals that consume it. Since publication of these reports, FDA has been gathering and analyzing relevant data and information, including data the Agency generated in a self-initiated research study, in order to evaluate whether there may be safety risks associated with arsenic-based animal drugs that were previously unknown.

As noted above, carbarsone has not been marketed since at least 1996 and arsanilic acid has not been marketed since 2005. Of the two remaining arsenic-based new animal drugs, roxarsone was the much more commonly used arsenic-based animal drug. As FDA began to reevaluate arsenic-based new animal drugs, the Agency decided to concentrate its research efforts on roxarsone in light of its more common use. In September 2009, FDA initiated a research study intended to determine whether treating chickens with roxarsone results in increased levels of inorganic arsenic in the edible tissues of those chickens. To FDA's knowledge, no previous study had detected inorganic arsenic in edible tissues of birds known to be treated with an arsenic-based animal drug.[5]

Scientists from CVM and FDA's Center for Food Safety and Applied Nutrition ("CFSAN") developed a new analytical method capable of detecting very low levels of inorganic arsenic in chicken liver.[6] This test method used state-of-the-art instrumentation (ion chromatography inductively coupled plasma mass spectrometry) to identify and measure very low levels (less than 10 parts per billion (ppb)) of inorganic arsenic in the presence of much higher concentrations (nearly 2 ppm or 2000 ppb) of roxarsone. The method was evaluated and validated by a second laboratory, FDA's Office of Regulatory Affairs ("ORA") Forensic Chemistry Center.

One hundred chickens were fed either medicated feed containing roxarsone at the approved dose or a control feed for a six-week period. FDA analyzed liver tissue from the chickens in the study to determine whether inorganic arsenic could be detected. FDA's analysis indicated that very low levels of inorganic arsenic were present in the livers of chickens treated with the roxarsone, while no measurable residues of inorganic arsenic were present in the livers from the untreated control chickens. Although

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[5] IATP's study referenced in your petition tested for *total* arsenic in retail packages of raw chicken and fast food chicken but did not speciate inorganic arsenic from organic arsenic. See David Wallinga, Inst. for Agric. and Trade Policy, Playing Chicken: Avoiding Arsenic in Your Meat 11 (2006), available at http://www.iatp.org/iatp/publications.cfm?accountID=421&refID=80529.

[6] Given that humans mostly consume chicken muscle, FDA attempted to develop an analytical method for detecting levels of inorganic arsenic in muscle. Due to technical difficulties in developing an analytical method for muscle tissue, FDA developed the method for the analysis of liver samples instead.

the analytical method FDA had developed could not be used to measure inorganic arsenic levels in chicken muscle; other appropriate methods were available to measure levels of total arsenic (both organic and inorganic) in muscle. Using those methods, FDA found substantially lower levels of total arsenic in muscle than in liver, reflective of the typical distribution of veterinary drug residues at higher levels in liver and kidney than in muscle. Data collection, analysis, and peer evaluation for the analytical method were completed in December 2010, and the study's final report was completed in February 2011.[7]

After FDA advised roxarsone's sponsor, Pfizer, Inc. ("Pfizer") (now Zoetis, Inc. ("Zoetis")[8]), of the results of FDA's study, Pfizer voluntarily suspended the sale of roxarsone in the United States in July 2011, and roxarsone has remained off the market since then.[9] Since 2010, the last full year that roxarsone was marketed, total U.S. sales of arsenic-based products have dropped by 84 percent. The only remaining arsenic-based animal drug marketed is nitarsone, the only marketed product approved for preventing blackhead (histomoniasis) in turkeys and chickens.

Although roxarsone's sponsor voluntarily suspended the sale of the drug, the sponsor also raised certain questions regarding FDA's study. For example, the sponsor expressed concerns that the study did not provide complete analyses to affirm the frozen storage stability and freeze-thaw stability of tissue samples for arsenical speciation. As a follow-up to its original study, FDA commenced additional analytical work to address this and other questions raised by the sponsor. This additional analytical work is ongoing. FDA's ongoing analyses include, but are not limited to, affirming the frozen storage stability and freeze-thaw stability of tissue samples for arsenical speciation, affirming the stability of arsenical species in the feed matrix, within laboratory validation of our analytical methods in a new analytical facility, and affirming the homogeneity and delivered dose of roxarsone in the medicated feed. This additional analytical work is an important aspect of FDA's ongoing evaluation of arsenic-based animal drugs as it is intended to address questions raised about the original study and to affirm and build upon the original study's findings. In addition, it will add to the body of scientific knowledge and assist the Agency in the determination of appropriate next steps.

In addition to this ongoing analytical work, FDA recently sent letters to the sponsors of the four arsenic-based animal drugs pursuant to section 512(l) of the FD&C Act.[10] Specifically, FDA ordered the sponsors to provide any data and information in their possession related to whether inorganic arsenic can be detected in edible tissues of animals administered their particular arsenic-based new animal drug(s);

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[7] See *Final Report on Study 275.30*, available at http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/UCM257545.pdf.

[8] In January of 2012, Pfizer announced that its animal health businesses would become a new company called Zoetis. In January 2013, Zoetis offered a minority ownership stake through an Initial Public Offering and became a standalone company. See http://www.zoetis.com/about/history.

[9] See Pfizer Media Statement, Pfizer To Suspend Sale Of 3-Nitro (Roxarsone) In The United States, June 11, 2011, available at http://www.pfizer.com/files/news/suspending_sale_3nitro_060711.pdf.

[10] Section 512(l) of the FD&C Act provides a procedure whereby the Agency may order a sponsor to submit records and reports to the agency if the Agency finds that such records and reports are necessary in order to enable the Agency to determine, or facilitate a determination, whether there is or may be ground for invoking section 512(e) to withdraw approval of the drug.

whether organic arsenic converts to inorganic arsenic *in vivo* in any animals administered any form of organic arsenic in any amount; and whether and to what extent information related to the behavior of one arsenic-based new animal drug is applicable to other arsenic-based new animal drugs. These orders were issued to help FDA obtain and review any relevant data and information in the possession of the sponsors that FDA may not have and thereby facilitate a determination about whether there are or may be grounds for invoking section 512(e) of the FD&C Act to withdraw approval of any of these drugs.

After receiving FDA's order pursuant to section 512(l) of the FD&C Act, by letter dated September 19, 2013, Zoetis requested that FDA withdraw approval of the NADAs for roxarsone and carbarsone. In addition, by letter dated September 26, 2013, Fleming Laboratories, Inc. (Fleming), requested that FDA withdraw approval of the NADA for its drug, arsanilic acid. FDA is preparing to issue notices of withdrawal of those applications in the Federal Register and to revoke the new animal drug regulations covering the conditions of use of the drugs as provided for in their applications. *See* 21 CFR 514.115(e) and 514.116.

FDA also continues to review and evaluate newly-published, relevant scientific literature, such as the study released on May 10, 2013, by researchers at the Johns Hopkins Center for a Livable Future at the Bloomberg School of Health ("Johns Hopkins"), which collected chicken breast samples from December 2010 to June 2011 (before the sale of roxarsone was suspended) and analyzed them for the presence of roxarsone and inorganic arsenic.[11] We have reached out to the Johns Hopkins investigators with questions about their reported results, primarily regarding the analytical method used, to inform our ongoing evaluation.

DISCUSSION

In your petition, you contend that the arsenic-based animal drugs roxarsone, arsanilic acid, nitarsone, and carbarsone are not safe for consumption and that their approvals must be suspended immediately and the products withdrawn from the market. You argue that consuming edible tissues of animals treated with arsenic-based new animal drugs is unsafe; that arsenic-based new animal drugs convert into inorganic arsenic, which can lead to an increased risk of cancer and other health risks for humans; that exposure to organic arsenic can also cause adverse health effects; that the use of arsenic-based animal drugs has a detrimental environmental impact and contributes to a cumulative exposure to arsenic that could create health risks for humans; and that the use of arsenic-based animal drugs likely contributes to antimicrobial resistance.

We considered your petition, the evidence cited in it, and your letter to Dr. Margaret Hamburg of August 9, 2011, discussing FDA's roxarsone study and Pfizer's suspension of the sale of roxarsone, as well as the comments submitted to the docket for your petition and other information before the Agency. We reviewed every publication you referenced and referenced by the comments and carefully considered your arguments.

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[11] Keeve E. Nachman, Patrick A. Baron, Georg Raber, Kevin A. Francesconi, Ana Navas-Acien, David C. Love. Roxarsone, Inorganic Arsenic, and Other Arsenic Species in Chicken: A U.S.-Based Market Basket Sample. *Environmental Health Perspectives*, 2013; DOI: 10.1289/ehp.1206245.

As noted above, Zoetis has requested that FDA withdraw approval of the NADAs for roxarsone and carbarsone, and Fleming has requested that FDA withdraw approval of the NADA for arsanilic acid. The Agency is in the process of formally withdrawing approval of those applications and amending the new animal drug regulations referencing those approvals. Your requests regarding roxarsone, carbarsone, and arsanilic acid are therefore moot.

With respect to your requests for FDA to suspend approval of the NADA for nitarsone, initiate withdrawal proceedings by publishing a Notice of Opportunity for an Evidentiary Hearing, issue an order withdrawing the NADA approval, and revoke all associated regulations, FDA has not yet made a finding that the grounds for initiation of such proceedings are present under section 512(e)(1) of the FD&C Act. We acknowledge your concerns regarding the safety of arsenic-based animal drugs. However, three of the four arsenic-based drugs you mention are no longer being marketed, resulting in a substantial decrease of arsenic-based animal drugs on the market. Of the 101 NADAs for products containing one of the four arsenic-based new animal drugs, only three are currently marketed in the U.S.: nitarsone and two combination drugs containing nitarsone.

FDA believes, as a matter of science and regulatory policy, that the most appropriate course of action at this time is to continue to pursue the Agency's ongoing scientific research and evaluation. As discussed above, FDA is seeking additional information to enable the Agency to more fully evaluate any potential concerns related to the safety of arsenic-based animal drugs. This information includes completing our ongoing analytical work to address questions raised by roxarsone's then-sponsor and build upon the Agency's first study related to inorganic arsenic in the edible tissue of birds known to be treated with roxarsone. It also includes requiring the sponsor of nitarsone to submit any data and information in its possession related to whether inorganic arsenic can be detected in edible tissues of animals administered its arsenic-based new animal drug, whether organic arsenic converts to inorganic arsenic *in vivo* in any animals administered any form of organic arsenic in any amount, and whether and to what extent information related to the behavior of one arsenic-based new animal drug is applicable to other arsenic-based new animal drugs.

The Agency has decided to review the results of the analytical work and evaluate the response from Zoetis prior to reaching any conclusions about whether there may be grounds to undertake the actions you request regarding nitarsone. Review of this information will enable FDA to better understand the current state of the science surrounding arsenic-based new animal drugs and thus make a more informed scientific determination regarding nitarsone. Moreover, we anticipate that most of the additional information FDA is seeking will be available for review by the Agency's scientific staff by the end of the first quarter of 2014. Specifically, by that time, we plan to have completed a critical portion of our ongoing analytical work,[12] and we also expect to have received and reviewed the response from Zoetis

[12] The additional analytical work that FDA is in the process of completing is resource intensive and has required significant time to complete. Currently, there are three ongoing studies. One study examines feed stability and distribution of roxarsone in the feed. This study involves mixing and testing of multiple feed samples. A second study entails feeding a small group of chickens medicated feed and a control group of chickens non-medicated feed in order to generate liver samples from both groups to use in the third study. The third study analyzes some of the liver samples after they have been frozen for various periods and some samples that have not been frozen in order to affirm the frozen storage stability and freeze-thaw stability of tissue samples for arsenical speciation. We

to the order we sent regarding nitarsone, as well as the answers to the questions we sent to the investigators from the Johns Hopkins study noted above.

Once we have completed the efforts discussed above, we intend to promptly evaluate all of the information before the Agency to reach a conclusion about next steps, including whether there may be grounds for initiating withdrawal proceedings for nitarsone.

CONCLUSION

We appreciate your concerns regarding the safety of roxarsone, arsanilic acid, nitarsone, and carbarsone. Prior to receiving your petition and since that time, we have been actively gathering additional information to enable us to more fully evaluate any potential concerns regarding the safety of those drugs. The applications for roxarsone, carbarsone, and arsanilic acid are in the process of being withdrawn at the sponsors' requests, and therefore your requests regarding those drugs are moot. For the reasons discussed above, the Agency has decided to review the results of its analytical work and evaluate the response from the sponsor of nitarsone to the order issued by the Agency prior to reaching any conclusions about whether there may be grounds to initiate proceedings to withdrawal approval of that drug. Although we are not taking the actions you request regarding nitarsone at this time, we are committed to promptly collecting the additional data and completing our evaluation of the safety of that drug.

Sincerely,

Michael R. Taylor
Deputy Commissioner for Foods and
Veterinary Medicine

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cannot complete the third study until we have completed the feeding study and have collected and stored liver samples from the treated birds. In addition, CVM will determine whether to conduct a fourth study after it reviews the results of the other three studies.

ELECTRONIC CODE OF FEDERAL REGULATIONS

e-CFR Data is current as of May 12, 2014

Title 21: Food and Drugs
PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS
Subpart B—Food Additive Listing

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§573.780 Polyethylene.

(a) *Identity.* Polyethylene consists of basic polymers manufactured by the catalytic polymerization of ethylene.

(b) *Specifications.* (1) For the purposes of this section, polyethylene shall meet the specifications in item 2.1 of §177.1520(c) of this chapter.

(2) The polyethylene is designed in a pellet form in a configuration presenting maximum angular surface having the following dimensions in centimeters:

0.9 ±0.1 × 0.8 ±0.1 × 1.2 ±0.1

(c) *Use.* It is used as a replacement for roughage in feedlot rations for finishing slaughter cattle.

(d) *Labeling.* The labels and labeling shall bear in addition to the other information required by the Act:

(1) The name of the additive "polyethylene roughage replacement."

(2) Adequate directions for use which shall provide for the administration of one-half pound of polyethylene pellets per head per day for 6 successive days. All natural roughage should be removed for a minimum of 12 hours prior to administration of polyethylene roughage replacement. Roughage replacement must be adequately mixed in the ration for uniform distribution.

[41 FR 38652, Sept. 10, 1976, as amended at 54 FR 18282, Apr. 28, 1989]

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Final Tables

Food-Labeling Poll 2008

For Public Release

November 11, 2008

NRC #2008.18

Consumer Reports National Research Center

Methodology

- Telephone surveys were conducted among 1,001 random adults comprising 500 men and 501 women 18 years of age and older. Interviewing took place over October 23-26, 2008.

- The questionnaire was fielded via Opinion Research Corporation's Caravan twice-weekly national telephone omnibus survey. ORC used random digit dialing to achieve a nationally representative probability sample and weighted completed interviews by age, sex, geographic region and race.

- A comparable methodology was used for a previous food-labeling survey fielded June 7-10, 2007.

- The results of this study are intended for external communications. Methodology statement for public release:

  The Consumer Reports National Research Center conducted a telephone survey using a nationally representative probability sample of telephone households. 1,001 interviews were completed among adults aged 18+. Interviewing took place over October 23-26, 2008. The sampling error is +/- 3.2% at a 95% confidence level.

Responsibility for Food-Shopping

INTRODUCTION:

SF - Do you have primary or equally shared responsibility for food shopping for your household?

SF - Food-Shopping Responsibility

	TOTAL	Gender	
		Men	Women
	%	%	%
Primary responsibility for food shopping	51	32	68
Equal responsibility for food shopping	35	44	26
No responsibility for food shopping	14	24	6
Don't know	0		1

Willingness to Buy Cloned or GE Food

C1ALL - Which of the following types of food would you buy if they were available?

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Meat or milk products from genetically engineered animals	29	42	16	28	29	30	22	30	41	26	29	28	33
Milk or milk products from cloned animals or their offspring	26	40	13	25	30	24	19	24	38	20	25	25	34
None of these	62	46	77	63	60	63	67	63	52	65	60	65	56
Don't know	2	2	3	2	2	2	3	0	2	2	3	2	2

Willingness to Pay More for Specialty Food

C2ALL - Would you pay more for the following types of food?

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Milk/milk products produced w/o artificial growth hormones	57	51	62	58	61	50	55	61	60	57	54	58	56
Meat products labeled as tested for mad cow disease	49	49	50	49	51	48	46	51	50	55	51	51	42
Milk from organic cows that were confined indoors and did not graze outdoors	19	22	17	26	20	13	25	16	19	18	19	20	21
None of these	26	29	23	21	24	33	28	26	21	24	29	25	27
Don't know	1	1	1	0	1	1	1	1		1	0	1	1

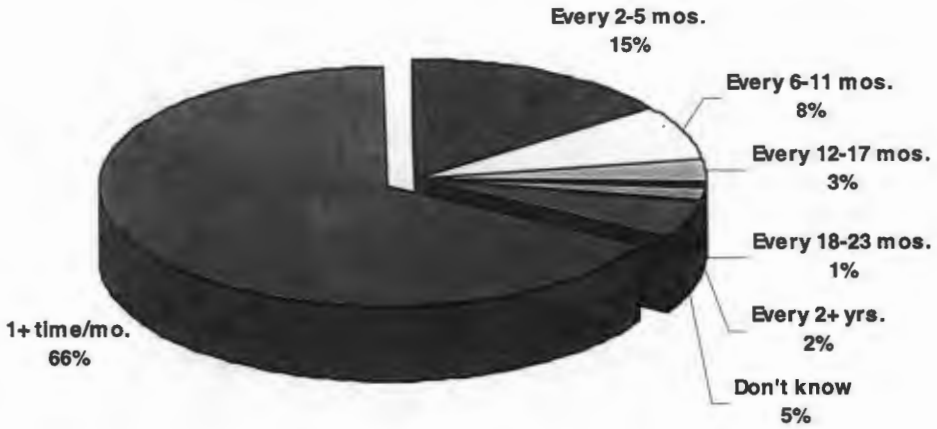
FDA Inspection of Domestic Food Production Facilities

INTRODUCTION:

C3A - The FDA inspects food-processing facilities periodically. Approximately how often do you feel the FDA should conduct its inspections of DOMESTIC food-processing facilities?

C3A - FDA Inspection: Domestic Facilities

Median: 0.7 Months



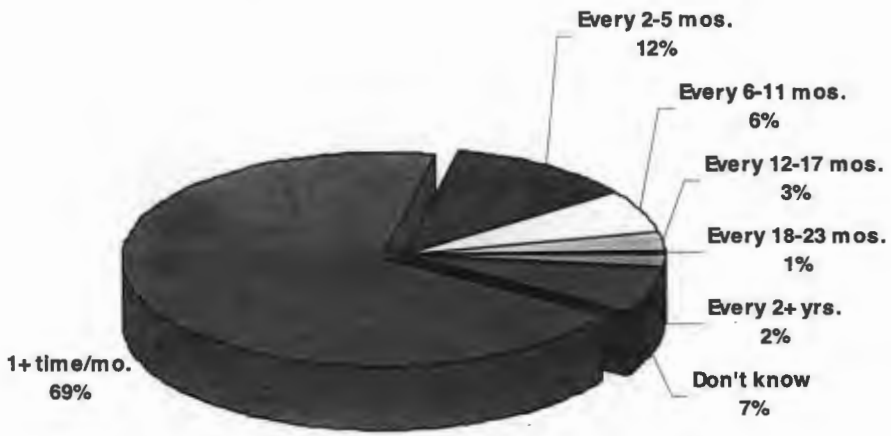
FDA Inspection of Foreign Food Production Facilities

INTRODUCTION:

C3B - The FDA inspects food-processing facilities periodically. Approximately how often do you feel the FDA should conduct its inspections of FOREIGN food-processing facilities?

C3B - FDA Inspection: Foreign Facilities

Median: 0.7 Months



Concern With Food-Related Issues

INTRODUCTION:

C4ALL - I will read you several issues that may be relevant to consumers. For each issue, please indicate whether you are very concerned, concerned, somewhat concerned or not concerned at all.

C4ALL - Very Concerned or Concerned: Concern With Issues
[4 boxes: Very Concerned...Not Concerned at All]

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Harmful bacteria or chemicals in food	83	78	88	87	79	85	88	85	75	81	82	88	79
Safety of imported foods	81	77	84	80	80	83	88	80	72	80	79	86	74
Dairy cows given synthetic growth hormones	70	58	81	70	67	72	80	71	56	74	69	69	68
Safety of meat treated with carbon monoxide to preserve red color	67	58	75	74	61	66	77	65	53	66	67	71	60
Eating meat or milk products from cloned or genetically engineered animals	58	47	68	60	56	58	69	60	40	64	54	62	50
Ocean pollution caused by fish farms advertised as organic	57	52	62	61	55	55	67	55	47	59	51	58	59
Degradation of plastics used to make or line food and beverage containers	54	47	60	46	56	60	59	54	49	58	54	54	51
Genetic engineering of food crops or animals to produce drugs, such as insulin	43	35	51	48	39	44	55	40	33	43	38	46	43
Health problems associated with eating fish caught in the wild	41	33	48	46	39	38	49	36	34	44	38	46	34

Concern With Food-Related Issues (cont.)

INTRODUCTION:

C4ALL - I will read you several issues that may be relevant to consumers. For each issue, please indicate whether you are very concerned, concerned, somewhat concerned or not concerned at all.

C4ALL - Very Concerned: Concern With Issues
[4 boxes: Very Concerned...Not Concerned at All]

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Harmful bacteria or chemicals in food	62	59	65	63	61	62	63	63	58	63	61	65	58
Safety of imported foods	58	56	61	51	59	64	62	57	56	59	61	62	49
Safety of meat treated with carbon monoxide to preserve red color	45	35	53	45	43	46	53	44	33	48	45	45	41
Dairy cows given synthetic growth hormones	43	33	52	38	43	46	48	40	37	47	45	39	43
Eating meat or milk products from cloned or genetically engineered animals	39	30	48	39	40	39	46	40	28	40	37	43	35
Ocean pollution caused by fish farms advertised as organic	34	31	36	35	32	34	42	31	27	35	32	34	35
Degradation of plastics used to make or line food and beverage containers	31	25	36	23	32	36	30	31	30	35	32	31	25
Genetic engineering of food crops or animals to produce drugs, such as insulin	22	16	27	20	22	24	28	19	18	22	22	22	21
Health problems associated with eating fish caught in the wild	22	19	24	22	22	21	26	17	18	22	22	25	15

Food Safety and Regulation

INTRODUCTION:

C5ALL - For each of the following statements, please indicate whether you strongly agree, somewhat agree, somewhat disagree or strongly disagree.

C5ALL - Strongly or Somewhat Agree: Agreement With Regulatory Statements
[4 boxes: Strongly Agree...Strongly Disagree]

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
The government should have the ability to require a food recall when there are concerns about food safety	98	96	99	98	97	98	97	98	97	99	98	98	95
When food safety problems arise, the government should be able to quickly and accurately trace food from production to sale	97	97	98	95	99	98	95	99	99	95	97	99	96
When food safety problems arise, the FDA should disclose to the public information about the origin and retailer location of potentially harmful food	96	95	97	93	97	98	94	98	95	98	98	95	94
The USDA should disclose to the public information about schools, healthcare facilities, and other public and private institutions that receive recalled meat	96	94	97	93	99	94	93	97	97	97	96	95	95

Food Safety and Regulation (cont.)

INTRODUCTION:

C5ALL - For each of the following statements, please indicate whether you strongly agree, somewhat agree, somewhat disagree or strongly disagree.

C5ALL - Strongly Agree: Agreement With Regulatory Statements
[4 boxes: Strongly Agree...Strongly Disagree]

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
When food safety problems arise, the FDA should disclose to the public information about the origin and retailer location of potentially harmful food	86	83	90	82	87	90	85	88	85	94	85	86	83
The government should have the ability to require a food recall when there are concerns about food safety	85	83	88	83	86	87	87	86	85	89	83	87	83
When food safety problems arise, the government should be able to quickly and accurately trace food from production to sale	83	80	86	79	84	87	85	84	82	87	82	84	79
The USDA should disclose to the public information about schools, healthcare facilities, and other public and private institutions that receive recalled meat	82	78	86	77	85	84	81	88	79	86	84	81	79

Food Production and Safety

INTRODUCTION:

C6ALL - For each of the following statements, please indicate whether you strongly agree, somewhat agree, somewhat disagree or strongly disagree.

C6ALL - Strongly or Somewhat Agree: Agreement With Food Production and Safety Statements

	TOTAL	Gender		Age			Household Income			Region			
		Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Meat companies should be allowed to test and label meat products as "tested for mad cow disease"	96	96	96	98	95	95	96	95	97	95	98	97	93
Processed or packaged foods should be labeled by their country of origin	95	95	96	93	96	96	97	98	93	95	96	96	94
Country-of-origin labeling for products should always be available at point of purchase	95	94	97	92	97	97	94	98	96	94	98	96	93
Food products made from genetically engineered animals should be labeled as such	95	93	96	96	93	95	96	97	92	97	96	94	93
Specialty meat and fish stores should label their products by country of origin	94	94	95	90	96	97	94	97	93	93	96	95	94
Meat and dairy products from cloned animals should be labeled as such	94	90	97	93	95	94	96	97	91	97	93	94	92
Meat treated with carbon monoxide should be labeled as such	93	91	96	95	95	91	93	97	94	95	95	93	92
Fish labeled organic should be produced from 100% organic feed like all other organic food animals	93	91	95	94	93	93	93	94	95	95	94	92	92
Dairies that produce milk and milk products without artificial growth hormones should be allowed to label their products as being free of these hormones	93	90	95	92	95	90	91	93	94	91	95	92	92
Meat that contains any irradiated components should be labeled as such	92	90	94	93	93	90	93	95	89	93	94	90	91
Organic fish farms should be required to recover all waste so it can't pollute the environment	90	87	93	91	90	89	93	91	89	96	89	87	90
Cloning of food animals should be prohibited	69	59	79	73	67	67	80	70	53	79	63	71	63

C6ALL - Strongly Agree: Agreement With Food Production and Safety Statements

	TOTAL	Gender		Age			Household Income			Region			
		Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Meat and dairy products from cloned animals should be labeled as such	79	71	86	76	81	82	84	84	71	82	78	81	75
Food products made from genetically engineered animals should be labeled as such	78	71	85	74	80	79	83	81	72	79	80	75	80
Meat treated with carbon monoxide should be labeled as such	77	69	84	75	77	78	85	81	67	79	80	75	76
Meat companies should be allowed to test and label meat products as "tested for mad cow disease"	77	74	79	78	75	78	84	75	71	78	77	79	71
Dairies that produce milk and milk products without artificial growth hormones should be allowed to label their products as being free of these hormones	75	70	80	72	79	75	74	76	75	73	78	75	76
Processed or packaged foods should be labeled by their country of origin	75	76	75	64	77	84	79	80	71	73	75	77	76
Country-of-origin labeling for products should always be available at point of purchase	73	71	76	62	74	84	72	81	71	69	75	77	70
Specialty meat and fish stores should label their products by country of origin	73	72	74	64	72	82	73	78	71	66	75	73	76
Meat that contains any irradiated components should be labeled as such	72	63	80	68	73	75	77	73	67	75	72	71	71
Fish labeled organic should be produced from 100% organic feed like all other organic food animals	69	63	74	68	68	71	69	71	69	69	68	70	68
Organic fish farms should be required to recover all waste so it can't pollute the environment	68	63	73	74	62	72	78	66	60	76	67	67	64
Cloning of food animals should be prohibited	49	39	59	50	46	52	60	52	33	48	46	52	48

"Naturally Raised" Meat Label

C7ALL - Do you think that the "naturally raised" label on a meat product should mean...

	TOTAL	Gender		Age			Household Income			Region			
		Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
It came from an animal whose diet was free of chemicals, drugs and animal byproducts	86	82	90	89	87	83	86	91	86	90	82	87	86
It came from an animal that was raised in a natural environment	85	84	86	84	88	83	85	88	88	87	88	85	83
It came from an animal that ate a natural diet	85	82	88	85	88	83	85	90	85	89	82	84	88
It did not come from a cloned or genetically engineered animal	78	75	81	83	76	76	83	85	68	83	77	76	77
It came from an animal that had access to the outdoors	77	77	77	78	77	75	80	81	75	81	75	77	76
It came from an animal that was treated humanely	76	68	84	78	77	74	76	81	72	75	78	77	74
No salt water was added to the cut of meat	69	65	72	71	65	71	72	70	68	74	64	67	73
It came from an animal that was not confined	68	63	72	71	68	66	68	74	63	71	64	68	70
None of these	2	2	1	1	2	2	1	0	2	1	2	2	2
Don't know	1	0	1		0	2	1	0		1	0	1	1

Engineered Nanomaterials

C8ALL - Which of the following statements describe what engineered nanomaterials are?

	TOTAL	Gender		Age			Household Income			Region			
		Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
[True] Very small synthetic ingredients that can have different properties	46	50	42	51	51	36	50	48	45	56	39	43	50
[False] Living organisms carry genetic material that has been altered	42	42	41	50	43	32	46	43	40	47	39	40	43
[True] Chemicals created on the scale of a billionth of a meter	41	42	40	45	45	33	42	41	47	41	38	40	45
[False] Materials that have been irradiated to kill bacteria	36	35	37	47	33	31	46	35	30	41	31	38	36
Don't know/I haven't heard of engineered nanomaterials	36	32	40	30	32	47	34	36	33	29	41	38	37
True Only (Net)	*13*	*15*	*11*	*10*	*17*	*11*	*9*	*13*	*18*	*13*	*13*	*12*	*14*
False Only (Net)	*10*	*10*	*9*	*12*	*8*	*10*	*9*	*10*	*9*	*9*	*11*	*11*	*7*

Current Safety of Food Supply

C9 - How would you rate the CURRENT safety of the nation's food supply? Would you say...

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Safe (Net)	73	79	68	70	73	76	70	74	77	70	77	72	74
Very safe	12	15	9	6	13	16	8	12	17	10	12	12	12
Somewhat safe	61	64	59	64	60	60	62	63	60	59	64	61	62
Somewhat unsafe	21	14	28	23	22	19	22	19	22	24	19	23	18
Very unsafe	5	7	4	8	4	4	7	7	1	5	4	4	7
Unsafe (Net)	26	21	32	30	26	23	29	26	23	30	23	28	25
Don't know	1	0	1		1	1	1		0	1	1	0	1

Change in Safety of Food Supply

C10 - Thinking about the PAST SEVERAL YEARS, would you say that your confidence in the safety of the nation's food supply has increased strongly, increased somewhat, stayed the same, decreased somewhat or decreased strongly?

		Gender		Age			Household Income			Region			
	TOTAL	Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Increased (Net)	*20*	*18*	*22*	*25*	*17*	*19*	*28*	*16*	*18*	*13*	*24*	*22*	*19*
Increased strongly	4	4	5	5	2	7	9	2	2	2	4	7	2
Increased somewhat	16	14	17	19	15	13	19	14	16	11	19	15	17
Stayed the same	32	39	24	31	32	32	25	31	36	34	30	30	34
Decreased somewhat	35	32	38	33	38	34	33	34	38	40	33	34	35
Decreased strongly	13	10	15	11	12	14	15	18	8	12	11	14	12
Decreased (Net)	*48*	*43*	*53*	*44*	*50*	*48*	*47*	*52*	*46*	*53*	*45*	*48*	*47*
Don't know	1	0	1		1	1	0	0	0		1	0	0

Government Protection of Food Supply

C11 - Please rate your agreement with the following statement:
The government is doing all it can to ensure the safety of America's food supply. Do you...

	TOTAL	Gender		Age			Household Income			Region			
		Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+	NE	NCntrl	South	West
	%	%	%	%	%	%	%	%	%	%	%	%	%
Agree (Net)	*54*	*57*	*51*	*57*	*53*	*51*	*52*	*47*	*56*	*48*	*53*	*55*	*56*
Strongly agree	10	12	8	12	8	12	14	7	10	11	10	11	10
Somewhat agree	43	44	42	45	45	39	38	39	47	36	43	45	46
Somewhat disagree	28	26	29	27	30	27	28	33	30	35	31	23	26
Strongly disagree	18	16	19	16	16	21	19	19	13	17	16	21	15
Disagree (Net)	*45*	*43*	*48*	*43*	*46*	*48*	*47*	*52*	*43*	*52*	*47*	*44*	*41*
Don't know	1	1	1		2	1	1	1	1	1	0	1	2

Profile

	TOTAL	Gender		Age			Household Income		
		Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+
	%	%	%	%	%	%	%	%	%
UNWEIGHTED BASE	1,001	500	501	173	344	479	305	247	272
							a		
GENDER									
Male	48	100		50	47	48	43	46	56
Female	52		100	50	53	52	57	54	44
AGE									
18-34	30	31	30	100			44	22	25
35-44	19	20	17		49		10	22	29
45-54	19	17	22		51		16	21	24
55-64	14	16	13			47	12	16	14
65+	16	15	18			53	18	19	7
Refused/Nr	1	1	1				0		
MEDIAN (Years)	45.2	43.1	46.2	26.0	45.2	66.3	40.9	47.5	42.7
EDUCATION									
Some HS or less	9	10	8	13	5	9	17	3	4
HS graduate	28	26	29	31	25	27	42	30	13
Some college	28	29	28	33	26	27	27	32	26
College grad+ [Net]	*33*	*33*	*33*	*21*	*41*	*35*	*13*	*35*	*57*
College grad	21	22	21	17	24	23	11	23	36
Postgrad degree	12	11	12	4	17	12	3	12	22
Refused/Nr	2	3	2	1	3	2			
HOUSEHOLD INCOME									
Under $25,000	17	14	20	24	10	20	49		
$25,000 but less than $50,000	27	25	30	34	22	28	51	37	
$50,000 but less than $75,000	16	17	16	11	19	18		63	
$75,000 but less than $100,000	16	17	14	18	18	10			48
$100,000 or more	17	21	14	9	26	13			52
Refused	6	6	6	3	5	10			
MEDIAN (000s)	$53.6	$62.0	$47.4	$42.6	$70.3	$47.5	$25.3	$55.0	$104.3

Profile (cont.)

	TOTAL	Gender		Age			Household Income		
		Men	Women	18-34	35-54	55+	<$40K	$40-74K	$75K+
	%	%	%	%	%	%	%	%	%
UNWEIGHTED BASE	1,001	500	501	173	344	479	305	247	272
EMPLOYMENT									
Employed full time	48	57	39	50	68	23	34	47	70
Retired	20	19	21		3	61	24	24	8
Not employed	16	10	22	24	17	9	26	15	10
Employed part time	13	10	16	25	8	6	16	13	11
Refused/Nr	3	3	2	2	4	2	0	1	1
MARITAL STATUS									
Married	55	58	53	37	69	58	29	64	82
Single and never been married	23	23	22	55	11	5	38	17	10
Divorced	9	9	10	3	10	15	18	8	3
Widowed	6	3	9		0	20	11	4	1
Living as married	3	3	3	3	5	1	2	5	4
Separated	1	1	1		1	1	1	2	
Refused/Nr	2	3	1	1	3	1			
RACE									
White/Caucasian	73	72	74	56	77	84	63	72	87
Black/African-American	12	11	13	23	8	7	20	9	7
Some other race	12	14	10	18	10	8	16	15	8
Asian/Asian-American	2	2	2	3	2	1	2	3	2
Refused/Nr	4	5	3	3	5	2	1	3	
REGION									
Northeast	19	19	18	15	21	20	19	17	18
North Central	22	23	22	19	22	25	23	26	20
South	36	36	37	37	36	37	37	34	36
West	23	22	23	29	22	18	20	23	26

21 U.S.C.
United States Code, 2011 Edition
Title 21 - FOOD AND DRUGS
CHAPTER 12 - MEAT INSPECTION
SUBCHAPTER I - INSPECTION REQUIREMENTS; ADULTERATION AND MISBRANDING
Sec. 601 - Definitions
From the U.S. Government Printing Office, www.gpo.gov

§601. Definitions

As used in this chapter, except as otherwise specified, the following terms shall have the meanings stated below:

(a) The term "Secretary" means the Secretary of Agriculture of the United States or his delegate.

(b) The term "firm" means any partnership, association, or other unincorporated business organization.

(c) The term "meat broker" means any person, firm, or corporation engaged in the business of buying or selling carcasses, parts of carcasses, meat, or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person, firm, or corporation.

(d) The term "renderer" means any person, firm, or corporation engaged in the business of rendering carcasses or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines, except rendering conducted under inspection or exemption under this subchapter.

(e) The term "animal food manufacturer" means any person, firm, or corporation engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines.

(f) The term "State" means any State of the United States and the Commonwealth of Puerto Rico.

(g) The term "Territory" means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

(h) The term "commerce" means commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

(i) The term "United States" means the States, the District of Columbia, and the Territories of the United States.

(j) The term "meat food product" means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(k) The term "capable of use as human food" shall apply to any carcass, or part or product of a carcass, of any animal, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human food, or it is naturally inedible by humans.

(*l*) The term "prepared" means slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

(m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title,

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title,

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: *Provided*, That an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or

(9) if it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance.

(n) The term "misbranded" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if its labeling is false or misleading in any particular;

(2) if it is offered for sale under the name of another food;

(3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;

(4) if its container is so made, formed, or filled as to be misleading;

(5) if in a package or other container unless it bears a label showing (A) the name and place of

business of the manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (B) of this subparagraph (5), reasonable variations may be permitted, and exemptions as to small packages may be established, by regulations prescribed by the Secretary;

(6) if any word, statement, or other information required by or under authority of this chapter to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 607 of this title unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) if it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary under section 607 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) if it is not subject to the provisions of subparagraph (7), unless its label bears (A) the common or usual name of the food, if any there be, and (B) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each: *Provided*, That to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary;

(10) if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health and Human Services, determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses;

(11) if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That, to the extent that compliance with the requirements of this subparagraph (11) is impracticable, exemptions shall be established by regulations promulgated by the Secretary; or

(12) if it fails to bear, directly thereon or on its container, as the Secretary may by regulations prescribe, the inspection legend and, unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

(*o*) The term "label" means a display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

(p) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(q) The term "Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]" means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary

thereto.

(r) The terms "pesticide chemical," "food additive," "color additive," and "raw agricultural commodity" shall have the same meanings for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(s) The term "official mark" means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article or animal under this chapter.

(t) The term "official inspection legend" means any symbol prescribed by regulations of the Secretary showing that an article was inspected and passed in accordance with this chapter.

(u) The term "official certificate" means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(v) The term "official device" means any device prescribed or authorized by the Secretary for use in applying any official mark.

(w) The term "amenable species" means—

(1) those species subject to the provisions of this chapter on the day before November 10, 2005;

(2) catfish, as defined by the Secretary; and

(3) any additional species of livestock that the Secretary considers appropriate.

(Mar. 4, 1907, ch. 2907, title I, §1, as added Pub. L. 90–201, §2, Dec. 15, 1967, 81 Stat. 584; amended Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–571, title I, §107(14), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 109–97, title VII, §798[(a)](2), Nov. 10, 2005, 119 Stat. 2166; Pub. L. 110–234, title XI, §11016(b)(1)(A), May 22, 2008, 122 Stat. 1369; Pub. L. 110–246, §4(a), title XI, §11016(b)(1)(A), June 18, 2008, 122 Stat. 1664, 2130.)

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in pars. (q) and (r), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

Codification

Pub. L. 110–234 and Pub. L. 110–246 made identical amendments to this section. The amendments by Pub. L. 110–234 were repealed by section 4(a) of Pub. L. 110–246.

Amendments

2008—Subsec. (w)(2), (3). Pub. L. 110–246, §11016(b)(1)(A), added par. (2) and redesignated former par. (2) as (3).

2005—Par. (w). Pub. L. 109–97 added par. (w).

1992—Par. (m)(2)(D). Pub. L. 102–571 substituted "379e" for "376".

Change of Name

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in par. (n)(10) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

Effective Date of 2008 Amendment

Amendment of this section and repeal of Pub. L. 110–234 by Pub. L. 110–246 effective May 22, 2008, the date of enactment of Pub. L. 110–234, except as otherwise provided, see section 4 of Pub. L. 110–246, set out as an Effective Date note under section 8701 of Title 7, Agriculture.

Pub. L. 110–234, title XI, §11016(b)(2)(A), May 22, 2008, 122 Stat. 1369, and Pub. L. 110–246, §4(a), title XI, §11016(b)(2)(A), June 18, 2008, 122 Stat. 1664, 2131, provided that: "The amendments made by paragraph (1) [enacting sections 606 and 625 of this title, amending this section, and repealing former section 606 of this title] shall not apply until the date on which the Secretary of Agriculture issues final

regulations (after providing a period of public comment, including through the conduct of public meetings or hearings, in accordance with chapter 5 of title 5, United States Code) to carry out such amendments."

[Pub. L. 110–234 and Pub. L. 110–246 enacted identical provisions. Pub. L. 110–234 was repealed by section 4(a) of Pub. L. 110–246, set out as a note under section 8701 of Title 7, Agriculture.]

Effective Date of 2005 Amendment

Pub. L. 109–97, title VII, §798(b), Nov. 10, 2005, 119 Stat. 2166, provided that: "The amendments made by subsection (a) [amending this section and sections 603 to 605, 608, 609, 615, and 617 to 621 of this title] shall take effect on the day after the effective date of section 794 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006 [section 794 of Pub. L. 109–97, 119 Stat. 2164, effective 120 days after Nov. 10, 2005]."

Effective Date

Section 20 of Pub. L. 90–201 provided that: "This Act [see Short Title note below] shall become effective upon enactment [Dec. 15, 1967] except as provided in paragraphs (a) through (d):

"(a) The provisions of paragraph (b)(1) and (c) of section 10 and the provisions of section 20 of the Federal Meat Inspection Act, as amended by sections 7 and 10 of this Act [sections 610 and 620 of this title], and the provisions of section 18 of this Act repealing paragraph (b) of section 306 of the Tariff Act of 1930 [section 1306(b) of Title 19, Customs Duties], shall become effective upon the expiration of sixty days after enactment [Dec. 15, 1967], hereof.

"(b) The provisions of title I of the Federal Meat Inspection Act, as amended by this Act [this subchapter], shall become effective with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof upon the expiration of sixty days after enactment [Dec. 15, 1967] hereof.

"(c) Section 11 of this Act, amending section 23, of the Federal Meat Inspection Act [section 623 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Dec. 15, 1967].

"(d) Section 204 of the Federal Meat Inspection Act, as added by section 14 of this Act [section 644 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Dec. 15, 1967]."

Short Title of 1986 Amendment

Pub. L. 99–641, title IV, §401, Nov. 10, 1986, 100 Stat. 3567, provided that: "This title [amending sections 606, 609, 621, 671, and 676 of this title and enacting provisions set out as notes under sections 606, 609, 621, 671, and 676 of this title] may be cited as the 'Processed Products Inspection Improvement Act of 1986'."

Short Title of 1978 Amendment

Pub. L. 95–445, §1, Oct. 10, 1978, 92 Stat. 1069, provided: "That this Act [amending sections 603, 610, and 620 of this title and sections 1902 and 1904 of Title 7, Agriculture, repealing sections 1903 and 1905 of Title 7, and enacting provisions set out as notes under this section and section 603 of this title] may be cited as the 'Humane Methods of Slaughter Act of 1978'."

Short Title

Section 1 of Pub. L. 90–201 provided in part: "That this Act [enacting this section and sections 602, 624, 641 to 645, 661, 671 to 680, and 691 of this title, amending sections 603 to 623 of this title, repealing section 96 of this title and section 1306(b) of Title 19, Customs Duties, and enacting provisions set out as notes under this section] may be cited as the 'Wholesome Meat Act'."

Section 1 of Pub. L. 90–201 provided in part that the provisions of act Mar. 4, 1907, as amended, classified to subchapters I to IV–A of this chapter, are designated as the "Federal Meat Inspection Act".

Regulations

Pub. L. 110–234, title XI, §11016(b)(2)(B), May 22, 2008, 122 Stat. 1370, and Pub. L. 110–246, §4(a),

title XI, §11016(b)(2)(B), June 18, 2008, 122 Stat. 1664, 2131, provided that: "Not later than 18 months after the date of the enactment of this Act [June 18, 2008], the Secretary of Agriculture, in consultation with the Commissioner of Food and Drugs, shall issue final regulations to carry out the amendments made by paragraph (1) [enacting sections 606 and 625 of this title, amending this section, and repealing former section 606 of this title]."

[Pub. L. 110–234 and Pub. L. 110–246 enacted identical provisions. Pub. L. 110–234 was repealed by section 4(a) of Pub. L. 110–246, set out as a note under section 8701 of Title 7, Agriculture.]

Separability

Section 19 of Pub. L. 90–201 provided that: "If any provision of this Act or of the amendments made hereby [see Short Title note above] or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the Act and the remaining amendments [see Short Title note above] and of the application of such provision to other persons and circumstances shall not be affected thereby."