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Farmers' Perceptions of Biopharming

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This article investigates farmers' perceptions of biopharming in the United States through a survey administered to tobacco farmers from several tobacco growing states. Responses indicate that farmers have very limited knowledge of biopharming and most of them do not have any concerns about risks associated with this emerging technology. In addition, results reveal that farmers' willingness to grow biopharming crops depends largely on economic incentives. Given that some biopharming products are already making their way to the market more efforts to increase farmers' knowledge of biopharming may help future interactions between farmers, policy makers concerned with biopharming regulations and biopharmaceutical companies.

***Key words*:** agricultural biotechnology, biopharming, farmer surveys, risk perception, technology acceptance, transgenic tobacco, willingness to grow.

Introduction

Biopharming, which has created a new generation of genetically engineered crops, has the prospect of becoming a cheaper and more efficient alternative to producing pharmaceutical products for human use. Biopharming is the cultivation of crops for a pharmaceutical purpose, giving them the ability to produce desired therapeutic proteins that are then extracted, purified, and used by the pharmaceutical industry to produce large-molecule, protein-based drugs. Corn, rice, tobacco, and alfalfa are among the top candidates for being widely used in biopharming (US Department of Agriculture [USDA], Animal and Plant Health Inspection Service [APHIS], n.d.).

Among others, biopharming is important for four primary reasons. First, studies show that biopharming can be significantly cheaper than the most common method of therapeutic protein production[1] (e.g., Hood, Woodard, & Horn, 2002; Mison & Curling, 2000; Morrow, 2002). Second, biopharming may be able to provide a more stable supply and increase consumers' access to much needed medicines (Ahmad et al., 2012). Third, therapeutic proteins from biopharming are believed to be purer than the ones produced by mammalian cell cultures because generally plants do not carry potentially harmful human or animal viruses (Elbehri, 2005). Finally, biopharming offers possibilities to develop new treatments that have thus far been too complex to reproduce by current production methods (Rehbinder, Rehbinder, Engelhard, Hagen, & Jorgensen, 2009).

Private firms have invested hundreds of millions of dollars in research and development for plant-made pharmaceuticals. Some of the therapeutic proteins that have already been successfully produced in plants can be used in the treatment of different types of cancer, HIV, diabetes, cholera, Alzheimer's disease, cystic fibrosis, Hepatitis B, and malaria (Ahmad et al., 2012).

Although not many plant-made pharmaceuticals have made their way to the market, this is not because biotechnology firms are not attracted to the technology; rather, it is due to the fact that biopharming is a relatively new field and it usually takes about 12 years to get a product from the lab stages to the pharmaceutical market. Before this technology can be commercialized, it must overcome many regulatory challenges from the US Food and Drug Administration (FDA; same approval process that all other non plant-made pharmaceutical go through) and from the USDA if grown in the field.

Among these challenges, an important one is to eliminate the risk of biopharming crops contaminating the food supply. This is the main reason why tobacco is one of the most commonly researched crops (USDA APHIS, n.d.). Tobacco also has other unique advantages

1. *The current most common method of therapeutic protein production is to use bioreactors (big steel containers with controlled temperature, humidity, etc.) where suspension cells with the desired proteins are grown. This is called the upstream process. After the cells are fully grown, they are harvested and go through several steps in order to extract and purify the desired protein. This is called the downstream process (Hood & Howard, 2002).*

that address some of the other concerns regarding biopharming. First, the plant is harvested before it reaches maturity or the tops are cut so that the tobacco plant does not flower, thus reducing the risk of contamination through pollen drift (Nevitt et al., 2003). Second, there is also a novel gene that delays the expression of the foreign protein in the field. The new protein would not be expressed until after the tobacco is harvested (Nevitt et al., 2003). Additionally, the nicotine found in tobacco makes the plant less desirable for animal species to feed on, which reduces the risks of contaminating the food supply and endangering local animals (Nevitt et al., 2003).

Biopharming is surrounded by policy and legal controversies involving animal and plant biopharming, pharmaceutical companies, and farmers. The regulatory process involves several important regulatory agencies (e.g., FDA, Environmental Protection Agency [EPA], and USDA APHIS) and policymakers continue to face emerging challenges to establish the correct legal framework. Several bills have been introduced in Congress aiming at protecting the interests of different stakeholders. For example, the Genetically Engineered Safety Act (H.R. 5578) would prohibit open-air cultivation of genetically modified (GM) pharmaceutical and industrial crops and prohibit use of common human food or animal feed as the host plant for a genetically engineered pharmaceutical or industrial chemical. Another bill, the Genetically Engineered Technology Farmer Protection Act (H.R. 5579), would provide various legal protections for farmers and ranchers that may be harmed economically by GM seeds and assign liability for injury caused by GM organisms (Cowan, 2011).

As biopharming progresses, regulatory agencies face the challenge of addressing public environmental (and other) concerns, while at the same time allowing biotech firms and farmers to advance the industry. There have been several studies that evaluate public opinions toward biopharming (e.g., Cook & Fairweather, 2007; Einsiedel & Medlock, 2005; Nevitt, Mills, Reaves, & Norton, 2006). However, thus far, there have been no quantitative studies that evaluate farmers' perceptions of biopharming. Most public opinion research was conducted in the mid 2000s, and with the exception of 17 tobacco producers interviewed in a qualitative study conducted by Nevitt et al. (2003), to our knowledge, there has been no research on US farmers' opinions on biopharming.

Farmers are an important link in the prospect of commercialized biopharming, and a better understanding of farmers' knowledge and how they feel about biopharming is crucial for setting up the appropriate regulatory framework for the technology. In addition to general knowledge on farmers' perception of biopharming, it is also particularly important to understand whether they would be willing to grow biopharming crops and under what conditions.

To begin answering some of these questions, we conducted a survey with tobacco farmers. Our analysis of this data aims to augment the biopharming literature by shedding some light on farmers' knowledge of biopharming, attitudes, and conditions under which they would be involved in biopharming. The findings of this study will benefit not only tobacco farmers, but also biopharming companies, consumers, and policymakers by allowing for a better understanding of producer knowledge of biopharming and their attitudes.

Biopharming Progress and Market Approvals

Research on biopharming started more than two decades ago. However, the first commercial approval did not come until 2006 when Dow AgroSciences received the first approval of a plant-made pharmaceutical for a poultry vaccine created from tobacco cells (Katsnelson, Ransom, Vermij, & Waltz, 2006). Since then, many biotechnology firms have attempted to receive approval from the FDA and other countries' regulatory agencies (Obembe, Popoola, Leelavathi, & Reddy, 2011).

In 2006, Planet Biotechnology received approval in Europe for CaroRX™, which is a topical treatment for the prevention of tooth decay (Planet Biotechnology, Inc., n.d.). However, CaroRX™ was registered as a medical device, so the product avoided the approval process as a plant-made pharmaceutical (Twyman, Schillberg, & Fischer, 2012). The company is currently in Phase II clinical trials in the FDA approval process in the United States (Planet Biotechnology, n.d.).

A Hepatitis B antibody made from tobacco plants was approved in Cuba in 2006 (Twyman et al., 2012). The antibody is not the active ingredient in the vaccine, but it is used in the purification of the vaccine during the traditional production method. However, this product was subject to the same approval process as plant-made pharmaceuticals that are used as active ingredients (Twyman et al., 2012). Additionally, there have been several approvals for plant-made products used for non-pharmaceutical purposes because of more lenient regulatory policies (Spök & Karner, 2008).

In May 2012, Protalix Biotherapeutics (an Israeli company) received the FDA's first approval for a plant-

made pharmaceutical product intended for humans. The protein is used for the treatment of Type I Gaucher's disease and is cultured in genetically engineered carrot cells (Maxmen, 2012; Opar, 2011; Protalix Biotherapeutics, n.d.). Pfizer is currently marketing it in the United States and Israel under the product name Elelyso (Maxmen, 2012; Opar, 2011; Protalix Biotherapeutics, n.d.). However, this protein is currently produced in carrot cells under laboratory conditions, and there are no farm-based whole plants used in the production method (Morrow, 2012). Nevertheless, many stakeholders in biopharming working with whole plants believe the approval of Elelyso sets a precedent for future approvals (Maxmen, 2012).

Studies (e.g., Rehbinder et al., 2004; Twyman et al., 2012) indicate that the global value of the biopharmaceutical market continues to grow by billions each year. Therefore, biotechnology firms have substantial incentives to invest in research. However, as one biotechnology executive stated, "pharmaceutical companies don't grow tobacco; only farmers do" (Nevitt et al., 2003, p. 5). Thus, to further understand the prospects of this emerging technology, it is important to examine plant producers' attraction to it as well as adoption barriers.

Studies have found that biopharming will have low acreage requirements compared to agricultural crops. For example, Kostandini, Mills, and Norton (2006) found that less than 3% of the US tobacco acreage in 2006 could meet the world demand for human serum albumin, a widely used blood protein. However, as biopharming progresses, if major tobacco biopharming products are approved, biopharming may be able to provide significant returns to tobacco farmers in the United States given that tobacco acreage is very small compared to other crops (Kostandini, Hesterman, & Mills, 2013). Kostandini et al. (2013) also examine recent trends on biopharming and suggest that while important biopharming products are either in the pipeline or in the market, acreage requirements for major biopharming applications will not be a significant source of income for farmers in general.

Prior Research on Producers' and Consumers' Attitudes on Biopharming

Nevitt et al. (2003) conducted a broad study on the opinions of different stakeholders in tobacco biopharming including the agricultural sector, private industry, academia, activist groups, and government officials. Among others, 17 tobacco producers from Tennessee, Virginia, and North Carolina were interviewed. Most of those interviewed had some knowledge of biopharming technology, but none reported a great deal of knowledge. All tobacco producers expressed an interest in growing pharmaceutical tobacco and had little concern about production as long as it was profitable. The concerns were focused on purchasing new equipment and changing current production practices. A few reported concern with maintaining a relationship with their contracted tobacco companies.

Nevitt et al. (2006) also administered a telephone survey of US consumers on their opinions of tobacco biopharming. First, respondents were asked if they held concern in the following categories: (a) companies owning the rights to genetically engineered tobacco, (b) negative effects on human health, (c) negative effects on the environment, and (d) moral/ethical considerations. Health and environmental concerns were the most frequent responses. They found that socioeconomic characteristics and prior knowledge did not have significant correlation with concerns about biopharming. They also found that acceptance of the technology depended on the intended pharmaceutical purpose, as well as societal benefits (Nevitt et al., 2006). Overall, this study concluded that most consumers accept biopharming technology, but there is also a considerable share of the public that is strictly opposed to it. The next step to help advance this technology, in terms of public acceptance, is to educate people about the associated benefits and risk. People's unwillingness to support the technology would be anticipated to change thereafter.

Researchers at the University of Calgary conducted a biopharming perception study in 2005, with focus groups in four regions of Canada (Einsiedel & Medlock, 2005). The study aimed to report public awareness, reactions to specific biopharming uses, and opinions on different containment strategies. Since most of the public is unaware of biopharming, the researchers provided background information and gave participants more time to reflect on the issues. The study reported that only 2 of the 48 participants had heard of biopharming before the study. The initial reactions were mixed, but the number of positive reactions was slightly higher. The most common areas of concern were contamination with food crops, regulations, long-term health effects, and commercial interests overriding public safety. In terms of acceptability, when considering the end product from biopharming crops, participants had mixed views but tended slightly more toward acceptability. In addition, results indicated that participants tended to be more acceptable or less acceptable, as opposed to the

Table 1. Personal characteristics of participants.

Attribute	% of responders
Male	95.0%
Age > 55 years	67.7%
Income $100K - $120K	63.4%
Four-year degree or higher	36.0%
Growing tobacco 31-40+ years	73.6%
Prior knowledge	
A lot	5.1%
Some	26.5%
Not much	41.9%
Nothing at all	26.5%

extremes of fully acceptable and unacceptable found by Nevitt et al. (2006).

In New Zealand, Cook and Fairweather (2007) also studied public attitudes toward biopharming. They found that only 26% would support biopharming. However, this is high compared to consumers' willingness to purchase GM food, which is only 10%. They also reported that a high percentage of support is correlated with a higher medical benefit. This study concluded that public support would likely change when apprehension about the technology was lessened. The apprehension is largely based on the same concerns from the other studies (Einsiedel & Medlock 2005; Nevitt et al., 2006) and, if addressed, would be expected to change the public's overall opinion of biopharming.

Data

In July 2012, we conducted a telephone survey with 1,129 tobacco producer contacts and collected data on 145 tobacco farmers in Georgia, Kentucky, North Carolina, Tennessee, and Virginia, with a response rate of 13%. First, the respondents were presented with the following statement: "Currently scientists are using genetic engineering to develop tobacco that can be used to create pharmaceutical medicines. Some believe this technology can be used as a cost-efficient alternative to meet the demand for medicines. Others believe it might lead to unexpected effects on humans or the environment." The only other information they were provided with was this statement: "Tobacco plants used to create medicines are regulated by the USDA APHIS. They require that plots of transgenic tobacco be a minimum of 1,320 feet from any other tobacco in the field. Non-transgenic tobacco cannot be grown in the same plot for one year following transgenic tobacco. Regulators will visit the site several times a year."

Table 2. Production characteristics of participants.

Production category	Average	St. Dev.	Min	Max
Acres	143	145.45	1	750
Total production (tons)	121	119.57	1	700
Price ($/lbs)	1.82	0.19	1	2.6

Then we asked a series of questions to tobacco producers that consisted of (a) concerns about unexpected effects from biopharming; (b) willingness to grow tobacco for pharmaceutical uses under different conditions regarding production methods and net return per acre; (c) knowledge of biopharming prior to the survey; and (d) characteristics such as gender, age, income, and education.

Table 1 summarizes respondents' personal characteristics and prior knowledge about biopharming. The sample of 145 was composed of 95% men and the average age was 57. Among respondents who reported their income, 63.4% earned between $100,000 and $120,000 in 2011, 36% hold a four-year degree or higher, and 73.6% have been growing tobacco for 31 to 40 or more years. Questions targeted at eliciting the respondents' level of knowledge on the subject prior to the survey show that 68.4% of those interviewed knew "not much" or "nothing at all" prior to the survey.[2]

Table 2 summarizes the respondents' acres of tobacco planted, production, and average prices earned in the previous year. In 2011, 50% of the respondents planted 100 acres of tobacco or less, 51% produced 100 tons or less, and the average price received was $1.82 per pound, with the commodity having a relatively uniform price (standard deviation was 0.19) considering that farmers grow different varieties of tobacco.[3]

Below we present our findings on concerns about biopharming and willingness to grow transgenic tobacco using summary statistics as well as probit models to examine factors that may affect farmers' decisions. One concern that may arise with our data is the selection bias of the respondents. In other words, of those that were called, is there any selection into who chooses to complete the survey or not? We ran a few probit models where the dependent variable is whether one completed the survey and the independent variables were the time intervals at which the respondents were called. The results revealed that during certain time intervals (e.g., 6-7 pm and 7-8 pm) there was a higher

2. *The question about how much they knew prior to the survey was asked towards the end of the survey.*
3. *Farmers were not asked about the tobacco variety they grow.*

Table 3. Types of concerns about biopharming.

Type of concern	% of responders
Unexpected effects	18.5%
Health	4.8%
Environment	4.4%

propensity for the respondents to complete the survey. This suggests that time in which the respondents are called is important for one to complete the survey and it is unlikely that our sample suffers from selection bias.

Results

Concerns about Biopharming

As noted, survey participants were told that scientists can use tobacco to create pharmaceutical medicines, and some believe it can be a cost-efficient alternative to meet demand for medicines. They were also told that others believe this technology could lead to unexpected effects. Then they were asked if they were concerned with (a) unexpected effects, (b) human health effects, and (c) environmental effects. These results are presented in Table 3. Despite reporting little familiarity with the technology, only 18.5% said they were concerned with the unexpected effects from biopharming, 4.8% were concerned with health effects, and 4.4% were concerned with the environmental effects.

Willingness to Grow

In order to examine their willingness to grow tobacco for pharmaceutical use, tobacco growers were asked the following questions: "If your net return per acre was more than the net return per acre when growing conventional tobacco, (a) would you be willing to grow tobacco using current equipment and production methods for a pharmaceutical company, (b) would you be willing to grow transgenic tobacco for medicine if you were required to change production methods and work closely with a biopharmaceutical firm, and (c) would you be willing to grow it if you have to purchase additional equipment and change production methods?" For each scenario, each tobacco grower was given a randomized net return per acre above growing conventional tobacco. The assigned returns were randomized over farmers and scenarios, such that, even within respondents the percentage of net return per acre for a growing scenario was not dependent on the percentage given for the other two scenarios.

Results on willingness to grow questions are reported in Table 4. Among those that answered,[4] regardless of net return per acre, (a) 81% reported they would be willing to grow tobacco using current production methods, (b) 68% reported they would be willing to grow if required to change production methods and work closely with a biopharmaceutical firm, and (c) 60% reported they would be willing to grow if they had to change production methods and purchase additional equipment. Table 4 also reports the percentage of tobacco producers that answered yes for a given net return per acre and production scenario. Under current production methods, with a 5% increase in net return per acre, 58% would be willing to grow pharmaceutical tobacco. As expected, changing production and additional equipment scenarios decreased the willingness to grow under all net returns per acre. Changing production methods and the requirement of additional equipment dramatically affected whether a tobacco producer answered yes with only 17% and 7% willing to adopt, respectively, if they receive a 5% increase in returns. However, the gap reduces as the net return per acre increases, indicating that profitability is a very important factor for farmers.

Table 4. Willingness to grow pharmaceutical tobacco.

Net return per acre	Current production methods	Change production method	Additional equipment
5%	58%	17%	7%
10%	65%	36%	24%
25%	93%	92%	68%
40%	93%	96%	81%
More than 50%	93%	94%	84%

We also estimate a probit model on the willingness to grow for each of the three growing scenarios using the predictors: net return per acre, gender, age, education, income, concern about unexpected effects, level of knowledge about biopharming prior to the survey, and experience with growing tobacco (Table 5).[5] Results suggest that the probability of a producer willing to grow pharmaceutical tobacco is largely influenced by economic incentives. Net return per acre is statistically significant and increases the probability that a farmer is willing to grow pharmaceutical tobacco under all three

4. 'Don't know' responses were treated as a refusal to answer for all summaries in this article.

5. The reason that the number of observations is not the same across columns in Table 5 is that as the question moved from using the current methods to changing methods and purchasing additional equipment, more respondents stated that they were not sure, and they could not state yes or no.

Table 5. Probit model for willingness to grow.

Variables	Current production methods	Change production methods	Change production methods and buy additional equipment
Net return per acre	4.820 ***	27.228 ***	5.348 ***
	1.754	5.708	1.188
Male	0.127	3.604 ***	1.066
	0.562	1.168	0.737
Age 50 to 85	0.004	-0.014	0.009
	0.015	0.019	0.016
Bachelor or higher	-0.605 *	0.143	-1.060 ***
	0.330	0.417	0.379
Income >$50K	0.085 **	0.015	0.081 **
	0.035	0.039	0.037
Concern about biopharming	0.406	-1.581	-0.915
	0.781	1.779	0.579
Level of prior knowledge	-0.359	-0.172	0.657 *
	0.342	0.412	0.352
More than 10 years of farming	0.251	-0.382	-0.711
	0.505	0.679	0.488
Constant	-0.564	-5.352 ***	-2.135 *
	0.980	1.647	1.166
Observations	117	105	101

*Note: *, **, or *** indicate significance at the 10, 5, and 1% levels, respectively.*

growing scenarios. Additionally, male farmers with an income of more than $50,000 are more likely to adopt the technology. Interestingly, those that have at least a four-year degree are less likely to adopt using current methods or if they have to purchase additional equipment.

To further investigate their willingness to grow pharmaceutical tobacco, as noted, producers were told about some of the current regulations with growing tobacco on the field, including a 1,320 foot fallow zone from other fields and a one-year restriction to grow non-pharmaceutical crops after they have planted biopharming crops. These regulations do not seem to deter willingness to grow, as 86.5% reported it would not prevent them from growing pharmaceutical tobacco. However, when asked what percentage of their acres they would be willing to use for pharmaceutical tobacco, only 15.4% were willing to use 31% or more of their acres. Half of the respondents answered they would be willing to experiment with 6% to 20% of their acres.

A second probit model was used to analyze the probability that regulations would prevent them from growing pharmaceutical tobacco (Table 6). The predictors used were the same ones as in the first probit model. Results suggest that those with prior concerns were more likely to say that regulations would prevent them from growing transgenic tobacco; producers earning more than $50,000 a year through farming and those

Table 6. Probit on regulations preventing willingness to grow.

Variables	Regulations would prevent adopting
Net return per acre	1.711
	1.293
Male	-1.372 *
	0.745
Age 50 to 85	0.010
	0.018
Bachelor or higher	-1.076 *
	0.623
Income >$50K	-0.107 ***
	0.039
Concern about biopharming	1.646 ***
	0.635
Level of prior knowledge	0.201
	0.376
More than 10 years of farming	-0.174
	0.621
Constant	-0.098
	1.140
Observations	121

*Note: *, **, or *** indicate significance at the 10, 5, and 1% levels, respectively.*

with a bachelor degree or higher were less likely to report that regulations would prevent them from growing pharmaceutical tobacco.

In the participatory assessments that Nevitt et al. (2003) conducted, they reported that some tobacco producers expressed concern with maintaining relationships with the companies they currently contract with. Our study reveals a different outcome. We find that 95.4% of the tobacco farmers would be willing to grow tobacco for a company different than the one they usually contract with.

Conclusions

Previous research on perceptions of biopharming has focused on the consumers and the challenges policymakers face in addressing the diversity in public opinion. We explore producers' perceptions, as they are also important stakeholders and will be subject to biopharming regulations when more commercialization takes place.

Compared to the general public, a higher share of tobacco farmers have some knowledge of biopharming (21.7% said they knew some or a lot about biopharming in Nevitt et al. [2006] as compared to 31.6% of the farmers in our study), a similar share has environmental concerns (about 4%), and a smaller share (4.8% vs. 7% in Nevitt et al. [2006]) is worried about negative health effects.[6] Overall, our results suggest that tobacco producers know little about biopharming and their responses are largely driven by the information presented to them, and most importantly, by economic profits. In addition, producers appear to have relatively fewer concerns about the technology compared to consumers.

As biopharming progresses and producers become more aware of the technology, more research will be needed to find how producers' willingness to grow changes and the characteristics of those that will participate. This survey did not address estimates of revenues and additional costs for producers or the specifics of contractual relationships between the biopharmaceutical firm and the producer. These could be important topics for future biopharming research.

Finally, given the low level of biopharming awareness, it is very important to provide producers with appropriate information on biopharming, as well as its challenges and opportunities. This way, they can better evaluate their costs, risks, and benefits and supply important insights that will help shape current and future regulation.

6. Note that there is a seven-year timeframe between these two studies.

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