U.S. Tobacco Growers' Concern about the Impact of the FDA Regulation of Tobacco Products

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Abstract The objective of the paper is to establish an empirical relationship between household characteristics and tobacco growers' perception of the impact of the FDA regulation. A logistic model is applied on primary data that came from the Center for Tobacco Grower Research's (CTGR's) 2011 mail survey of tobacco producers. Results indicate that over 80 percent of the sample tobacco growers are concerned about the impact of the FDA regulation. The profiles of growers who reported to be concerned about the impact of the FDA regulation are not significantly different from those of growers who reported that they are not concerned or somewhat concerned. This result highlights the importance of engaging all groups of growers in discussion to elaborate whether, and if so how the FDA regulation would actually affect tobacco production, and how growers should adjust in light of the expected changes. This would help growers build confidence in the industry, and work towards making the necessary changes in agricultural practices that would help address the regulatory issues related to the *contents* of tobacco products. Given the widespread concern, the failure to do so could have a negative impact on resource allocation and investment decisions because of an overreaction to a potentially erroneous perception of the impact of the FDA regulation.

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1. Introduction

When the Federal Tobacco Program was ended in 2004, ushering in a new era of tobacco production and marketing dictated by market forces, the major concern was and still is price risks. Few years later, growers' concern about the future of tobacco production has increased enormously when the Family Smoking Prevention and Tobacco Control Act of 2009 (FSPTCA) became federal law on June 22, 2009, authorizing the Food and Drug Administration (FDA) to regulate the manufacturing and marketing of tobacco products in the country.

The FSPTCA is arguably the most significant policy change in the history of the manufacturing sector of the tobacco industry. Although the target of the FSPTCA is not

tobacco but rather tobacco products, obviously affecting cigarette manufacturers, it is not certain whether, and if so how it would affect tobacco growers. In fact, the FSPTCA has not authorized the FDA to regulate tobacco farms and tobacco leaf that is not in the possession of a tobacco product manufacturer. Yet, it is plausible that tobacco growers could be affected indirectly. One plausible scenario is that tobacco companies may demand contractual changes or modifications in tobacco farming practices owing to the fact that the major ingredients in tobacco products that the FDA is mandated to regulate are found in tobacco leaf.

From tobacco farmers' perspective, the major concern is whether manufacturers will require them to make changes in the way they grow and cure their tobacco. Should manufacturers demand changes in farming and curing practices, tobacco growers will have to decide what varieties to use, how and where to grow, how to cure, process and store tobacco. This could increase the risk of tobacco production in terms of higher costs of production, reduction in the volume of contracts and loss of contracts.

In its 2011 annual tobacco mail survey, the Center for Tobacco Grower Research (CTGR) questioned tobacco growers whether, and if so how concerned they are about the potential impact of the FDA regulation of tobacco products. While all tobacco growers may be concerned about the potential impact of the FDA regulation on tobacco production, it is hypothesized that some growers tend to be more concerned than others depending, among other factors, on the type of tobacco they grow, the size of tobacco operations, tobacco's share of total farm income, the level of off-farm participation and education.

The objective of the paper is to establish an empirical relationship between household characteristics and growers' perception of the impact of the FDA regulation. As perceptions are conditioned by household characteristics, results will help better inform the design of specific programs to the particular groups of growers rather than having to design more generic programs aimed at all growers with a wide range of household characteristics.

The remainder of the paper is organized as follows. The next section presents an overview of the FSPTCA. Section 3 presents the sources of growers' concern about the impact of the FDA regulation. Section 4 presents the study area. Section 5 presents the empirical model, hypothesis and source of data. Section 6 presents results and discussion. The final section presents the conclusion.

2. Overview of the FSPTCA

The Family Smoking Prevention and Tobacco Control Act of 2009 (FSPTCA) became federal law on June 22, 2009, authorizing the U.S. Food and Drug Administration (FDA) to regulate the manufacturing and marketing of tobacco products in the country.

The FSPTCA has two principal components–manufacturing and marketing. The manufacturing component of the Act allows FDA to issue rules and regulations aimed at reducing or eliminating harmful or potentially harmful ingredients or otherwise modifying the design and characteristics of tobacco products if it is determined that such regulation is appropriate to protect the public health.

Similarly, the marketing component of the Act allows FDA to issue rules and regulations pertaining to labeling, advertising, promotion, distribution and sale of tobacco products. It is aimed at limiting accessibility to tobacco products, particularly among teenagers, through advertisement bans in some facilities and during sport and other similar events, informing the public about the health risks associated with smoking. The Act also allows the FDA to require manufacturers to disclose the contents of tobacco products and use explicit and conspicuous labels of prominent warnings on packages as well as instituting additional tobacco product standards.

As the promulgation of all the rules and regulations on the manufacturing and marketing of tobacco products is finalized, they are expected to be comprehensive and to reduce the use of tobacco products, particularly among young smokers. The Congressional Budget Office (CBO) estimates that over a period of ten years adult and underage smoking prevalence will decline by 2 percent and 13 percent, respectively.

3. Sources of Growers' Concern about the Impact of the FDA Regulation

Growers' concern about the impact of the FDA regulation on tobacco production arises from the result of a research (Hoffmann et al. 1994) showing that the chemical compounds in tobacco leaf give rise to a group of carcinogenic chemicals collectively known as tobacco–specific *N*–nitrosamines (TSNA) during all stages of tobacco production, from growing in the field to curing, processing, and storage. Further, research shows that every step in tobacco leaf production that affects plant metabolism could influence nicotine yields to a certain degree (Tso, 1990). As a result, growers may be required to make a host of hard decisions ranging from the type of tobacco they

grow, to the type and rate of chemical fertilizer and pesticides they apply on tobacco, to the timing and method of topping, harvesting, processing, curing and storing , to the physical characteristics of the area of production. All these decisions have important cost implications. Currently, tobacco growers make most of these production decisions, and bear both production and price risks. However, going forward with the implementation of the FDA regulation, manufacturers could dominate the terms of contracts and take greater control of the production process. As a result, it would not be unrealistic to expect that tobacco growers could pick up some of the compliance costs associated with the implementation of the FDA regulation. More recently, manufacturers have been demanding tobacco growers to adopt a program called Good Agricultural Practices (GAP), which allows them to exercise more control over the quality and characteristics of the tobacco leaf. Now with the evolving FDA regulation of the manufacture of tobacco products, it is likely that they will get involved in a way that they could even more influence production decisions. For example, the FSPTCA authorizes the FDA to set standards that could reduce nicotine content. While the FSPTCA prohibits the FDA from limiting nicotine content to zero, it is likely that the FDA may set the level of nicotine at a lower level in view of the fact that nicotine is the chemical compound responsible for continued use of tobacco products and most importantly the source for the formation of a group of carcinogenic chemicals. Should the FDA come to decide to reduce the nicotine level, manufacturers could demand growers to make significant changes in farming and curing practices.

4. Study area

This study focuses on tobacco growers in the four major tobacco-producing states - North Carolina, Kentucky, Tennessee and Virginia. The NASS/USDA data indicates that US tobacco production of all classes is valued at over 1.25 billion in 2010 with production of about 719 million lbs. on 337,500 acres of land. In terms of production, the four states account for 87 percent of the total production in 2010 with North Carolina (49%) and Kentucky (25%) contributing to 72% of the total tobacco production in the country. Tennessee and Virginia account for 6 percent of the total production, each. Kentucky and Tennessee are major burley tobacco producers while North Carolina is major flue–cured producer.

According to the 2007 Census of Agriculture, there are 16,234 farms with an average size of 22 acres. Three–fourths of the farms are in Kentucky (50%), North Carolina (16%) and Tennessee (10%).

5. Model

Following the random utility theory in Greene (2003), a grower's perception of the impact of the FDA regulation can be modeled as a dummy variable, Y^{th}, such that $Y_i = 1$ if the grower is concerned about the impact of the FDA regulation, and $Y_i = 0$ otherwise. Therefore, Y_i has the Bernoulli distribution at each covariate pattern, with mean$= p_i$ and variance$= p_i(1-p_i)$. To specify this discrete probability distribution as a function of the parameter estimates, we must assume that the relationship between p_i and the predictors take on a specific functional form. With the dependent variable being

dichotomous, we can assume either logistic or standard normal distribution, which will lead to logit or probit analysis, respectively. The question of which model to use is a natural one in that it is difficult to justify the choice of one model over the other on theoretical grounds (Greene 2000). Both logit and probit models provide similar parameter estimates, making it difficult to distinguish them statistically (Amemiya 1981). However, in practice the logistic distribution function is often a good model for p_i (Demaris 1992). Therefore, following Demaris (1992), the conditional probability of a grower's perception of the impact of the FDA regulation p_i can be given as:

$$p_i = \frac{1}{1+\exp(-z_i)}, \quad (1)$$

where the right-hand expression is the logistic distribution function; z_i is the conditional odds of a grower's perception of the impact of the FDA regulation.

Rearranging Eq. (1) the log odds of a grower's perception of the impact of the FDA regulation can be given as:

$$Ln(Z_i) = Ln\left[P_i/(1-P_i)\right] = X_i'\beta_j + \xi_i, \quad (2)$$

where Ln is natural log; X_i is a vector of the i^{th} grower's farm and family characteristics affecting a grower's a grower's perception of the impact of the FDA regulation; β_j is a vector of parameters representing the change in the log-odds due to a unit increment in the values of the predictors, X_i and ξ_i is the error term.

5.1. Hypotheses

A grower's perception of the impact of the FDA regulation is hypothesized to be dependent on a number of household characteristics. Table 1 presents the description of the explanatory variables X_i used in the model to explain why some growers tend to be more concerned about the impact of the FDA regulation than others.

Age of grower (**AGE**): Age, as a proxy for risk aversion, could influence the way growers perceive the impact of the FDA regulation. Older growers who have been invested in the production of tobacco for long find it difficult to switch to other enterprises. As a result, they tend to be more concerned than younger households, who have not yet made as much tobacco-specific investment. Hence, the coefficient of *age* is expected to be positive. Table 2 presents *a prior* expected signs of the parameter estimates of the explanatory variables included in the model.

Education (EDUC): The FSPTCA explicitly states that FDA can't regulate tobacco farms and tobacco leaf that is not in the possession of a tobacco product manufacturer. As a result, it is not apparent in the FSPTCA how the FDA regulation would actually affect tobacco growers. One needs to gather, process and synthesize pieces of provisions to suggest if the FDA regulation would actually affect tobacco growers. It may also be important to have a better understanding of how the tobacco industry operates. Tobacco growers with a college level of education are likely to obtain and process the necessary information and become well aware of the impact of the FDA regulation. The coefficient of EDUC is therefore expected to be positive.

Household size (HHSIZE**):** With the concern about the impact of the FDA regulation being loss or reduction in volume of contracts, the larger the size of the household as measured by the number of family members in the household, the higher the likelihood to be concerned. The coefficient of HHSIZE is therefore expected to be positive.

Off-farm income (OFF_INCOME): Households who have additional source of income from off-farm sources are less likely to be concerned than are households who have no additional sources of income. The coefficient of OFF_INCOME is therefore expected to be negative.

Tobacco type: Given that smokeless tobacco products (manufactured using dark tobacco) are perceived to have less health hazard than cigarettes (manufactured using burley and flue-cured), it may be argued that dark tobacco growers tend to be less concerned than burley and flue-cured growers. However, since the FDA regulation is applied on tobacco products manufactured and marketed in the U.S, it may be argued that dark tobacco growers tend to be more concerned about the effect of the FDA regulation because dark tobacco is grown largely for home consumption than for export. In contrast, burley and flue-cured tobacco are exported in greater proportion than dark tobacco. The NASS/USDA data shows that in the 2009/2010 marketing year, flue-cured exports and burley exports account for 62.3 percent and 53.6 percent, respectively. Hence, the coefficients of flue-cured tobacco (FLUE) and burley (BURLEY) are expected to be negative.

Farm size: The need for increased monitoring of the quality and other characteristics of the tobacco leaf may make it economically appealing for tobacco manufacturers to enter into contracts with larger farms rather than with smaller farms. As a result, growers with large scales of operation tend to be less concerned about losing their contracts and thus tend to be less concerned about the impact of the FDA regulation than growers of small operations. The coefficients of FARM_MEDIUM and FARM_LARGE denoting medium-size and large-size farms, respectively, are therefore expected to be negative.

Proportion of tobacco cash receipt: The proportion of tobacco cash receipt as measured by the percent of farm cash receipts derived from tobacco vis–à–vis other farm enterprises measures the relative importance of tobacco in the farming operation. The higher the proportion of tobacco receipts to total farm receipts, the higher the degree of reliance on tobacco production. Therefore, growers having a relatively higher ratio of tobacco receipts to total farm receipts (50 percent or more) tend to be more concerned. The coefficient of TOB_CASH is therefore expected to be positive.

Regional location: The regional location is represented by state boundaries. The states in which tobacco is grown (KY, TN, NC, VA) are included to capture the influence of regional differences in risk perceptions of the impact of the FDA regulation.

5.2. Sources of data

The Data for this study came from the Center for Tobacco Grower Research's (CTGR's) 2011 annual tobacco mail survey of tobacco producers in Kentucky, Tennessee, Virginia, North Carolina and other states. A standard questionnaire was administered to a

sample of 4,000 tobacco growers of whom 1,143 completed and returned the questionnaires representing a 28.6 percent response rate. Of the 1,143 growers who completed and returned the questionnaires, 928 are current growers, 133 are former growers who are still actively managing a farming operation and 82 growers are no longer in farming.

6. Results and Discussion

This section presents the descriptive statistics and model results, providing the individual and joint empirical relationship between growers' concern and farm and family characteristics.

6.1. Descriptive results

Over 80 percent of the sample growers reported to be concerned about the impact of the FDA regulation. Table 3 presents a summary of the farm and family characteristics of tobacco growers who reported to be concerned and not concerned about the impact of the FDA regulation on their tobacco production. On average the proportion of concerned growers is slightly higher among young tobacco growers with a college education, operating large farms of flue-cured and dark tobacco with more than 50 percent of total farm cash receipts coming from tobacco operations. For example, among farmers operating large farms, 87.4 percent reported to be concerned about the impact of the FDA regulation. In contrast, among famers operating small farms, 81.3 percent are concerned. Similarly, 85.6 percent of flue-cured and 90 percent of dark tobacco growers are concerned. In contrast, among burley growers, 79.5 percent of

growers are concerned about the impact of the FDA regulation on their tobacco production.

The next section provides the result of the multivariate analysis, assessing the joint effect of the above-mentioned characteristics as well as the effect of individual characteristics, holding all other things being equal.

6.2. Model results

The global null hypothesis that none of the predictors in the model have non-zero coefficients was tested using the likelihood ratio chi-squared test statistic, which is often referred to as the model chi-squared. The model chi-squared statistic is statistically significant at $p<0.05$ with 14 degrees of freedom. The null hypothesis is thus rejected, indicating that the predictors are jointly related to the log-odds of growers' perception of the impact of the FDA regulation. At least one of the predictors has an effect on the log-odds of the perception of the impact of the FDA regulation. In fact, the Wald chi-square statistic indicates that only two of the 14 predictors have non-zero coefficients.

Table 4 provides the ML parameter estimates of the model, measuring the change in the predicted log–odds (logit) of the perception of the impact of the FDA regulation for a one unit change in a given predictor, holding all other predictors constant. For discrete predictors, the one–unit change compares the predicted log–odds of the perception of the impact of the FDA regulation for the category of the predictor included in the model relative to the reference category, holding all other factors constant. The reference category is the level of the predictor not included in the model.

For instance, the reference category for the predictor tobacco type is DARK . The parameter estimates of burley (BURLEY) and flue-cure tobacco (FLUE) are interpreted in relation to that of DARK.

The predictors included in the model have been categorized into demographic, farm, and regional characteristics. Among the demographic characteristics, none of them are found to have a statistically significant influence on growers' perception of the impact of the FDA regulation, *ceteris paribus* (Table 4).

Similarly, results suggest that holding other factors constant, burley and flue-cured tobacco growers are as equally likely as dark tobacco growers to be concerned. This is in contrary to expectation. The expectation was that burley and flue-cured tobacco growers tend to be more concerned than dark tobacco growers because of the perception that smokeless tobacco products (made with dark tobacco) have less health hazard than cigarettes, which are made using burley and flue-cured tobacco.

Contrary to expectation, farm size as measured by total farm cash receipts is not also significantly related to the log-odds of the perception of the impact of the FDA regulation. Operators of medium-size and large-size tobacco farms are as equally likely as operators of small farms to be concerned about the impact of the FDA regulation.

As expected, tobacco cash receipts as measured by the percentage of total farm cash receipts accounted for by tobacco have a statistically significant positive relationship with growers' perception of the impact of the FDA regulation. The higher the percentage of total farm cash receipts accounted for by tobacco, the higher the likelihood of being concerned about the impact of the FDA regulation.

Finally, results suggest no differences in growers concern based on regional locations. Growers in the major tobacco growing states (Kentucky, North Carolina, Tennessee and Virginia) are as equally likely as growers in other tobacco growing states to be concerned about the impact of the FDA regulation.

6.3. Model characteristics

The model is tested for its goodness-of-fit using the Hosmer–Lemeshow statistic, which is calculated using the observed and expected counts for both concerned and unconcerned groups of growers, and has an approximate $\chi 2$ distribution with 8 degrees of freedom. Results indicate that the observed number of concerned growers is not significantly different from those predicted by the model ($\chi^2(\mathrm{df}=8)$=7.35; P=0.50). In other words, the observed frequencies match well with expected frequencies under the null hypothesis that the model in question is the true one that generated the data, suggesting that the model shows no evidence of lack of fit and that the overall model fit is good.

Unlike the case in linear regression, a logistic model goodness-of-fit is to be distinguished from predictive capacity because it is possible to have an excellent fit between the logit model and the data without having predictive efficacy (Schumacker 2005). The next section will present results of the assessment of the efficacy of the estimated model in predicting the probability of concern.

6.4. Predictive Efficacy of the Estimated Model

Predictive efficacy refers to the ability of one's model to generate accurate predictions of group membership on the dependent variable. The Receiving Operator

Characteristics (ROC) is used to provide the model's ability to discriminate between concerned and unconcerned groups of growers. The accuracy of the estimated model as measured by the area under the ROC is 81.5 percent. This means that the percentage of randomly drawn pairs of growers, for which the estimated model correctly classifies them into concerned and unconcerned groups, is 81.5 percent. For example, consider a situation in which tobacco growers are already correctly classified into two groups-concerned and unconcerned. If you randomly pick 100 pairs of growers with one coming from the concerned group and another from the unconcerned group, and incorporate their farm and family characteristics into the model and calculate both growers' predicted probabilities of concern, the estimated model will *correctly* classify 81.5 percent of the pairs into concerned and unconcerned groups. Given the reasonable predictive efficacy of the estimated model (81.5 percent based on the ROC measure, procedure), one can reasonably use the model to determine who is more likely to be concerned.

7. Conclusion

The study has assessed tobacco growers' concern about the impact of the FDA regulation on tobacco production by applying logistic regression to data that came from the Center for Tobacco Grower Research's 2011 mail survey of tobacco producers. Results indicate that over 80 percent of the sample tobacco growers are concerned about the impact of the FDA regulation. The physical, demographic and socioeconomic profiles of growers who reported to be concerned about the impact of the FDA regulation are not significantly different from those of growers who reported that they

are not concerned or somewhat concerned. In other words, tobacco growers are concerned about the impact of the FDA regulation irrespective of the type of tobacco they grow, the scale of tobacco operation, age, educational level, participation in off-farm employment, resource availability as well as area of production. This result highlights the importance of engaging all groups of growers in discussion to elaborate whether, and if so how the FDA regulation would actually affect tobacco production. It is not clear if growers' perception of the impact of the FDA regulation was influenced by lack of knowledge or strong negative attitude towards regulations in general. The finding that the concern is widespread across all groups of tobacco growers regardless of physical and socioeconomic characteristics suggests that a blanket extension program be designed and implemented to highlight expected changes in the farming sector and how growers should adjust in light of the expected changes. This would help growers understand what is and what is not actually going to happen and thus build confidence in the industry, and bring about the necessary changes in agricultural practices that would help address the regulatory issues related to the *contents* of tobacco products. The failure to do so could have a negative impact on resource allocation and investment decisions because of an overreaction to a potentially erroneous perception of the impact of the FDA regulation. Such reaction could keep potential young tobacco growers from entering the tobacco sector, and keep current growers from making new investments in their tobacco operations.

Table 1 Description of independent variables predicting tobacco growers' perception of the impact of the FDA regulation

Variables	Code and Levels
Growers' concern about the impact of the FDA regulation (dependent variable)	CONCERN=1: if the grower is concerned about the impact of the FDA regulation; otherwise CONCERN=0
Age	AGE1: If the age of the grower is below 45 years
	AGE2: If the age of the grower is between 45 and 64 years
	AGE3: If the age of the grower is 65 years or above
Education	EDUC = 1: If the grower has some college education or more; otherwise EDUC = 0
Household size	HHSIZE=1: If the household has three family members or more; otherwise HHSIZE=0
Off-farm work	OFF_WORK=1: If the grower has an off-farm employment; otherwise OFF_WORK=0
Tobacco type	BURLEY=1: If tobacco type is burley; otherwise BURLEY=0 FLUE=1: If tobacco type is flue-cured; otherwise FLUE=0 DARK=1: If tobacco type is dark tobacco; otherwise DARK=0
Farm size	FARMSIZE_SMALL=1: If total farm cash receipts < $10,000; otherwise FARMSIZE_SMALL=0 FARMSIZE_MEDIUM=1: If $10,000< = total farm cash receipts <$250,000; otherwise FARMSIZE_MEDIUM=0 FARMSIZE_LARGE=1:If total farm cash receipts >= $250,000; otherwise FARMSIZE_LARGE=0
Tobacco cash receipts	TOB_CASH=1: If proportion of tobacco receipts $\geq$50 percent of total farm receipts; otherwise TOB_CASH=0
State	KY=1: State of Kentucky; otherwise KY=0 TN=1:State of Tennessee; otherwise TN=0 NC=1:State of North Carolina; otherwise NC=0 VA=1:State of Virginia; otherwise VA=0 OTH=1:other states; otherwise OTH=0

Table 2 *A priori* expected signs of the coefficients of independent variables predicting tobacco growers' perception of the impact of the FDA regulation

Levels	Code	*A priori* expected signs
Age	AGE2; AGE3	+
Education	EDUC	+
Household size	HHSIZE	+
Off-farm work	OFF_WORK	-
Tobacco type	BURLEY	+
	FLUE	+
Farm size	FARM_MEDIUM	-
	FARM_LARGE	-
Tobacco cash receipts	TOB_CASH	+
State	KY	+
	TN	+
	NC	+
	VA	+

Table 3: Descriptive characteristics of the variables predicting tobacco growers' perception of the impact of the FDA regulation

Household characteristics	Variables	Not concerned	Concerned	Chi-square statistic
Age	AGE1	15.7	84.3	0.82
	AGE2	18.8	81.2	
	AGE3	18.8	81.2	
Education	EDUC=0	19.0	81.0	1.95
	EDUC=1	14.5	85.5	
Household size	HHSIZE=0	19.3	80.7	2.40
	HHSIZE=0	14.7	85.3	
Off-farm work	OFF_WORK=0	18.0	82.0	0.18
	OFF_WORK=1	19.1	80.9	
Tobacco type	BURLEY	20.5	79.5	9.12
	FLUE	14.4	85.6	
	DARK	10.0	90.0	
Farm size	FARM_SMALL	18.7	81.3	5.47*
	FARM_MEDIUM	19.9	80.1	
	FARM_LARGE	12.6	87.4	
Tobacco cash receipts	TOB_CASH=0	21.7	78.3	6.32***
	TOB_CASH=1	15.1	84.9	
State	KY	19.6	80.4	3.85
	NC	16.1	83.9	
	TN	15.9	84.1	
	VA	10.9	89.1	
	OTH	20.8	79.2	

Table 4: Parameter estimates of growers' perception of the impact of the FDA regulation

Parameter	Estimate	SE
Intercept	1.366	0.573**
AGE2	-0.101	0.255
AGE3	-0.114	0.329
EDUC_HH2	0.269	0.238
HHSIZE	0.338	0.237
OFF_WORK	-0.080	0.191
BURLEY	-0.512	0.322*
FLUE	-0.456	0.509
FARMSIZE2	-0.152	0.269
FARMSIZE3	0.329	0.341
TOB_INCOME	0.008	0.003***
KY	0.125	0.296
TN	0.367	0.372
NC	0.134	0.454
VA	0.617	0.522

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