Padua 2017 Abstract Submission

Title
ECONOMIC IMPACT OF THE UNITED STATES FOOD SAFETY MODERNIZATION ACT ON SMALL AND MEDIUM WINERIES

I want to submit an abstract for:
Conference Presentation

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Keywords
FOOD MODERNIZATION SAFETY CONTAMINATED MICROBIAL

Research Question
WHAT IS THE ECONOMIC IMPACT OF THE UNITED STATES FOOD SAFETY MODERNIZATION ACT ("FSMA") ON SMALL AND MEDIUM SIZED WINERIES

Methods
Analysis of applicable rules of FSMA, followed by the analysis of the costs of changes to procedures and capital changes, followed by impact on margin

Results
The FSMA will have a small but significant impact on the margins of small wineries such that some will suffer greatly from the costs of implementation or fine.

Abstract
“The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.” (i)

From a macro level, this rule seems like common sense. Imposing duties upon food manufacturers by way of regulation to have knowledge about the source and destination of their products and to have policies and procedures in place to protect the end users of the food from sickness or death due to contamination. Moreover, it seems like enforcement mechanisms of threats of surprise inspections and huge fines would be the only way to force manufacturers to actually comply with the rules and regulations because it would unquestionably not be in the manufacturer’s short term economic benefit to put in place the methodologies necessary to implement the rules because the chance of an actual contamination is relatively small. The purpose of the Act seems to be that despite this small chance, if all food manufacturers follow these rules and are forced to by the enforcement mechanism, the chance of anyone in the United States becoming sick from contaminated food certainly lessens. To what level and the extent of change from pre-FSMA times, will be subject to review in time.

Where the FSMA starts to deviate from common sense is where this presentation takes over. What is “food” is under the act. Under Section 201(f) of the Food Drug and Cosmetic Act, the term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(ii) This definition represents about the broadest definition one can imagine. Without going into crazy stuff that it might include, there is no question, that wine and spirits are all “foods” and therefore the manufacturers of these alcoholic beverages have been lumped into the larger pool of food manufacturers, with an obligation to comply with a huge array of new rules, regulations, and required capital improvements just to make wine. What makes this scenario quite tragic is the nature of alcoholic beverages, unlike most any other product is that garbage in, does not translate to garbage out. The very nature of the alcohol combined with the filtering process inherent in the making of alcoholic beverages kills the bacteria and finds the occasional “Material other than Grape” (that fell in the tank by accident) long before the alcoholic beverage product hits the shelves. In more scientific terms, it is known as a “microbiologically low safety risk,” (iii) as long as the alcohol content exceeds 7%, making high alcohol wine and distilled spirits an even lower safety risk. Moreover, this natural cleansing agent called Alcohol naturally breaks down fining agents such as milk, casein, sodium, potassium caseinate, egg-derived products and Isinglass.(iv) Almost everyone with allergies to those products has no allergenic reaction to wine that includes those products for fining. Rather, the allergic reactions came from histamine, salicylates or sulphites, and yeast which seemingly had nothing to do with the allergenic products contained therein.

So, despite the substantial evidence that alcoholic beverages manufactured by a winery (or distillery) simply cannot produce products that are contaminated with pathogens, allergens, or other biological contaminants, the FSMA applies. In looking for some justification why the Wine and Distilled Spirits Industry is now subject to these new duties and obligations under the FSMA, the Industry must buy into the potential that some molecules of whatever kind or nature that the alcohol cannot kill, could potentially creep into the wine and all of the controls as to policy, procedure, on the one hand, and product source and destination, on the other hand, will prevent drinkers of alcoholic beverages from getting sick or dying. This has to be the assumption, even though under the Federal Alcohol Act and CFR Title 27, Chapter I, Subchapter A. Part 24§, 24.175, et seq., only certain specific items can be added to wine such as sugar, fruit juice, acid, distillates containing aldehydes. Other items cannot be added without permission of the Formulation Division of the Alcohol Trade and Tobacco Bureau. If other materials are added to the wine that are not permitted by the Federal Alcohol Act or the TTB, the winery is subject to fines, penalties (including criminal) and revocation of their basic permit. The FSMA makes points that chemicals or radiation or other unknown contaminants could make it into the food, or in our case the wine. Clearly that does not happen in the course of ordinary winemaking. If it’s an intentional act, no FSMA rule or any regulation or perhaps even the potential criminal penalties, is going to stop an individual from creating poison wine or spirits That is how hundreds of people have died in Eastern Europe in recent years,(v) including 72 just recently. (vi)

So, we in the wine industry are left with a whole new set of rules, in addition to those that control the winemaking operations under the Federal Alcohol Act, every states’ liquor control board, and each individual county, city, or fiefdom, because there is a theoretical possibility that 1) some contaminate might accidently enter the wine and 2) that contaminate will not be of the sort that “leaves no trace” after being exposed to alcohol, filtration, and racking. Interestingly, in speaking to insurance and other industry personnel, no one has ever heard of any such claim for bodily injury in the 250 years of jurisprudence in the United States

Now that we all understand why this applies to the wine industry, we can now focus on whether one more set of regulations matter. The answer is yes. Maybe it’s because it hits a breaking point where the camel’s back is finally broken. These rules and regulations are not going to be so onerous for the big companies, the big players in the wine industry who own hundreds of brands of wine from the US and import hundreds more (the FSMA does apply to wine imported into the US as well, but that is not a topic for this paper.), but much more so to the small and medium sized wineries as well as the alternating proprietor hosts. To understand this next point, a brief explanation as to the nature of the US winery and distillery map is necessary, keeping in mind the terms boutique winery and craft distillery. Around the world there are recognizable mega brands of wine and spirits, all owned by Diageo, Constellation, Bacardi, Pernod, Gallo, Wine Group, etc. Let’s assume there are 100 such companies who own scores of brands. For each one of those, there are hundreds of small and medium sized producers of wines and spirits who do every they can to make a great product and sell that product. In the meantime, they must comply with all the federal, state and local alcohol rules and pay their taxes. With the new regulations which require duplicative paperwork produced in different ways, significant changes in policies and procedures, capital improvements, IT improvements, and hundreds of additional man hours, these small to medium sized manufacturers who incidentally are insured for any claims for bodily harm from this remote contingency, may just have to call it quits, or perhaps, be able to abide by the regulations to streamline their operations, make them more efficient, so in the long run, they will actually end up making more money. In either event, it seems absolutely clear that these regulations will not improve the actual product and in realty won't make it any safer, but remember those points do not matter.

In the presented version of this paper, we will take two wineries, one small and one medium and see how the regulations will impact their bottom line, in the short run and in the long run. We will also look at a small alternating proprietorship to see how the FMSA may affect its bottom line, in the short and long run. We will see any of them can theoretically survive long enough to see any return on investment or whether, in the process of complying, they simply give up and move their operations out of the United States.

Considering the California wine industry contributes $57.6 billion annually and 325,000 jobs to the state's economy and $114.1 billion annually 786,000 jobs to the U.S. economy "by providing quality jobs, bolstering economies through tourism and taxes and enhancing communities through environmental stewardship and charitable giving," (vii) FSMA may have a dampening effect on the wine industry and its contribution to the overall state and US Economies, or it may actually help it survive to the next century. Time will tell.

Endnotes
i: https://www.fda.gov/food/guidanceregulation/fsma/
ii: 21 U.S. Code § 321
iii: Microbiologically, Wine Is A Low Food Safety Risk Consumer Product, Undated White Paper by The World Wine Trade Group, FIVS, The International Wine Technical Summit
iv: FIVS, FIVS Good Fining Practices, October 2016.
v: http://www.rferl.org/a/1072399.html,
vi: http://abcnews.go.com/International/72-now-dead-siberia-drinking-counterfeit-alcohol/story?id=44342514
vii http://www.wineinstitute.org/resources/pressroom/02132017