United States Department of Agriculture

Office of the Chief Economist
1400 Independence Avenue, SW
Washington, D.C. 20250-3810

July 10, 2017

Mr. Mitchell Zeller, Director
Center for Tobacco Products
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: USDA Public Comments on FDA's proposed rule on "Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products" published in the January 23, 2017 Federal Register; FDA docket identification (ID) number FDA-2016-N-2527.

Dear Mr. Zeller,

America's farmers face numerous challenges as they work to produce the food, feed, fiber and other agricultural products for strong and healthy America. On January 23, 2017, the FDA proposed a new standard for N-nitrosonornicotine (NNN) levels in smokeless tobacco products of 1.0 µg NNN per gram of tobacco (on a dry weight basis) at any time through the product's expiration date. The FDA states that this level is achievable in smokeless tobacco products using current technology based on a Swedish study and a few observations of smokeless products meeting the standard in the U.S. market. Only three of 34 products analyzed by the Center for Tobacco Products could meet the standard as shown in a 2016 publication in the Journal of Agriculture and Food Chemistry.

It is not clear that it is technically feasible to meet the new standard using current production and processing methods. While the FDA assessment identifies several factors that influence the NNN level in smokeless tobacco, there is inadequate discussion of the role played by factors not under control of the grower or manufacturer relative to those factors amenable to changes in technology or agricultural practice. If the new standard cannot be met by the moist smokeless tobacco products, there will be an impact to growers. That impact is not examined in the FDA's economic assessment. We are willing to work with the FDA to assist with revising the economic assessment.

We submit our more detailed comments below.
Sincerely,

Robert Johansson, Chief Economist
US Department of Agriculture

USDA Public Comments on the FDA proposed rule, "Tobacco Product Standard for N'-nitrosonornicotine Level in Finished Smokeless Tobacco Products"

The Department of Agriculture is pleased to submit these comments pursuant to Section 907(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act. While it is clearly desirable to reduce health risks associated with the use of smokeless tobacco products where feasible, it is also important to consider the technical achievability and economic impact associated with reducing those risks. As proposed, this standard will have a significant adverse effect on a specific segment of the agricultural community. There was no discussion of effects of the standard on agriculture in the Preliminary Regulatory Impact Analysis (PRIA) that accompanied the proposed rule. I am providing this information for your consideration as you work toward developing your final rule.

Use of dark tobacco varieties in smokeless tobacco products in the United States

The smokeless tobacco products subject to the proposed regulation include a wide variety of different products, all of which deliver nicotine and other constituents into the human bloodstream through means other than inhalation into the lungs. Sales of smokeless tobacco products reached nearly $5.5 billion in 2015[1]. In the United States, this market is heavily dominated by a few major firms[2] and by one type of product – moist snuff (MST)[3].

Moist snuff in the United States relies on the use of fire-cured and air-cured dark tobacco varieties as well as burley tobacco. As the popularity of moist snuff has increased, so too has the demand for dark tobacco. The gross sales of tobacco varieties used in the production of moist smokeless tobacco (MST) are more than $170 million per year. This type of tobacco is grown in 23 counties in those two states and is of significant economic import in those counties.

Tobacco is unlike many other row crops in that the product is not simply grown, harvested, and shipped to the customer. Tobacco requires a significant amount of post-harvest work before it is a saleable product. Growers dry, cure, and age the harvested leaves before it can be sold to tobacco product manufacturers. For example, fire-cured dark tobacco is cured for more than three years before it is sold. These processes are both labor and capital intensive. The capital involved is also specific to the type of tobacco being produced. The barns and other equipment used to produce fire cured dark tobacco cannot be used to produce flue-cured bright leaf tobacco. As a result, if dark tobacco cannot be sold due to its N'-nitrosonornicotine (NNN) content, growers will be faced with both significant stranded cost[4] and an inability to readily replace the income generated through the growing of tobacco.

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[1] PRIA (FDA-2016-N-2527-0227) p. 18.
[2] Ibid.
[3] PRIA p. 19.
[4] Stranded costs should not be confused with sunk costs. A sunk cost refers to resources already spent and not recoverable. As such, sunk costs have no bearing on future decision making. Stranded costs, on the other hand, represent the present value of the income stream (or other measure of value) facilitated by a given asset. These costs represent real resource losses and should be factored into decisions about the future.

NNN levels in dark tobacco and burley

NNN levels are higher in dark tobacco and burley than they are in other types of tobacco such as bright. In 2007 when IARC wrote its report on smokeless tobacco products, there were no samples of burley that would meet the proposed standard, ranging from slightly over 1 ug/g to 9 ug/g.

NNN in finished tobacco has a wide and unpredictable range; some of this variability can be managed through on farm practices such as seed selection, topping practices, managing timing of harvest, curing method (though some methods are necessary to obtain a particular flavor profile), fertilizer use, and management of the curing process. However, a significant amount of variation in NNN formation is attributable to temperature, humidity, and rainfall, over which growers have little to no control.

Fortunately, NNN levels in tobacco have been coming down. This is in response to active intervention of by growers, producers, and seed manufacturers. For example, all of the seeds commercially available in the United States are screened low conversion (LC) varieties. These varieties, by design, produce less of the precursors necessary for the formation of NNN. Similarly most contracts between growers and tobacco product manufacturers stipulate the use of LC seeds. These changes have been reflected in NNN levels in moist smokeless tobacco over time.

In a study of NNN levels in cigarette filler and smoke, NNN levels decreased by over 50 percent between 2000 and 2014.[5] This trend is also reflected by looking at results from various surveys of NNN content in smokeless tobacco products over time.

Unfortunately, despite all of this active management, it is still impossible to reliably produce a crop of burley or dark tobacco that is capable of meeting the proposed standard.

Technical achievability of the proposed standard

The standard proposed by the FDA is based on grouping all smokeless tobacco products together and subjecting them to the same standard. The FDA argues that since one or more of those products have been shown to meet the standard at one time or another, the standard can be met by all of the products. This ignores the differences between the products and presumes that low NNN levels in a final product represent intent rather than serendipity.

In fact, the smokeless tobacco products covered under the rule are very different from each other. They have different ingredients, different flavor profiles, different methods of delivery, different doses, and the list goes on.

They also have very different methods of production. A plant designed to manufacture one product is not likely to be suitable for the manufacture of another. This is even the case for snus – a primarily Swedish moist tobacco product -- and MST – the more commonly seen U.S. made products such as

[5] Gunduz, et.al., Tobacco-specific N-Nitrosamines NNN and NNK levels in cigarette brands between 2000 and 2014, Regulatory Toxicology and Pharmacology 2016.

Copenhagen or Skoal. Although both are moist tobacco products used orally, they are produced using very different processes and ingredients.

Some of the products on the list, such as dry snuff, have never been shown to come close to meeting the standard, and likely never will. In this instance the proposal acts as a *de facto* ban on the product. Other products, such as dissolvables, will not be affected by the standard at all because they are inherently low in NNN. Products such as snus and MST face a more complex landscape where some products in each class are above the proposed standard and some below – again whether through design or luck is not discussed in the FDA preamble or the PRIA.

In the 2016 Journal of Agricultural and Food Chemistry, the Center for Tobacco Products published a survey of NNN content of 34 smokeless tobacco products it purchased in 2015[6]. Of these products 18 were MST products. None of them met the proposed standard. In fact, their average NNN content was 3.4 ug/g dry weight (over three times the proposed standard). Of all 34 products surveyed, only three would meet the proposed standard: one Swedish snus product, one U.S snus product, and one chewing tobacco (which was extremely close to the limit). A third snus product tested, manufactured in the U.S. did not meet the proposed standard.

In fact, there is no evidence provided that the MST products which dominate the U.S. market and U.S. production are capable of meeting the standard[7]. By treating all of the regulated products as equal, FDA avoids answering the technical achievability question by pointing to a specific product – Swedish snus – that currently meets the standard some of the time. But snus is not made with the same process or the same tobacco as the MST that dominates the U.S. market. The only way for U.S. manufacturers to comply is to completely retool their production facilities and rely on imported Turkish tobacco.

U.S. farmers have no role in this new system and are forced out of this business.

Effects on agriculture were not included in FDA's analysis

FDA's cost model includes only the following elements:

- Product batch and stability testing
- Reformulation costs
- Package labeling costs
- Recordkeeping
- Legal costs and non-conforming product disposal

None of these costs, with the potential exception of reformulation costs, address the ability to find compliant inputs or actually produce a compliant product. The PRIA indicates that FDA believes that

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[6] Ammann, Jeffrey R., et.al, A survey of N'-Nitrosonornicotine (NNN) and Total Water Content in Select Smokeless Tobacco Products Purchased in the United States in 2015, Journal of Agriculture and Food Chemistry, 2016.

[7] In fact a comment on the proposed rule submitted by Altria (see comment filed by Jose Luis Murillo on March3, 2017) indicates that the analysis in the PRIA incorrectly converted certain samples from wet to dry weight in a way that resulted in overstating the number of products that currently would comply with the proposed standards.

manufacturers who exceed the proposed standard would respond by changing their process or changing a major ingredient.[8] FDA claims it does not have the expertise to know what such changes would cost, so they use an existing model of food reformulation costs as a proxy. Unfortunately, the food reformulation model largely estimates the intellectual property costs associated with reformulation (what does it cost to change a recipe) and does not include either the capital costs associated with major process changes in the production and distribution of smokeless tobacco products, such as adding pasteurization or refrigerated storage and distribution systems, or the on farm costs associated with reducing NNN levels in the "major ingredient" the FDA is referring to.

The FDA refers to a number of ways that NNN content in a product can be influenced. This represents the tools that manufacturers have available to come into compliance. Most of these tools involve changes that need to be made at the farm level, not by manufacturers. However, none of the costs of implementing any of these approaches are included in the model that FDA uses to model compliance costs – either directly or indirectly.[9]

Tobacco type: The preamble to the proposal notes that the selection of tobacco type can have an influence on the amount of NNN in the finished product. Specifically, they draw attention to the fact that NNN concentrations are lower in bright leaf and oriental tobacco than they are in burley and dark varieties. However, MST is not made with bright tobacco. One must assume there is a reason for that, especially since bright tobacco is cheaper than either burley or dark tobacco. Presumably if a marketable product could be made with the cheaper tobacco, producers would choose to do so.

Nevertheless, if demand shifted pound for pound from burley and dark tobacco to bright in 2015, that would have represented a net reduction in farm revenues of $52 million dollars. That does not consider the stranded costs associated with curing barns and other equipment used in the production of burley and dark tobacco, the lost value of tobacco already in the curing process, or the additional capital required to meet the increased demand for bright tobacco.

FDA also references the advantages of switching to low converter seed. However, as discussed above, all of the commercially available seed in the United States is already low converter seed. So there are no additional reductions available there. If there were, the costs of purchasing potentially more expensive seed would need to be factored in as well.

Growing conditions:

FDA notes that climate, humidity in general, and specifically rainfall can influence NNN levels in tobacco. The data referenced by FDA shows that this influence can be as large as a factor of two[10]. Obviously, growers cannot control the weather and the uncertainty associated with this level of variation could

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[8] PRIA p.39

[9] These costs are not included as direct costs to growers or as increases in input prices to manufacturers. They are simply ignored.

[10] The referenced study actually looks at tobacco-specific N'-nitrosamines (TSNAs) of which NNN is a subset. We are assuming that the proportion of NNN to TSNA remains constant over this range.

make it unattractive for growers to plant tobacco, as growing a crop that you cannot sell for reasons beyond your control is a bad business model.[11]

Lower application of nitrogen fertilizer can also reduce NNN levels. There are many reasons to limit application of fertilizer to the minimum necessary. This is one of the recommended farm practices already put into effect. So, as with low conversion seed, there may not be much room for improvement here. Also recent work done by the Universities of Kentucky and Tennessee, North Carolina State, and Virginia Tech suggests that the effect of fertilizer use at current rates is minimal.[12]

Curing techniques:

The preamble also points out that curing methods and conditions within a particular method can influence NNN levels. With respect to the different curing methods FDA does note that the curing process dries and preserves the tobacco and "imparts characteristic flavor." In other words, choosing a different curing process to limit NNN levels is really choosing to make a different product altogether. This implies a more costly reformulation process than FDA's analysis reflects for manufacturers and/or, as discussed above, significant capital costs to growers (as well as potential reductions in yield and changes in input prices) associated with switching to a new product. As a result, costs to manufacturers are underestimated and costs to growers are ignored.

The preamble also notes that managing conditions during the curing process such as temperature, air flow, humidity, and even heat source can influence NNN formation. This is certainly the case. These are some of the factors that USDA has been working with growers to study and implement throughout the industry. Some of these management measures are already contained within best practices distributed by our extension services. Some of these measures, however, do have costs associated with retrofitting, redesigning, or replacing capital stock. So, they cannot be instantly implemented. Again, costs of these changes fall on growers, not manufacturers, and are not included in the cost models used by the FDA.

Production process:

American tobacco varieties used in the production of smokeless tobacco products, particularly MST, tend to be fermented. As FDA points out fermentation (like certain types of curing) affects both NNN levels and the flavor profile of the tobacco. Again, not fermenting tobacco could lower NNN levels but would be essentially a different product than what is currently used or produced.

Producing a product with a similar flavor profile, either from the farm or through manipulation of the final product "recipe" may be possible. However, the FDA's analysis treats this change as a simple manufacturing change without any evidence that this is the case. FDA is essentially saying that nobody will notice the difference if you make your Reuben sandwich with sauerkraut or coleslaw or that there is some readily available alternative additive to make them taste the same. Changing flavor profile of the

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[11] The study looked only at dark fire-cured tobacco. It is not clear what the effect might be on bright tobacco grown in other parts of the country, but the uncertainty may be sufficient to influence growers there as well.

[12] Jack, Anne et.al., TSNAs in Burley and Dark Tobacco, 2017-2018 Burley and Dark Tobacco Production Guide, 2016, p.63, http://www2.ca.uky.edu/agcomm/pubs/id/id160/id160.pdf.

primary ingredient in a product is likely to be a more complicated (and expensive) fix than the FDA analysis seems to imply.

The preamble also alludes to the pasteurization process that is a common step in the production of snus. It is believed that this process reduces the formation of NNN post pasteurization and this makes sense. Though, it is clear that this step is not, in itself, sufficient to meet the proposed standard. There are Swedish products that would not meet the standard irrespective of the fact that they are pasteurized and contain none of the higher NNN tobacco varieties. Again FDA's economic analysis does not appear to include any estimate of the capital costs associated with adding a pasteurization step to the process for U.S. manufacturers.

Storage conditions:

As in all steps along the entire post-harvest process from curing to distribution of finished smokeless tobacco products to the consumer, temperature and humidity affect NNN formation and cool and dry is best. Not all products or all inputs have the same reaction to temperature or humidity and water content of the product also plays a role. This ability for NNN to continue to increase over time is, of course, important for public health. But it is also relevant to the standard itself since the standard applies at the point of sale to the consumer, not at the factory gate. Again, the FDA analysis assumes that changing process or inputs will provide significant margin of safety to assure compliance at point and time of sale. The capital costs of refrigeration or other measures to manage temperature and humidity do not appear in the cost model.

Choosing the "correct" compliance strategy:

The FDA notes that all of the factors discussed above can affect NNN formation. However, the rule does not include, nor does the preamble discuss, which combination of these factors (and at what level of effort) would lead to compliance with the standard. The cost of understanding the degree to which making any given change affects NNN formation falls on manufacturers and farmers, as does the significant uncertainty associated with implementing any given set of actions. A set of best practice requirements that did not discriminate between tobacco types would, in the face of such uncertainty, likely be a more cost-effective approach to NNN reduction until the effectiveness of those practices is better understood.

In all of the areas discussed above, the FDA's cost model leaves out significant sources of cost. The costs that FDA does include in its analysis are all legitimate – though for some of the reasons discussed above the reformulation costs are likely to be understated. The costs discussed above are all additional to what has already been estimated. In particular, all of the costs to growers to provide a product that can be used as an input to a compliant smokeless tobacco product – changes in curing processes and methods, farming best management practices, and most importantly complete loss of a market for their tobacco type – must be accounted for and included.

Effects on agriculture are highly localized

The bulk of the tobacco potentially affected by this standard is grown in 23 counties in Kentucky and Tennessee. This is conservatively a $150 million per year industry. If, as the data indicates, burley and dark tobaccos could no longer be used in the production of MST, this revenue would be lost in a very concentrated area, creating real hardship to those communities.

Tobacco is an interesting agricultural product for many reasons. One of these reasons is that it is a high value crop on a per acre basis, but any given acre is planted infrequently due to the demands placed on the soil by the crop. As a result, tobacco farms in the affected region are often characterized by a small plot of tobacco on a larger farm where other crops are grown, but where that small plot makes up the bulk of the revenue for the entire farm. It is my understanding that many individual farmers submitted information illustrating this phenomenon in their public comments.

If the market for burley and dark tobaccos were to disappear, growers would in the best case, be able to switch tobacco varieties. As discussed in an earlier section, this is not simply a matter of planting a different type of seed. Other tobacco types have other curing and storage methods and the barns used to process tobacco are not the same across varieties. The existing capital stock[13] would be worthless. In order for tobacco growers in the affected area to switch to a bright tobacco variety, they would need to build all new curing barns at significant cost. At present, there is no bright tobacco grown in either Tennessee or Kentucky. Even if bright tobacco could be grown competitively in this region, bright tobacco has a lower return that would reduce revenues to growers in this region by over $50 million per year.

More likely, growers in this area would be forced to abandon tobacco entirely as it is more probable that any added demand for bright tobacco would be met through expanded production in areas that already grow this crop. In that case growers would be forced to convert their tobacco acreage to other crops that they already grow. This involves switching from a crop with returns of over $2000 per acre to alternatives with returns closer to $20 per acre.[14] Obviously the return to farming tobacco acreage by 90 percent is going to have a significant impact on the farmer and in the community.

So, assuming manufacturers could make a marketable product without burley or dark tobacco, tobacco growers as a whole would face revenue losses of over $50 million, but growers in Kentucky and Tennessee would face revenue losses in excess of $150 million plus losses associated with stranded capital and lost value of product already in the barns and warehouses.

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[13] $8,000 per acre according to the University of Kentucky https://darktobacco.ca.uky.edu/content/tobacco-statistics-policy-and-marketing

[14] Dark Fire-cured Budget at https://darktobacco.ca.uky.edu/content/tobacco-statistics-policy-and-marketing and Row Crop Budgets at http://www.uky.edu/Ag/AgriculturalEconomics/halich_greg_rowcropbudgets.php

Unintended adverse health effects

The stated goal of the FDA's proposal to reduce NNN levels in smokeless tobacco is to reduce premature cancer deaths. In isolation, such a policy may have some effects in this area.[15]

However, the proposal does not exist in isolation. It exists in a world where people are already addicted to nicotine and continue to become addicted to nicotine. Since nicotine is not, itself, considered to be particularly harmful, it is important to provide alternative means of delivering that nicotine that do not carry with them the significant health risks associated with combusted tobacco.

While preventing nicotine addiction in the first place is an important public health goal, encouraging and enabling smoking cessation, and harm reduction are also important public health tools.

It is clear that smokeless tobacco products (with the possible exception of dry snuff) are less harmful than cigarettes – even in terms of oral cancer incidence. Swedish snus may have lower concentrations of NNN than MST, but both snus and MST are significantly lower than cigarette smoke. Therefore, switching to, or even supplementing, ones smoking with smokeless tobacco use reduces the harm associated with satisfying nicotine addiction.

There have been studies that seem to indicate (particularly in Sweden) that smokeless tobacco use assists with smoking cessation and reduces the onset of smoking. There are other studies that indicate that smokeless tobacco does little to prevent smoking onset and results in dual use (using both cigarettes and smokeless tobacco as the situation dictates) rather than cessation. Whether or not smokeless tobacco helps lead to full smoking cessation, it is still the case that the lower dose of NNN as well as the absence of other toxic byproducts of tobacco combustion reduces the risk to consumers for every cigarette that is replaced with the use of smokeless tobacco.

If the FDA's rule makes smokeless tobacco less available, more expensive, or less palatable, it could actually increase the tobacco related risks faced by those who are addicted to nicotine today and in the future.

Conclusions and recommendations

It is clear that any standard that cannot be met using the tobaccos currently grown for this market will impose significant costs on both manufacturers and growers.

These costs have not been accounted for by FDA.

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[15] However, some commenters to the proposal provided analysis suggesting that the risk analysis conducted by FDA overstates risk due to the fact that the epidemiological studies underlying that analysis show that risks are driven by inhaled dry snuff. If this is the case, regulation of NNN in MST will not achieve the risk reductions claimed by FDA. See comments of Dr. Brad Rodu and Peter Lee.

We understand that FDA may not have the expertise required to estimate some of these costs. However, we do not think the answer is to use a cost model that has no relation to this industry at all. We stand ready to assist FDA in improving its estimates for any potential final rule.

It is also obvious that many of these costs stem from FDA's decision to treat all smokeless tobacco products as the same for the purposes of this standard. It is not necessary for FDA to eat this elephant in one bite. There are opportunities to reduce NNN in all product categories without requiring them to all to meet the same standard, especially if that results in the largest product categories simply disappearing from the market. It would be possible to set standards for each product category based on the demonstrated ability of manufacturers in those categories to meet that standard. This approach would be more cost-effective than a one-size-fits all standard.

Similarly, the FDA states that this rule is intended to address an information externality that makes it difficult for the consumer to obtain information on the NNN levels in smokeless tobacco products. However, the FDA has been collecting this information from smokeless tobacco manufacturers for a number of years and has decided not to make that information public or require its disclosure by manufacturers for fear that the public would misinterpret the information. Would the information externality not be more efficiently addressed by providing the information to the consumer along with any information required to properly understand the implications of the information.