October 6, 2023

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Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

Re: Proposed Rule: Requirements for Tobacco Product Manufacturing Practice;
Docket No. FDA-2013-N-0227

Dear Sir or Madam:

Cigar Association of America, Inc. (“CAA”) is the leading national trade organization representing the interests of cigar manufacturers, importers, distributors, and major suppliers of the industry. CAA was founded in 1937 as a non-profit trade organization. Today, its member companies come from all sectors of the industry, from major manufacturers of hand-made premium cigars to the largest producers of machine-made cigars. CAA members manufacture a significant share of the large, premium, little, and filtered cigars sold in the United States. Its members also include internet retailers of cigars, as well as leaf, and other suppliers to the cigar industry. CAA is a key stakeholder in the implementation of any regulation of cigars, as these regulations significantly affect its members’ ability to conduct business.
CAA submits these comments in response to the request by the Food and Drug Administration (“FDA”) for Comment on the Proposed Rule: Requirements for Tobacco Product Manufacturing Practice (“Proposed TPMP Rule”).

I. Executive Summary

- The Proposed TPMP Rule imposes a massive financial burden on cigar manufacturers without any articulated public health benefit;

- Cigars are inherently an agricultural product manufactured around the world in many different manners, distinctions that any TPMP Rule must allow and account for;

- The Proposed TPMP Rule fails to take into account intervening legal decisions as well as practical realities regarding the status of cigar regulation and foreign manufacturing facilities;

- The Proposed TPMP Rule does not account for the differences between product categories and subcategories within the cigar category;

- The traceability procedures in the Proposed TPMP Rule are wholly unworkable for cigars, for example:
  - FDA does not have authority to regulate tobacco itself and cannot require traceability to tobacco farms.
  - Current cigar manufacturing practices are not set up to accommodate the traceability procedures required by the Proposed TPMP Rule.

- The validation and verification provisions of the Proposed TPMP Rule are unnecessary, duplicative, and onerous;

- Provisions specifically relating to foreign manufacturing facilities:
  - Requiring English translation of all documents is unduly burdensome.
  - On certain issues, such as environmental concerns, sanitation, and pest control, foreign facilities should have to comply only with local laws, not laws of the United States; and

- Facilities that only repack or relabel cigars should not be subject to the same requirements as traditional manufacturers.

II. Introduction

The Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) requires FDA to promulgate regulations outlining good manufacturing practices for tobacco products.\(^2\) Unlike other sections of the Tobacco Control Act, however, Section 906(e) does not contain any time requirement for promulgation of these rules. After fourteen years of regulating tobacco products, FDA has now issued a Proposed TPMP Rule. In the time since the Tobacco Control Act was enacted, initially regulating cigarettes, smokeless tobacco, and roll your own tobacco, the product categories regulated by FDA and therefore covered by a TPMP Rule have expanded drastically. A TPMP Rule must apply to products – such as cigars – that are based on the agricultural product of tobacco but that are manufactured in many different countries, in many different ways, using many different processes. In addition, it also needs to apply to products – such as e-liquids and nicotine pouches – manufactured in ways fundamentally different from traditional tobacco products.

While the Proposed TPMP Rule makes efforts to account for the clear differences between and among various product categories, as set forth below it fails to recognize numerous realities relating to the manufacture of various types of cigars. For this reason, certain of the provisions are simply not relevant to cigars, are not reasonably susceptible to compliance by cigar manufacturers, or as a practical matter will fail to achieve the Proposed TPMP Rule’s stated goals.

The Proposed TPMP Rule was released in March 2023 but FDA first addressed the issue in 2013, in response to a proposal made by thirteen tobacco companies to establish good

manufacturing practices. The documents submitted by the companies were intended to present a “common perspective and interpretation of the provisions of the proposed cGMP regulations.” At the time the proposal was issued, FDA only had jurisdiction over cigarettes, smokeless tobacco, and roll-you-own tobacco products. In response to receiving this proposal, FDA opened a public docket for comments. Cigars were not yet deemed subject to regulation but, recognizing that at some point they could be, CAA submitted comments to that docket. In those comments, CAA noted, as it will throughout this comment, that “[b]ecause of the significant differences between cigarette and cigar manufacturing operations, the implementation of the GMP requirements must, and does, differ between the two industries.” CAA welcomes the opportunity to comment on the Proposed TPMP Rule, for while TPMPs are both required and useful, they must take into account the unique nature of the manufacturing process for each category of tobacco products and the current public health needs for each category of products.

a. CAA Members and Manufacturing Facilities

CAA member companies range from the largest manufacturers of machine-made and premium cigars to some of the smallest. The manufacturing facilities of member companies range


4 Id.

5 CAA Comments to 2013 Proposed TPMPs, dated May 20, 2013, are attached as Exhibit A (“CAA 2013 TPMP Comments”).

6 Exhibit A, CAA 2013 TPMP Comments at 2.

7 CAA refers to “premium cigars” throughout this document. On August 9, 2023, Judge Mehta vacated the Final Deeming Rule subjecting a certain category of “premium cigars” to regulation by FDA. See Cigar Ass’n of Am., et al. v. U.S. Food & Drug Admin., 1:16-cv-01460, ECF No. 276 (D.D.C. Aug. 9, 2023). This ruling applies to cigars
from large factories with near state-of-the-art machines to small factories in foreign countries
where hand-made cigars are created in small quantities by a limited number of skilled artisans.
CAA member companies have factories all over the world, including the United States and Puerto
Rico, the Dominican Republic, Nicaragua, Honduras, the Philippines, Germany, and elsewhere.
CAA member companies include small tobacco product manufacturers, tobacco product
manufacturers, repackers and relabelers, and component suppliers for cigars.

CAA member companies manufacture a variety of different cigars, in many different
manufacturing contexts. In addition to the geographical and size variety, there is also incredible
variety in the cigar manufacturing process. As discussed more fully below, cigar industry
manufacturing operations are not uniform, and any TPMPs must take these differences into
account. Cigar manufacturing ranges from machine-made cigars to hybrid, hand-rolled cigars
(where the filler and binder are combined by machine and the resulting “bunch” is wrapped by
hand), to entirely hand-made premium cigars crafted by skilled artisans. All of these processes
rely on different equipment, skill sets, training, quality controls, and facilities.

that meets the following criteria: (1) is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder;
(3) contains at least 50 percent (of the filler by weight) long filler tobacco; (4) is handmade or hand rolled; (5) has no
filter, nontobacco tip, or nontobacco mouthpiece; (6) does not have a characterizing flavor other than tobacco; (7)
contains only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weighs more than 6
pounds per 1,000 units.

CAA has demonstrated in many different forums that the proper, objective, definition of a premium cigar is a cigar
with the following characteristics: (i) wrapped in whole leaf tobacco; (ii) contains a 100% leaf tobacco binder; (iii) is
made by manually combining the wrapper, filler, and binder; (iv) has no filter, tip, or non-tobacco mouthpiece and is
capped by hand; and (v) weighs more than 6 pounds per 1000 units.

While many cigars will meet the definition of “premium cigar” adopted by Judge Mehta and therefore no longer be
subject to FDA’s authority (subject to any appeal see infra Section III.B), many premium cigars, as defined by the
trade and using the CAA definition, may still be subject to regulation. Accordingly, manufacturing facilities may
produce some hand-made cigars that are subject to the TPMP Rule and some that are not. Whenever the term
“premium cigar” is used in this comment it refers to products that meeting the CAA definition of “premium cigar.”
Not only is training of employees going to vary among types of manufacturing facilities, but quality control will necessarily be unique to each facility as well. When a cigar is machine-made, the machine is responsible for most of the quality control requirements. In the hand-made context, however, all quality controls are manual. Even within the machine-made cigar category, there is huge variety in operation. Some machines are automated for almost all steps of the process (though still drastically different from the speed and precision of cigarette manufacturing) whereas some manufacturers use older machines that require more manual assistance, such as refilling the hopper with tobacco and manually transferring bunches over to rolling machines for wrapping. In sum, there is no standard manner in which cigars are manufactured and any TPMP Rule must account for this variability in manufacturing activity.

b. Proposed TPMPs Are Required and Useful But Must Take Into Account Product Category Differences

Congress clearly contemplated that good manufacturing practices for tobacco products could not be a “one size fits all” approach when it drafted the Tobacco Control Act. Specifically, Section 906(e) states “[i]n applying manufacturing restrictions to tobacco, the Secretary, shall…prescribe regulations (which may differ based on the type of tobacco product involved).”8 FDA, however, has written the Proposed TPMP Rule as a “one size fits all” rule – and while it does provide some flexibility, it fails to recognize that some provisions are simply not applicable to all products. CAA is encouraged by FDA’s statement that:

[t]he proposed requirements are written in general terms to allow manufacturers to establish procedures appropriate for their specific products and operations….Tobacco product manufacturers who have a complex manufacturing process would likely need to establish more detailed procedures to comply with the

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rule, while tobacco product manufacturers who have less complex manufacturing processes may need less extensive procedures.9

CAA views this statement as critical and believes it should supersede any “one size fits all” provision incompatible with some or all cigar manufacturing practices or facilities.

The Proposed TPMP Rule further states that “if a tobacco product manufacturer engages in some operations subject to the requirements of proposed part 1120, but not others, the manufacturer need only comply with those requirements applicable to the operations in which it is engaged.”10 FDA further states that “when a requirement is qualified with “where appropriate” it is deemed to be appropriate unless the tobacco product manufacturer documents in writing … an adequate justification prior to abstaining from implementing the requirement.”11 From the first statement, one would assume this simply does not apply to the manufacturer and therefore they do not need to comply with it. From the second statement, however, it would imply that the manufacturer has to somehow justify not complying with an inapplicable requirement. FDA needs to be clear that while it is taking an “umbrella approach,” there are still parts of the Proposed TPMP Rule that simply do not apply to every cigar manufacturer and that manufacturers will need to comply only with the provisions of the Proposed TPMP Rule that are applicable to their products.

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10 Id. at 15,186.
11 Id. at 15,187.
III. Legal Issues

a. FDA Has Not Yet Proposed a Rule Regarding Foreign Manufacturer Registration

FDA’s Proposed TPMP Rule attempts to include foreign manufacturers within its auspices, thereby imposing burdensome and detailed requirements upon them. FDA seeks to do so, however, without proposing a facility registration requirement on foreign manufacturers. From a practical and functional perspective, FDA is placing the proverbial cart before the horse by proposing to require that foreign manufacturers comply with a TPMP Rule, even though they are not required to register with FDA. CAA understands FDA may believe its other authorities allow it to require foreign manufacturer compliance with a TPMP Rule. From a practical perspective, however, doing so prior to requiring registration and receiving inspection authority makes little sense.

b. The Proposed TPMP Rule Must Account for Court Decisions that Change the Course of Regulation

The Proposed TPMP Rule does not address or account for various court decisions that have changed the scope of permissible regulation under the Proposed TPMP Rule.

First, the Proposed TPMP Rule, at § 1120.92, requires manufacturers to establish and maintain procedures to control packaging and labeling activities, and to ensure the packaging and labeling “comply with all requirements off the MMR as well as all other applicable requirements of the FD&C Act.”\(^\text{12}\) The Proposed TPMP Rule goes on to state that:

Other applicable requirements . . . includes warning rotation plan requirements for packages pursuant to section 4(c)(1) of FCLAA, section 3(b)(3)(C) of CSTHEA and § 1143.5(c). For example, under § 1143.5, packaging for cigars is required to

\(^{12}\) Id. at 15,229.
contain certain warning statements in accordance with an FDA-approved warning plan. Accordingly, under this proposed provision, finished cigar manufacturers would have to establish and maintain procedures to control packaging and labeling activities to ensure that the correct required warning statement is applied to the cigar package, that the formatting requirements are met, and that the warnings on the package label follow the approved warning plan.\textsuperscript{13}

But this ignores the United States District Court for the District of Columbia’s ruling vacating the Final Deeming Rule’s warning requirements for cigars and pipe tobacco.\textsuperscript{14} FDA therefore has no authority to require cigar manufacturers to include anything related to warning plans within the requirements of the Proposed TPMP Rule. Including this provision within the Proposed TPMP Rule does little to alleviate the concerns CAA has about FDA’s ability to look at each product category individually, and in the context of how the Tobacco Control Act applies to each in a different manner. FDA currently has no legal authority to require health warnings on cigars; including this provision in the Proposed TPMP Rule shows a concerning lack of knowledge of the laws and the manufacturing and packaging activities governing these products.

Second, the United States District Court for the District of Columbia held that FDA’s decision to regulate premium cigars (as defined by the court) was “arbitrary and capricious” and vacated FDA’s decision to regulate the category of premium cigars (as defined by the court).\textsuperscript{15} At

\textsuperscript{13} Id. at 15,229.

\textsuperscript{14} See Cigar Ass’n of Am. v. U.S. Food & Drug Admin., 1:16-cv-01460-APM, ECF No. 228, at 3 (D.D.C. Sept. 11, 2020); see also Cigar Labeling and Warning Statement Requirements, U.S. FOOD AND DRUG ADMIN., available at https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigar-labeling-and-warning-statement-requirements#:~:text=The%20United%20States%20District%20Court,tobacco%20back%20to%20the%20Agency (last updated Oct. 6, 2020) (“The United States District Court for the District of Columbia recently issued an order vacating the health warning requirements for cigars and pipe tobacco set forth in 21 CFR §§ 1143.3 and 1143.5 and remanding the Final Deeming Rule’s warning requirements for cigars and pipe tobacco back to the Agency . . . Although the requirement has been vacated, cigar and pipe tobacco firms may choose to \textbf{voluntarily} comply with these health warning provisions.”) (emphasis supplied).

a minimum, the Proposed TPMP Rule must be revised to address this ruling, which vacates the entire regulatory scheme as to these premium cigars, leaving FDA with no authority over these products. FDA has filed a notice of appeal which adds additional uncertainty to what the scope of FDAs authority regarding the cigar category will be.\textsuperscript{16} FDA must take into account this legal reality, and the fact that there will be facilities that manufacture cigars both subject to and exempt from regulation at the same time, when issuing any final TPMP Rule. For instance, if a facility manufactures both regulated and unregulated cigars, at a minimum FDA cannot require any validation, verification, traceability or Master Manufacturing Record (“MMR”) records for the unregulated products.

c. The Proposed TPMP Rule Cannot Impose Product Standards

CAA supports reasonable regulation in the Proposed TPMP Rule. It must be clear, however, that while this proposed rule requires manufacturers to document manufacturing activity, it cannot be used to impose back door product standards. FDA has the authority under Section 907 of the Tobacco Control Act to impose product standards for specific tobacco products and must go through notice and comment rulemaking in order to do so. The Proposed TPMP Rule cannot be used to set any tolerances, limits, ingredient restrictions or other restrictions or limitations on the production of cigars that would be akin to a product standard. For instance, the Proposed TPMP Rule states many times that manufacturers need to establish “procedures [to]
address testing and acceptance of raw tobacco to ensure that raw tobacco suppliers [complies with specifications for pesticide chemical residues].” Pesticide residues is already a product standard outlined in the Tobacco Control Act, and one for which FDA admits there are no established tolerance limits. How can companies be expected to set specifications for something that the federal government so far has been unable to? Including provisions such as this in the Proposed TPMP Rule is akin to issuing a separate product standard on this issue. Should FDA wish to impose any product standards on the manufacture of cigars it must use the provisions outlined by Congress in Section 907 of the Tobacco Control Act to do so.

IV. Overall Concerns and Objections

a. Structure of TPMP Final Rule Fails to Account for Product Differences

FDA states many times throughout the Proposed TPMP Rule that it is employing an “umbrella approach” to the proposed TPMPs. That said, while it does recognize that each facility will need to create its own documentation and requirements related to the specifics of the facility, it does not take into account the extreme variety of regulated tobacco products. For instance, tobacco products dependent on the agricultural product of tobacco (such as cigars and pipe tobacco) could never have manufacturing processes similar to those for medical devices or certain pharmaceuticals, whereas products such as e-liquids, e-cigarettes and even oral nicotine pouches


18 See id. at note 5.

19 At the Tobacco Product Scientific Advisory Committee meeting on the Proposed TPMP Rule many members raised the possibility of setting nicotine limits for e-liquids through this rulemaking. While not an issue that directly relates to cigars, it is troubling that the scientific advisory body for the Center for Tobacco Products (“CTP”) is so unfamiliar with the limits of CTP’s rulemaking authority under different sections of the Tobacco Control Act.

are most likely going to be closer to the manufacturing processes used for medical devices or certain pharmaceuticals. 21

A cigar – no matter how manufactured – is, by definition, a “roll of tobacco wrapped in tobacco.”22 Cigars may contain other additives, but at its core they are a consumer product made from an agricultural product. No matter how a cigar is manufactured it will never meet exacting specifications and is not intended to. FDA has previously recognized the natural variability inherent in working with tobacco, and to manufacturing cigars with it. FDA’s “umbrella approach” does state that “if a tobacco product manufacturer engages in some operations subject to the requirements of proposed part 1120, but not others, the manufacturer need only comply with those requirements applicable to the operations in which it is engaged”23 and that certain provisions of the rule only apply “where appropriate.” This is helpful, though FDA should consider evaluating the requirements proposed through the viewpoint of what is appropriate to each product category. This will be in the interest of public health to ensure each product category is following manufacturing procedures that are necessary to protect the public health for that product as opposed to trying to determine those which FDA will agree are necessary or not. It should not be controversial that there are different public health concerns relating to ensuring products such as

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21 FDA states many times throughout the Proposed TPMP Rule that it is modeling many of these provisions and requirements based off those for medical devices. It is inappropriate, however, when FDA has already rejected modeling tobacco regulation of medical devices, to now try to model TPMPs off the regulations for those devices. If the 510K decision making trees cannot be used for evaluating whether substantial equivalence submissions are needed in the context of tobacco products, then GMPs for medical devices are not appropriate for tobacco products either.


e-liquids are manufactured to specification and have recall ability than products, such as cigars, that have inherent variability and have never needed to issue a wide-spread consumer recall.

In addition to needing to recognize product category differences, FDA must also recognize that cigar manufacturers range from small, hand-made premium cigar manufacturers to large multi-national machine-made cigar manufacturers. The Proposed TPMP Rule appears to recognize this by stating that the “extent of the procedures necessary to meet the regulation requirements may vary with the size and complexity of the design and manufacturing operations.”

24 CAA supports this concept and the implementation of it and hopes FDA understands that resources available to manufacturers vary based on the size and complexity of the operation. It is not enough to simply give small tobacco manufacturers additional time to implement the proposed TPMPs; FDA must recognize that the implementation will vary drastically depending on both the company resources and the type of product and manufacturing process. For instance, hand-made, premium cigar manufacturers will have much less sophisticated processes than will manufacturers of machine-made cigars. Additionally, companies operating in the United States and its territories will have different environmental controls and personnel procedures than those in foreign countries who are subject to different laws. Further, in the cigar category, there are companies that are solely “manufacturers” because they repack or relabel cigars. In this instance, the vast majority of the Proposed TPMP Rule will not apply to these facilities. FDA must take all of these factors into account when determining if a TPMP Rule applies to a company and, if so, whether it is in compliance with it.

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24 Id. at 15,185.
b. Concerns with Proposed Traceability Procedures

One of the main themes in the Proposed TPMP Rule is that all ingredients, components and finished tobacco products must be traceable looking back to their original source and forward to distribution into domestic commerce. The forward-looking piece presents certain challenges that will be outlined below, but the backward-looking piece presents even more challenging burdens for the cigar industry.

i. Ingredients and Components

As discussed above, the primary ingredient in a cigar, regardless of the type of cigar, is tobacco, an agricultural product. The Tobacco Control Act specifically excludes anything to do with the agricultural product from the scope of FDA’s authority:

The provisions of this division (or an amendment made by this division) which authorize the Secretary to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.\(^{25}\)

The Proposed TPMP Rule must take into account that FDA has no authority over tobacco itself — until it enters a manufacturing facility.

CAA members include not only major cigar manufacturers, but also some of the largest tobacco leaf suppliers in the industry. Cigar tobacco, usually dark air-cured tobacco, is grown all over the world, often in second and third world countries. FDA has absolutely no authority over these farms or this tobacco until it crosses the threshold of a manufacturer making cigars for import into the United States. Again, as in other cases, CAA is concerned FDA does not recognize the limits of its authority related to cigars and foreign operations. For instance, the Proposed TPMP

Rule states that a required provision of any MMR is pesticide chemical residues for raw tobacco.\textsuperscript{26} First, FDA and the Environmental Protection Administration have yet to establish any pesticide chemical residue limits for raw tobacco in the United States.\textsuperscript{27} Second, FDA does not have authority over foreign tobacco farms. Third, a requirement like this looks to the agricultural product and the different requirements implemented in different countries regarding pesticides. Specifications for pesticide chemical residue for raw tobacco cannot be a requirement for any MMR for cigars.\textsuperscript{28}

Further, many companies purchase tobacco through large purchasing contracts; the tobacco is then stored in warehouses until needed for the specific cigars to be manufactured. Some of this tobacco is blended, some are whole tobacco leaves. While companies may need to know the tobacco that is in each batch of cigars, FDA cannot require the backward-looking traceability to the tobacco farm or cooperative. As noted in the Proposed TPMP Rule, companies have differing types of acceptance procedures for incoming components, including tobacco. These acceptance procedures ensure that the tobacco that will be incorporated into any finished cigars will not create an adulterated product. There should be no further requirements in any TPMP Rule related to the tobacco used in cigars other than that companies must have acceptance procedures regarding tobacco shipment intake.

\textsuperscript{26} Proposed TPMP Rule, 88 Fed. Reg. at 15,209.

\textsuperscript{27} Coresta Agrochemical Guidance Residue Levels (GRLs) are being applied in the absence of agency regulated limits.

\textsuperscript{28} See supra, Section III.C for discussion related to the existing product standard for pesticide residue.
Additionally, the Proposed TPMP Rule outlines incredibly onerous requirements to qualify as a “supplier.” While these procedures may make sense for certain product categories, CAA believes that requiring this level of “qualification” for every supplier a cigar manufacturer relies upon is unduly burdensome and unnecessary. The agency should accept industry risk management initiatives identifying suppliers to be qualified based on a defined set of assessment criteria. Manufacturers certainly should have the right to visit, audit, and test samples of the tobacco, ingredients or components supplied, but this should not be a requirement for the manufacturer to continue using a supplier it may have used for decades. For instance, for cigar manufacturers who purchase tobacco directly from small farmers in second or third world countries, as opposed to the larger leaf companies, it may be impossible to qualify these suppliers under the requirements FDA outlines in the Proposed TPMP Rule. This should not mean that the manufacturer is prohibited from using the tobacco simply because it cannot “qualify” the supplier under FDA’s rubrics, instead the manufacturer should be able to rely on its own procedures to establish that the tobacco is acceptable for use in cigars. CAA proposes that companies can achieve the same goals with their own acceptance procedures for all incoming materials, and that the requirement to qualify suppliers is unnecessary, unduly burdensome, and will greatly impact current manufacturing processes for many cigar manufacturers. FDA should outline procedures companies can take should they wish to audit suppliers but make clear that a company’s internal regulatory compliance, acceptance and purchasing controls satisfy the requirement to ensure suppliers are meeting any established specifications necessary for the components or ingredients they supply.

29 Id. at 15,212.
ii. Finished Products

CAA is not aware of, and does not believe there has been, a situation where the cigar industry or individual companies could not recall products when necessary. Based on this history, and the reality that all companies currently could initiate a recall if necessary, the traceability procedures outlined in the Proposed TPMP Rule are overly burdensome and unwarranted. More importantly, the traceability requirements FDA proposes appear appropriate for ensuring tax collections occur, or perhaps for e-liquids, where the ingredients alone would be more likely to have a recall initiated. For cigars, the proposed provisions are unduly burdensome and not tailored to the product category.

While there have been no widespread cigar recalls initiated by CAA members, this does not mean that CAA members could not, and have not been able to, recall products if this was deemed necessary. The only issue would be the extent of the recall and the volume of product that would be impacted. CAA believes a recall using current procedures would likely cover a greater volume of products than would a recall based on the traceability provisions of the Proposed TPMP Rule, but allowing companies to continue current business practices would be a less burdensome alternative that would achieve the same goal.

FDA’s proposal – that every product have a “manufacturing code” consisting of both a manufacturing date and a batch code – does not take into account the current manufacturing reality of many cigar products. Even in the most sophisticated machine-made cigar facilities, the

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30 The Proposed TPMP Rule only addresses traceability in terms of initiating a recall of finished products distributed to consumers, as opposed to a manufacturing recall that requires companies to do an internal recall prior to distribution. CAA is only addressing the provisions as outlined in the Proposed TPMP Rule.

tracking that FDA outlines will require equipment changes, packaging and labeling changes, and in certain respects changes to the actual manufacturing process. In hand-made cigar manufacturing facilities trying to incorporate a “manufacturing code” into a printed record on the label of the product will require almost an entire overhaul of how all manufacturers manufacture hand-made cigars as very few use batch codes as outlined by FDA in their manufacturing processes today. In a hand-made cigar manufacturing process, all materials and steps may be able to be traced (they currently may not be, but most likely can be) up until the cigars are put in a resting room (this room is called a variety of things by different manufacturers). Once the cigars have rested for a certain period of time (depending on the manufacturer and the size of cigar) they are brought out and are generally “color sorted” prior to packaging. This happens at almost all hand-made cigar manufacturing facilities, so that when a customer opens a box, they see cigars that are as close in color as possible.\textsuperscript{32} Many different “batches” of hand-made cigars are now co-mingled through this process, and prior to being sent to packaging. To include any specific date on final packaging will almost certainly require in nearly all instances (1) changing the manufacturing process; (2) changing the recordkeeping process; and (3) require changes to packaging and labeling processes and procedures.

Another troubling requirement in the Proposed TPMP Rule is that the “manufacturing code” will “need to be applied in a manner that assures it would remain on the packaging and label through the expected duration of a consumer’s use of a tobacco product.”\textsuperscript{33} For example, FDA

\textsuperscript{32} Due to the use of completely whole leaf wrappers, there is inherent variation in the wrapper color even with identical tobacco. Color-sorting is used to manually seek as uniform a color range as possible in any box or bundle of hand-made cigars.

relies on single packs and cartons of cigarettes as well as smokeless tobacco cans and sleeves of cans, noting that each of these will need to be labeled with the manufacturing code. CAA believes that, in some cases that machine-made cigars packaged in smaller quantities and sold to retailers in larger multi-pack quantities, the manufacturing code could be placed on both packages, albeit at great expense and time to reprogram machinery or to add in a manual process to the packaging process. For hand-made cigars, however, often sold by retailers as individually cellophane wrapped cigars, such an approach is impossible. Even if a manufacturing code could be determined, it cannot be affixed to the cellophane without severely impacting production, packaging, and current manufacturing processes, and potentially damaging the cigar. This should not be a requirement for individually wrapped products. No matter the manufacturing process, the requirements outlined in the Proposed TPMP Rule will cause severe disruption to current cigar manufacturing processes, potentially cost firms hundreds of thousands if not millions of dollars to implement, all against the backdrop of a theoretical need – a widespread cigar industry product recall. FDA must revisit and revise these provisions based on the actual public health concerns of each product category and craft a rule that recognizes the concrete differences in risk between product categories.

Further, the Proposed TPMP Rule in addition to proscribing the requirement for a “manufacturing code” also prescribes what the “manufacturing code” must contain, and in what order: (1) the manufacturing date, in 2-digit numerical values in the month-day-year format (MMDDYY); and (2) the finished or bulk tobacco product batch number. Requiring all manufacturers, including foreign manufacturers, to apply a MMDDYY format for its manufacturing date – a prime example of Americentrism – will be incredibly confusing for foreign manufacturers, which do not all employ this date format. For example, there is the British-English...
date convention – used throughout Europe and other countries around the world – which is DDMMYYYY. Then, there is the increasingly popular ISO 8601 date convention, which is YYYY-MM-DD.

Simply put, imposing the Proposed TPMP Rule requirements for a manufacturing code is, from the outset, incredibly onerous. Requiring foreign manufacturers to adopt the American date format will only add confusion. It will require foreign manufacturers to possibly have two separate dating conventions for their manufacturing processes, depending on where in the world a product will end up (something that may not even be determined at the time of manufacture) or how they have already instituted procedures regarding date conventions.

For these reasons, should FDA require a manufacturing code, a proposal CAA opposes, CAA proposes that FDA permit manufacturers to choose from their preferred date format convention otherwise used in their manufacturing processes, whether it be American, British-English or ISO 8601. The purpose of the manufacturing code is to permit traceability of manufacturing batches, which a manufacturer will internally be able to do using their own preferred dating conventions as part of the code. Imposing the American-convention date format on all manufacturers will only serve to needlessly complicate existing manufacturing processes.

FDA must reconsider and revisit (i) its reasons for requiring traceability in the context of cigars; and (ii) if it is going to require a method of traceability for cigars, it must be one which will not require a change to current manufacturing capabilities and takes into account the history of a lack of wide-spread recalls or adverse events within the category. The current proposal is

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34 In many countries the employees who will need to manually affix any potential manufacturing date may not be (i) fluent in English; or (ii) familiar with the American date system. Requiring this date format for all manufacturers simply adds a chance for error as opposed to a simple tracking system.
unworkable and is unduly burdensome when overlaid on current cigar industry manufacturing practices.

c. Validation and Verification Requirements are Duplicative and Onerous

Throughout the Proposed TPMP Rule, FDA proposes to require manufacturers to “validate” and perform “verification” of many processes, specifications, and other procedures. These requirements as written are duplicative, unduly burdensome and at times contradictory. In the definitions section of the Proposed TPMP Rule FDA defines these words in relevant part as follows:

- “Validation” – “confirmation by examination and objective evidence that the particular requirement can be consistently fulfilled.”
- “Verification – “confirmation by examination and objective evidence that specified requirements have been fulfilled.”

The term “validation” appears no less than 68 times in the Proposed TPMP Rule and the term “verification” appears no less than 43 times. As discussed above, even for cigars made on machines, there will be great variability in the products given the variability of the underlying tobacco. While all cigar manufacturers have some form of specifications for their products, they are usually not created with the exacting precision of cigarettes or have any validation or verification such as FDA is expecting. As an example, in the hand-made cigar context, most cigars have three design parameters: length, ring gauge, and weight. A cigar is “tested” to determine if


36 In many instances this recorded or measured weight is of a cigar in a bundle – not even an individual weight.
it “meets” specifications based on whether it fits in its packaging, the bundle is the correct weight, and if the cigar fits in the right ring gauge. Many factories will have certain cigars smoked to determine if the draw is correct, but this is by no means “examination and objective evidence;” instead, it is examination and subjective evidence. Further, even in the context of ingredients, FDA will observe that most ingredient quantities are provided as calculated values as opposed to actual values. This is because tobacco absorbs ingredients in different ways, and the addition of ingredients to cigars and components of cigars may not occur in a manner that has specific targets and tolerances. Instead, calculated values can be determined based on consumption and manual processes. These procedures, again, inherent to the cigar manufacturing process, are not susceptible to the exacting validation and verification processes that FDA envisions. Further, while some cigars do have some specifications, these specifications are not controlled to the same extent as for cigarettes. As discussed elsewhere, whether made on a machine or by hand, cigars all have the inherent variability of cigar tobacco imbedded in the product. This makes it impossible to have tightly controlled specifications for these products. Looking at this in terms of FDA’s suggested requirement for continuous validation and verification of all manufacturing requirements and specifications, it once again sets up cigar manufacturers to fail. FDA must understand that procedures such as validation and verification may be appropriate for cigarettes or certain e-cigarette products, but they simply are not appropriate for cigars.

FDA expects all products and packaging to go through design validation and verification if they are first commercially marketed after the effective date of the TPMP Rule. This is a critically important point for the cigar industry. As FDA knows, a majority of cigars are pre-

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existing products, or were introduced prior to August 8, 2016. While the cigars may not have the same brand name they were originally commercially marketed with as they do today, the design and specifications will be the same. This is because re-labeling products does not create a new tobacco product.\textsuperscript{38} In addition to pre-existing products, many cigars will be commercially marketed prior to the effective date of the Proposed TPMP Rule either due to being subject to marketing orders or because they are the subject of pending marketing orders. Similarly, all of these cigars may be relabeled into different brand names. It must be clear in any final TPMP Rule that simply because a product has a new brand name, does not mean that it should be required to do through design validation and verification.\textsuperscript{39}

Finally, contract manufacturing is a very large part of the cigar industry. This means a manufacturer may be manufacturing a product for a specific brand owner. The Proposed TPMP Rule does not address which entity – the manufacturer or the brand owner – owns the product for purposes of compliance with the Proposed TPMP Rule. The question is critical for many aspects of compliance with the rule but is certainly critical to whether design validation and verification must occur, when it must occur, and who has the responsibility to perform it. CAA proposes that the manufacturer be the responsible party as it will have the best access to the required information.

Overall, FDA must revisit and reconsider its approach to validation and verification requirements throughout the Proposed TPMP Rule. In many instances cigar manufacturers, through no fault of


\textsuperscript{39} The proposed validation and verification requirements also do not take into account changes in product ownership that could hinder a company’s ability to establish the original objective evidence for validation of design and development controls.
their own, will be unable to comply with these provisions, which were not thoughtfully proposed to cover the varied aspects of tobacco product manufacturing.

d. Comments Concerning Timeframes Under the Proposed TPMP Rule

First, the compliance timeframes as set forth in the Proposed TPMP Rule (two years from the date of publication of the final rule, or six years from the date of publication for small tobacco product manufacturers) must be maintained in order for companies, big or small, to be able to have time to put a plan in place for compliance. CAA was pleased that the Proposed TPMP Rule appears to understand the immense time, focus and expense bringing manufacturers into compliance with all of these regulations will take; a shorter compliance period will pose an undue hardship on manufacturers.

Second, FDA has requested comment on the four-year record retention policy and whether it should be extended one to two years after a product reaches its expiration date (if one exists). With respect to cigars, there generally is no expiration date. Therefore, tying a document retention policy for cigars to an expiration date would not be a valid or appropriate approach. That said, CAA believes that four years is an adequate, if not overly lengthy, period within which to retain records and this record retention policy need not be extended beyond this period.

e. Comments Concerning Record-Keeping Throughout the Proposed TPMP Rule

CAA submits that the records required to be created and maintained under the Proposed TPMP Rule are voluminous, especially for small manufacturers. Further, the Proposed TPMP Rule is ambiguous as to which records can be electronic versus those that must be kept as paper
copies. 40 While CAA appreciates FDA’s desire to have every document and every change to every document signed by a responsible official, this does not recognize the reality of current business practices or of electronic record keeping. Additionally, the Proposed TPMP Rule is inconsistent on many record keeping requirements. For instance, the Proposed TPMP Rule states “documents that are established to meet requirement proposed part 1120 would be required to be available at all locations for which they are designated, used, or otherwise necessary, and all such documents that are superseded and obsolete would have to be promptly removed from all points of use or otherwise prevented from unintended use.”41 In the same respect, the Proposed TPMP Rule requires all documents to be retained for four years, and “superseded and obsolete documents be archived.”42 Depending on the systems set up at a facility, an “archived” document could be just as confusing on the manufacturing floor as not updating a current document. Also, the Proposed TPMP Rule says that “maintaining change records on computers would be acceptable” but does not outline what is acceptable for “archives.”43 This is especially critical given many of today’s software programs contain automatic update and override features.44 FDA needs to understand that record keeping procedures will vary by the type of manufacturer and the sophistication of the

40 21 C.F.R. Part 11 governs electronic recordkeeping, however, the Proposed TPMP Rule appears to at time contradict this or be unclear if the provisions of this rule or Part 11 will govern. CAA offers these comments based on the face of the Proposed TPMP Rule.


42 Id.

43 Id. at 15,237.

44 For instance, it is a well-known setting in Microsoft Word that updates the date of a document every time the document is opened. While settings such as this can be changed, the Proposed TPMP Rule must take into account the technological advances related to record keeping.
system. As outlined further below, this may also be different based on the type of product and records associated with that product.

The record keeping provisions of the Proposed TPMP Rule serve multiple purposes. In addition to ensuring consistent manufacturing, they should help guide both FDA and regulated industry in what to expect during an inspection. The Proposed TPMP Rule, however, has such voluminous data and record keeping requirements that it is impossible to discern what will be necessary in an inspection. To date, every cigar manufacturer inspection conducted has resulted in FDA asking for slightly different documentation at each. This directly ties into the record-keeping requirements. CAA proposes that FDA create an “Inspection Checklist” that manufacturers can rely upon to ensure that all facets of the Proposed TPMP Rule are being complied with. Such an “Inspection Checklist” and/or “Inspection Guide”, would assist cigar manufacturers in knowing that they are maintaining adequate records under the Proposed TPMP Rule and would assist with having efficient manufacturing inspections. FDA could also designate within this guidance which documents would be necessary to have maintained in English versus other documentation required under the Proposed TPMP Rule which would not require English translation.

f. Exemption and Variance Procedures

The Proposed TPMP Rule contemplates that not all the provisions will apply to all manufacturers and that manufacturers should be able to document which procedures do not apply to its activities and simply not comply with those procedures when they would be unable to do

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45 Further, many corporations have record keeping policies that may be different from what FDA proposes. If a company has a corporate record keeping policy in place at the time of the effective date of the Proposed TPMP Rule this record-keeping policy should satisfy the Proposed TPMP Rule.
so.46 Seeming to diverge from that position, the Proposed TPMP Rule also contains detailed procedures to request exemptions or variances to the Proposed TPMP Rule.

Requesting a variance seems to be appropriate when an unforeseen event occurs, and a manufacturer needs the flexibility to continue operations but may not be able to comply with specific parts of the Proposed TPMP Rule. In this case a variance would be appropriate. CAA suggests a notification process is preferable to an application procedure (so that manufacturing can continue) and submits that the Tobacco Control Act variance or exemption “petition” provision allows such an approach.

Regarding exemptions, the Proposed TPMP Rule states that “this provision would require a detailed explanation setting forth the basis for the petitioner’s determination that compliance with the requirement(s) is not required to assure that the public health will be protected and the tobacco product will be in compliance with the FD&C Act.”47 FDA has failed, however, to clearly outline its expectations between what are manufacturing activities that do not apply to a certain manufacturer, as opposed to those for which a manufacturer would be required to seek an exemption. For instance, a manufacturer of hand-made premium cigars will not have specifications regarding machine maintenance and will not be able to comply with this part of the Proposed TPMP Rule. While it should be obvious that given the type of manufacturing activity this requirement does not apply, the Proposed TPMP Rule could be read to require an exemption to this requirement. FDA must specify what standards will be applied to require manufacturers to

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46 See above at 11-13.

request an exemption from the requirements of the Proposed TPMP Rule, as opposed to what standards will be used to determine if provisions simply do not apply to certain manufacturers.

g. Cost-Benefit Analysis

The Proposed TPMP Rule posits its estimated benefits as the “value of reduced adverse events due to non-conforming finished and bulk tobacco products and from reduction of costs associated with reduced product recalls and market withdrawals.”

CAA submits that this cost-benefit “analysis” is overbroad and inapplicable to the cigar product category. Namely, CAA is unaware of, and does not believe there have been, wide-spread recalls or adverse event reports relating to cigars. This is a critical point, as it demonstrates, that in large part, even without the overly burdensome requirements of the Proposed TPMP Rule, CAA manufacturers are manufacturing a quality product to specifications without deviation. For the Proposed TPMP Rule to broadly impose these requirements upon all tobacco product manufacturers based upon these stated “estimated benefits” is unduly burdensome. While the costs to comply with the Proposed TPMP Rule will certainly vary by manufacturer depending on size, the costs will be substantial regardless of the facility’s size. Moreover, everything is relative. For example, a large, sophisticated cigar manufacturer may already be implementing many of the requirements outlined in the Proposed TPMP Rule, and therefore will have to expend less time and costs to come into compliance. On the other hand, small tobacco product manufacturers may have a lot more work to do in order to be compliant with the Proposed TPMP Rule, and therefore may need to expend more time and costs than a large manufacturer.

48 Id. at 15,177.

49 For instance, some CAA companies have facilities that are ISO 9001 certified.
Additionally, there are many costs of implementation of the Proposed TPMP Rule that FDA fails to account for. First, manufacturers will have to hire and train additional personnel to (i) understand what requirements apply to each facility; (ii) implement the requirements; and (iii) continually update and audit the records to ensure compliance. Second, the additional record-keeping (and the Proposed TPMP Rule is imposing additional record keeping even for facilities that are ISO 9001 certified, let alone for less sophisticated facilities) will at a minimum slow down production process, and at worst require a complete overhaul of production processes, ensuring the facilities will not be able to run at current production times. Adding inefficiency to processes will result in lost revenue, at a time when additional personnel will be required. Third, there will be necessary software and equipment upgrades. To store four years of voluminous and burdensome records will either require significantly enhanced server storage space, or creation of secure, climate controlled, record-keeping locations. No matter whether a company chooses to house all records electronically or in paper form, the investment for a four-year record retention of this volume of records will be substantial. It will certainly involve investment in additional software, servers and potentially changes to a company’s software policies and document control and retention policies.

CAA recommends that FDA revisit its broad “cost benefit” analysis and consider implementing requirements upon manufacturers based upon the actual relative risk and history of adverse events – of which CAA member companies have not experienced.

V. Additional Concerns Specific to Foreign Manufacturing Facilities

The Proposed TPMP Rule proposes that foreign manufacturers of finished or bulk tobacco products that are imported or offered for import into the United States be covered under the Proposed TPMP Rule. CAA does not oppose the Proposed TPMP Rule’s general application to
foreign manufacturers.\textsuperscript{50} The Proposed TPMP Rule, however, largely misses the mark with its attempt to cover foreign manufacturer operations and fails to account for several factors – a failure which demonstrates a myopic, US-centric viewpoint and may make it near impossible for foreign manufacturers to comply. Many of these considerations have been addressed above; below are additional considerations that apply only to foreign manufacturers.

\textbf{a. Requirement that all Documents be in English}

The Proposed TPMP Rule does not adequately account for the fact not all countries speak, read, write, or understand the English language. Proposed TPMP Rule § 1120.122 states that “[a]ll documents and records must be written in English, or an accurate English translation must be made available upon request,” and the Proposed TPMP Rule further provides that “[d]ocuments and records (including any source data) could be maintained in the native language of a foreign tobacco product manufacturer as long as a translation is made available upon request.”\textsuperscript{51} While foreign manufacturers based in English-speaking regions, such as the United Kingdom, will not face a language barrier, the same cannot be said for foreign manufacturers in non-English speaking countries. This is particularly true for countries such as Nicaragua, Honduras, and the Dominican Republic, where most foreign cigar manufacturers have their factories. While it may be appropriate to have certain documents in English, it is unnecessary to require foreign manufacturers to have, if requested, English-translated versions of all documents and records required under the Proposed TPMP Rule – which are voluminous.

\textsuperscript{50} See above, however, Section III(a) regarding FDA’s legal authority relating to foreign manufacturers and the pending decision regarding the regulation of premium cigars.

\textsuperscript{51} Proposed TPMP Rule, 88 Fed. Reg. at 15,234.
i. Actual Translation Issues

In addition to the burden of having documents in more than one language, the Proposed TPMP Rule’s parameters for “demonstrating” the adequacy of translations are unduly vague. The Proposed TPMP Rule states that “[t]he accuracy of the English translation could be demonstrated by, for example, providing a certification of the translation, using a certified translator, or providing information on the competency of the translator.”\(^{52}\) But this is not sufficiently detailed to explain what is actually required to satisfy the Proposed TPMP Rule. For example, would it be sufficient for a bilingual employee (to the extent available) to serve as a translator? To the extent FDA requires “certified” translations, this could become prohibitively expensive for foreign manufacturers given the volume of records required to be maintained under the Proposed TPMP Rule. As CAA members have learned during the process of translating documents from foreign manufacturers for submittal with Substantial Equivalence Reports, a certified translation of even just several pages can cost thousands of dollars alone. This is not to mention that FDA proposed to vaguely require that “a manufacturer would fulfill requests for documents or records translations promptly to ensure no delays of inspections or investigations.”\(^{53}\) However, the Proposed TPMP Rule does not expound upon what FDA expects “promptly” to be. Would FDA expect translations within days? Weeks? Or months? The speed at which FDA expects translations to be provided could also make certified translations even more prohibitively expensive.

Separately, the Proposed TPMP Rule fails to address other issues inherent in FDA’s attempt to capture foreign manufacturers in these regulations. For example, how are non-English

\(^{52}\) Id.

\(^{53}\) Id.
speaking foreign manufacturers expected to understand the Proposed TPMP Rule, and comply with all of its recordkeeping requirements? Will the Proposed TPMP Rule be made available in the foreign manufacturer’s native language? How will FDA communicate with foreign manufacturers – in their native language, or in English? It is not enough that a foreign manufacturer is *allowed* to maintain records in their native language – this should be the default. Even with that, FDA has failed to create or address a mechanism by which foreign manufacturers will be able to comply with the Proposed TPMP Rule or engage with FDA concerning such compliance.

**ii. Documents Subject to Translation**

The purpose of the Proposed TPMP Rule is “to ensure that tobacco products conform to established specifications and to help prevent the manufacture and distribution of contaminated or nonconforming products, thereby assuring that the public health is protected.”\(^{54}\) CAA submits that in order to for manufacturers to comply with this rule it is critical their employees, as opposed to FDA officials, understand all documents and data regarding the products. While it may be important for FDA to have certain specific documents in English, it is equally important for foreign manufacturers to be permitted to maintain the documents and records in the language native to their employees who will be creating and maintaining the records. The Proposed TPMP Rule as written does not recognize that it is (i) burdensome; (ii) potentially expensive; and (iii) unnecessary to ensure proper manufacturing for all of the required records and documents to be made available at FDA’s request in English.

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\(^{54}\) *Id.* at 15,175.
FDA should identify a limited subclass of critical documents that it would have the authority to require be translated upon request as well as maintained in a native language. This subclass of documents should be limited to, at most, manufacturing-related standard operating procedures and top-level manuals and documents. For example, it would be unduly burdensome and unnecessary to translate every employee-facing document, such as employee personnel rules or work instructions or even batch or manufacturing records which by necessity will be maintained in a local language for employees to understand and record. Limiting the subclass of documents necessary to have in two (or more) languages will allow for FDA to determine if a facility is complying with the Proposed TPMP Rule but will also allow the facility to translate only documents of actual relevance to the manufacturing process, as opposed to every single record keeping requirement under the Proposed TPMP Rule. Further, rather than requiring all records be maintained in both languages, FDA could require an English-speaking employee be on site during an inspection to verbally translate any documents or records about which FDA has questions. There are many less onerous or more narrowly tailored methods by which FDA could accomplish its goals of not needing bi-lingual employees and viewing relevant records. FDA must revise and reconsider these requirements to create a less onerous option for manufacturers.

b. Requirements Relating to Environmental, Sanitation and Pests

While the Proposed TPMP Rule states that it employs an “umbrella approach,” intended to be “flexible” and adjustable based on a manufacturer’s individual practices, Subpart C of the Proposed TPMP Rule is filled with highly specific and intensive requirements that permeate nearly every facet of a manufacturer’s practice. And while United States manufacturers may be able to comply with many of these requirements, given the existing requirements under various Federal,
state and local laws, the same cannot be said for foreign manufacturers governed by laws of their local jurisdictions. By limited way of example:

- “Proposed § 1120.34(a)(2) would require that buildings and facilities have adequate heating, ventilation, and cooling (HVAC).”

- “Proposed § 1120.34(a)(3) would require finished and bulk tobacco product manufacturers to utilize adequate plumbing (including control of drainage, backflow, sewage, and waste) to avoid being a source of contamination . . . In addition, floors cleaned with water (or water-soluble products) should be designed with floor drains to facilitate adequate drainage.”

- “Proposed § 1120.34(e) would require finished and bulk tobacco product manufacturers to establish and maintain procedures for monitoring, controlling, and minimizing the presence of animals and pests in the buildings, facilities, and grounds to protect against contamination of tobacco products.”

- “This paragraph also would require that the procedures include a requirement that any pesticide, including rodenticides, insecticides, or fungicides used in the buildings, facilities and grounds be registered in accordance with the Federal Insecticide, Fungicide and Rodenticide Act…”

Foreign manufacturers – understandably – operate within the confines of their given country/locale’s laws and regulations. It would be excessive and unnecessary for FDA to require foreign manufacturers to not only have to follow local laws related to environmental, sanitation and pest control, but also the laws of the United States, which in many instances may be inconsistent with or go beyond requirements of a foreign manufacturer’s country.

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56 Id.
57 Id.
58 Id. at 15,200.
In addition, certain of these strictures, such as HVAC systems, may not even be *available* in every country or region where tobacco products are manufactured or there may be restrictions on the use of power for such systems. For these and other reasons, requiring compliance with such provisions may well create insurmountable obstacles to compliance in the local jurisdictions. For these reasons, with respect to foreign manufacturers, all regulations in the Proposed TPMP Rule related to environmental, sanitation and pest controls should strictly be limited to compliance with relevant and applicable local environmental laws, regulations and requirements.

c. Corporate Set Up and Distribution

Many foreign cigar manufacturers are part of a “group” of companies, meaning that the foreign manufacturer in many instances is not the company that is consumer facing; the foreign manufacturer’s sole customer is a U.S. distribution company. Numerous requirements in the Proposed TPMP Rule do not take into account the fact that foreign manufacturers are rarely the entity that sells directly to U.S. consumers or to U.S. accounts or has any direct contact with them.

i. Consumer Complaints

The Proposed TPMP Rule devotes almost four pages to complaint procedures stating that they can come from anywhere, including “healthcare professionals, consumers, the public, and businesses (e.g. retailers, other tobacco product manufacturers).”\(^{59}\) While foreign manufacturers may have procedures for complaints from the trade (e.g. broken packages) they generally do not have procedures for consumer complaints, as these companies do not sell directly to the public. Industry takes seriously all types of complaints, but companies process them differently based on their nature -- a complaint from the public is different from a complaint from a commercial

\(^{59}\) *Id.* at 15,192.
customer. Further, while FDA states that it does understand that manufacturers may have corporate complaint departments that handle all complaints, the manufacturer still must designate the individual responsible for the complaints. First, CAA is again concerned that FDA may not actually understand the corporate complaint system and how it would work and be more beneficial than what FDA is proposing. Second, designating an individual is not an efficient means of establishing consistent and reliable procedures. Instead, corporate titles should be designated, with updates regarding the individual currently holding the position. Third, housing compliance departments in foreign facilities where there may be language barriers will not lead to the quickest, best resolution to the complaint. FDA must acknowledge and create a flexible framework so that companies can handle complaints, no matter where they originate, in the manner in which best suits the business and the resolution of the complaint.

ii. Distribution and Direct Accounts

The Proposed TPMP Rule states that “[t]hese proposed requirements would apply only to tobacco product distribution within the manufacturer’s direct control (i.e., the initial consignee and direct account).” This seemingly does recognize that cigar manufacturer “XXX” may only distribute to one direct account, which is cigar manufacturer “XXX’s” U.S. Distribution entity. The Proposed TPMP Rule then goes on to state that the rule “would require finished and bulk tobacco product manufacturers to maintain a list of direct accounts…this information would

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60 This is a common problem with the Proposed TPMP Rule that applies to all manufacturers. FDA is insistent about knowing the names of individuals responsible for each activity within the rule, but employees change often, yet the position tasked with responsibility changes less frequently. FDA should not require the names of specific individuals be in all records but instead the title of the job that has responsibility for different action items. Current corporate organizational charts will allow for the knowledge of which individual holds the responsible position.

facilitate notification…to efficiently conduct a product recall.”\footnote{Id. at 15,234.}  CAA understands this rule is meant to be flexible and manufacturers need comply only with the portion of the rule that applies to its business.  As written, however, CAA is concerned that, if FDA is presented with only one direct account, it will not recognize that it is the full list of direct accounts for the foreign manufacturer.

VI. Concerns Related to Manufacturers that Only Repack or Relabel Cigars

There are cigar companies in the United States that are registered domestic manufacturing facilities only because they repackage and relabel cigars, which under the Tobacco Control Act is considered “manufacturing.”  These facilities do not do anything to the cigars except open boxes and bundles that contain individually wrapped cigars and repackage them into different quantities (i.e., taking a box of 20 and creating 4 bags of 5 cigars) or relabel cigars that are bought in bulk in different brand names.  No matter the size of the operation, these processes are entirely manual.

These facilities have an incredibly limited scope of manufacturing activities and therefore, while they will be covered by the Proposed TPMP Rule, most of its provisions will not apply to these facilities.  These facilities should not have to document any deviation from a TPMP Rule, or apply for any exception or variance from such a rule.  Instead, as noted at the beginning of the rule, they should have to comply only with the provisions relevant to the business model and the manufacturing activity occurring at the facility.  Again, FDA must understand that not all facilities perform all manufacturing activities and that not all TPMP requirements should apply equally to all business models.
VII. Conclusion

For the reasons set forth above, CAA requests FDA revise and reconsider the Proposed TPMP Rule to eliminate the unduly burdensome provisions so that cigar manufacturers can comply with the requirements of the Proposed TPMP Rule in a manner that is cost efficient and reflects the unique nature of the products they manufacture.

Respectfully Submitted,

[Signature]

David M. Ozgo
President
Cigar Association of America, Inc.
EXHIBIT A
May 20, 2013

VIA WWW.REGULATIONS.GOV
(Original Sent By Courier)

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-N-0227

Dear Sir or Madam:

The Cigar Association of America, Inc. (CAA), on behalf of the association and its individual member companies, and Altadis USA, Inc., General Cigar Co., Inc., Swedish Match North America, and Swisher International, Inc., submits the following comments in response to the Food and Drug Administration’s (“FDA’s”) March 19, 2013 request for comments on “Tobacco Product Manufacturing Practice”, 78 Fed. Reg. 16824 (March 19, 2013). This docket was opened to allow public comment on recommendations for regulations on good manufacturing practices submitted by 13 cigarette and smokeless tobacco companies on January 10, 2012 (“the Recommendations”). Because of the significant differences between cigars and cigarettes, the tremendous variability in manufacturing processes within the cigar industry, and the language in the Recommendations that applies to tobacco products yet to be regulated, CAA submits these comments to express its belief that the proposal should be limited to cigarettes and smokeless tobacco.

CAA is a trade organization that represents cigar manufacturers, importers, distributors and major industry suppliers. Its manufacturing members range from producers of high-end premium cigars to manufacturers of popular priced, machine-made cigars. As a result, CAA believes it is uniquely positioned to provide input and feedback to FDA regarding the cigar industry’s manufacturing operations and the unique considerations that apply to this industry. CAA and its member companies believe that the recommendations for tobacco product good manufacturing practice (“GMP”) regulations submitted by a group of 13 tobacco companies representing cigarette and smokeless tobacco manufacturers describe
high level procedures that could be applicable to the cigar industry, albeit with alteration. Importantly, however, as outlined in these comments, the implementation of GMPs will differ substantially between the cigarette and cigar industries, and even within the cigar industry there is a significant amount of product and manufacturing variation that will require different approaches to the implementation of a quality system.

Differences Between Cigarette and Cigar Manufacturing Processes

Because of the significant differences between cigarette and cigar manufacturing operations, the implementation of the GMP requirements must, and does, differ between the two industries. At the outset, it is important to appreciate that cigar manufacturing, unlike cigarette manufacturing, is not a standardized or uniform process. Rather, the manufacturing operations for cigars range from the largely automated manufacture of machine-made cigars to the semi-automated production of cigars that are “hand-rolled” to the entirely manual process of making hand-made premium cigars. Cigarette manufacturing, on the other hand, is highly standardized and its output is uniform in that cigarettes generally have the same shape, length, ingredients, and packaging. Moreover and importantly, even the most automated cigar manufacturing operation is not nearly as sophisticated or automated as the cigarette manufacturing process that is fully automated. Indeed, all cigar equipment requires some level of manual assistance.

For example, with some older-type equipment that remains in use by a number of cigar manufacturers, the important function of filling and re-filling the hopper that feeds tobacco into the machine is manual, not through an automated tobacco feeder. Differences in sophistication between cigarette and cigar manufacturing equipment are also reflected in the quality control measures. While cigarette manufacturing equipment includes automated weight checks and quality controls, cigar manufacturers rely mainly on manual and visual quality checks, especially for hand-made cigars. As a result, the implementation of a GMP requirement relating to instruments or controls that are used in the manufacturing or holding of tobacco products, packaging, and materials that are used to measure, regulate, or record any information necessary to determine conformance with specifications or protect against contamination, see proposed XXX.60(c), would differ significantly between the cigarette and cigar industries, and implementation differences would occur even within the cigar industry. For example, a requirement to calibrate instruments or controls before first use and at specified frequencies is meaningless in the context of the simple, manual tools that are used in the manufacture of hand-made cigars. Moreover, the need for, or approach to, calibrating equipment would differ depending on its automation and sophistication, which is not uniform within the cigar industry.

Similarly, there are significant differences with regard to the type of facilities in which cigarettes and cigars are manufactured. While cigarette factories are large facilities with sophisticated equipment and an extensive staff, cigar factories vary greatly in terms of facility size and staff, and the type of equipment varies depending on the geographic location and type of cigar being manufactured. For example, premium hand-made cigars are mostly manufactured abroad, such as in Nicaragua, Honduras, and the Dominican Republic in facilities that have no automated or electronic equipment. The sophistication of
the facility will have a crucial impact on the implementation of any sanitation requirements, see proposed XXX.114. Specifically, how you implement the requirement to have “adequate sanitation principles” will differ significantly between state-of-the-art cigarette facilities located in the U.S. and foreign-based cigar factories. These differences must necessarily lead to variances in the implementation of a broad sanitation requirement, particularly given the fact that these differences do not adversely affect product quality, or present different or greater public health concerns.

Traceability is another important consideration included in the proposed tobacco product GMPs. Specifically, while cigarette tobacco is mainly domestic, thus, allowing cigarette manufacturers the ability to trace tobacco from farm to machine, cigar tobacco often is sourced from, and usually blended, abroad. Because cigar manufacturers interact primarily with sales agents, they usually have no knowledge about others who are involved with processing and blending the tobacco they receive. Indeed, sales agents, likewise, do not always know the full source of the product they sell. Moreover, this difficulty is significantly compounded by limitations in the scope of the Tobacco Control Act, thus making cigar tobacco considerably less traceable than cigarette tobacco. As a result, requiring procedures for traceability between a finished tobacco product and its materials and tobacco used to produce a given lot or batch of the finished tobacco product, see proposed XXX.95, would be challenging, if not impossible to implement for the cigar industry to achieve. Such successful traceability would likely be uneven, at best, and historically, highly specific traceability to each and every entity that touched tobacco used in cigar making has not been necessary to ensure quality product.

In sum, significant differences exist between cigarette and cigar manufacturing operations, including differences in equipment, facilities, products produced and number of employees. These differences should be considered in defining necessary and appropriate GMP requirements for the respective industries. Additionally, these differences, and the quality requirements relevant to them should be considered in the context of the overall historical high quality of cigar products.

Differences Within Cigar Industry

Manufacturing operations within the cigar industry are not uniform and, as a result, it would be challenging to apply the Recommendations’ highly specific and general requirements within the cigar industry and expect uniform and predictable implementation. Specifically, cigar manufacturing ranges from machine-made cigars, to hybrid (hand-rolled) cigars where the filler and binder are combined by machine and the resulting “bunch” is wrapped by hand, to entirely hand-made premium cigars. All of these processes rely on different equipment, skill sets, training, and quality controls. For example, learning how to operate an automated cigar-making machine has very little overlap, if any, with learning to become a skilled roller of hand-made cigars using only a few simple tools. Likewise, while a machine operator could become proficient within a few months, acquiring an acceptable level of skill to make a variety of handmade cigar shapes could be part of lengthy and continuing training that could encompass years. Simply put, the level of training required for each undertaking differs significantly.
Similarly, quality controls will be different for the various types of cigars and the related cigar making operations. For example, hand-made cigars are manually and visually checked for consistent ring gauge (diameter), weight, size, and draw quality, and for any imperfections in the wrapper or in the shape of the cigar. Machine-made cigars, while subject to the similar types of quality controls, can at least partly rely on the manufacturing equipment to ensure consistent output, thereby making reliance on the visual and manual component of final product inspection considerably less important than for hand-made cigars.

Even within the machine-made category of cigars there are a number of differences in manufacture. While a substantial percentage of manufacturers use equipment that is largely automated to manufacture portions of their cigar output (although still much less automated than cigarette equipment), a not insignificant number of manufacturers still use older-type equipment that relies heavily on manual assistance, such as keeping the hopper filled with tobacco and manually transferring bunches to over-rolling machines for wrapping.

Finally, the manufacture of hand-made cigars covers a number of unique manufacturing steps that do not apply to manufacturers of cigarettes and machine-made cigars who receive tobacco from leaf dealers that is ready for use in the manufacture of the tobacco products. In contrast, for hand-made cigars, the tobacco can be grown by the manufacturer and subjected to a number of manufacturing operations such as curing, grading, fermenting, conditioning and casing before it can be transferred for use in the production of cigars.

Conclusion

In sum, there are significant differences in manufacturing operations between the cigarette and cigar manufacturing industries and within the cigar industry that would affect the applicability and implementation of the proposed GMPs in the context of cigar manufacturing.

Importantly, Congress, in providing for GMP requirements for tobacco products, contemplated that there would be differences between tobacco products that would translate into unique manufacturing practice considerations. See 21 U.S.C. § 387f(e)(1)(A) (“In applying manufacturing restrictions to tobacco, the Secretary shall . . . prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this subchapter.”).

Consistent with the Congressional mandate, CAA requests that should the agency consider defining GMP requirements for cigars, it take these basic differences into account. Because CAA believes that differences between cigarette and cigar manufacturing are too great to have one quality control regulation cover both, the association recommends that the Recommendations not apply to “tobacco products” and
apply only to cigarettes and smokeless tobacco. To do otherwise, is to ignore the large variability of operations within the cigar industry. To the extent that a significant portion of the cigar manufacturers would be unable to comply with the Recommendations, this would result in illicit product entering the market. CAA believes that a GMP regulation for cigars that outlines general requirements for cigar manufacture, possibly combined with a guidance document that provides additional detail on the agency’s expectations for compliance from different types of manufacturing operations, would be the most appropriate and feasible means of achieving the goal of ensuring quality products.

CAA requests the opportunity for a meeting with FDA prior to the agency’s issuing GMP regulations for tobacco products.

Sincerely,

Craig Williamson
President
Cigar Association of America, Inc.