DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE

Docket No. FDA-2013-N-0227

Preliminary Regulatory Impact Analysis

Initial Regulatory Flexibility Analysis

Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). We believe that this proposed rule is a significant regulatory action as defined by Executive Order 12866. Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small entities are likely to incur a large portion of the costs to comply with the proposed rule, we find that the proposed rule would have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The proposed rule, if finalized, would establish requirements for manufacturers of finished and bulk tobacco products on the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation, packing, and storage of tobacco products. The tobacco product manufacturing practice (TPMP) requirements described in the proposed rule are intended to ensure that tobacco product manufacturers control the design and specifications of finished and bulk tobacco products, providing a level of assurance of conformity in the production of tobacco products to established and required specifications that does not occur in the existing market for tobacco products, to prevent the adulteration and misbranding of finished and bulk tobacco products, and establish controls for traceability purposes.

We quantify two potential benefits of the proposed rule. First, the manufacturing controls required by the proposed regulation are likely to reduce the likelihood that nonconforming products are manufactured and commercially distributed which, in turn, would reduce social costs associated with product recalls and market withdrawals. The social costs of a recall due to inadequate or insufficient controls may extend beyond the costs to the manufacturer conducting the recall and may include shareholders as well as consumers, retailers, and wholesalers. If a recall or market withdrawal were necessary, the records required by the proposed regulation would help locate nonconforming products that were commercially distributed, which would also be expected to reduce the cost of conducting recalls and market withdrawals, both voluntary and involuntary. Since 2009, tobacco product manufacturers have initiated eight voluntary recalls, resulting in at least three million cans of smokeless tobacco and 62 million cigarettes recalled or withdrawn from the market. Furthermore, we estimate that, if the proposed rule is finalized, the undiscounted costs

of product recalls and market withdrawals may fall by between $4 million and $213 million per year.

Another quantified potential benefit of the proposed rule is that adverse events due to nonconforming finished and bulk tobacco products would decrease as a result of improvements in the control of tobacco product manufacturing operations. We use data on exposure calls to Poison Control Centers (PCs) throughout the U.S. to quantify the impact of the proposed rule on the number of exposure calls reporting clinical effects such as vomiting, nausea, abdominal pain, etc. associated with the consumption of tobacco products that, according to the PCs' Certified Specialists in Poison Information, had been tampered with or contaminated. We estimate, from 2001 to 2030, a total of 11,135 projected exposures, or an annual average of 371 exposures per year, associated with the consumption of such products.[1] Based just on these data regarding calls to PCs, if the proposed rule is finalized, we estimate that the total (undiscounted) monetized health losses associated with contaminated tobacco products may be reduced by between $908 and $2,723 per year.

There are other potential benefits associated with the proposed rule which we have not quantified. First, the proposed recordkeeping provisions will also support FDA's regulatory compliance activities and help FDA implement and enforce other provisions of the Federal Food Drug & Cosmetic Act (FD&C Act) which would likely generate government cost savings. Second, the proposed rule, if finalized, may further reduce losses to health and property for users and nonusers associated with nonconforming tobacco products, beyond those estimated in the quantified benefits. Third, the proposed rule's risk assessment, CAPA, tobacco product

[1] The 11,135 projected exposures are estimated from observed 2001-2017 exposures (adjusted for under-reporting) and adjusted to account for an apparent trend of increasing exposure calls from 2018 through 2030. We use this forecast to estimate a baseline trend (the world without this rule). Figures are also adjusted for underreporting as explained in the Benefits of the Proposed Rule section D. 2.

complaints and related provisions will facilitate investigation and identification of causes and root causes of consumer complaints and other reports of adverse events. Other benefits include avoided spillover costs to capital markets.[2]

The potential costs of the rule include tasks associated with establishing and maintaining procedures for various aspects of the manufacturing, preproduction design validation, packing and storage processes. Examples of these tasks include conducting new or more stringent manufacturing activities, writing, and updating standard operating procedures (SOPs), training employees to engage in new or more stringent manufacturing activities, and keeping new or additional records. We estimate that (undiscounted) one-time domestic costs range from $39 million to $73 million and (undiscounted) recurring costs range from $15 million per year to $56 million per year. FDA is also proposing that any final rule become effective two years after the date of the final rule's publication. FDA is further proposing in § 1120.130 of this rule that manufacturers meeting the definition of small tobacco product manufacturer would be required to comply with the requirements of this rule four years after the effective date of the final rule, i.e., six years after the date of the final rule's publication. Because small manufacturers would have more time than non-small manufacturers to comply with the requirements of this proposed rule, we estimate all costs to reflect the staggered compliance dates. We estimate learning costs for both non-small and small manufacturers to begin one year after publication (year 1). Non-small manufacturers and small manufacturers would incur costs one and five years, respectively, after the publication date of a final rule as they work to come into compliance with the rule two and six

[2] Estimated quantified benefits of avoided recalls include reduced external costs in the supply chain of the recalled or withdrawn products (or they exclude reduced recall costs to manufacturers). Estimated external costs of conducting a recall or market withdrawal include lost sales to retailers and wholesalers, expenses associated with notifying tobacco retailers (for wholesalers) and consumers, removal and storage of inventory costs collection and shipping costs, disposal costs, and legal costs, among others. Estimated quantified benefits do not include avoided spillover costs to capital markets.

years from the date of final publication.[3] We therefore estimate the present value of total domestic costs annualized over ten years using a discount rate of seven percent is estimated to range from $13 million per year to $41 million per year, and from $14 million per year to $43 million per year using a discount rate of three percent. Our estimated benefits will begin to accrue on the same years as the compliance dates (years 2 and 6). The present value of total benefits annualized over ten years using a discount rate of seven percent is estimated to range from $1.9 million per year to $97.0million per year, and from $2.1 million per year to $106.5million per year using a discount rate of three percent. Table 1 summarizes our estimate of the annualized costs and benefits of the proposed rule.

Table 1.— Summary of Benefits, Costs and Distributional Effects of the Proposed Rule ($ millions/year)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$27.2	$1.9	$97.0	2020	7%	10 years	Quantified benefits include a summation of potential reductions in (1) cost of recalls and market withdrawals and (2) adverse health effects associated with contaminated or otherwise nonconforming tobacco products.
		$29.9	$2.1	$106.5	2020	3%	10 years	
	Annualized Quantified					7%	10 years	
						3%	10 years	
	Qualitative	Non-quantified benefits include (1) Government costs savings due to aiding FDA compliance efforts; (2) potentially reducing					10 years	

[3] The year of publication is year zero and the effective date is year two. In order for non-small manufacturers to comply with the requirements of this rule by the effective date (year two), we assume they will begin to incur compliance costs on year one. For small manufacturers to comply four years after the effective date or year six, we assume they will begin to incur compliance costs on year five. Benefits from non-small and small manufacturers begin to accrue on year two and year six respectively. All values have been adjusted to reflect 2020 dollars. Estimated costs in Table 1 represent estimated costs incurred by domestic manufacturers and domestic importers. Estimated benefits in Table 1 are from reduced exposure and reduced recall related costs associated with both domestic and imported tobacco products sold in the U.S.

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
		losses to consumers due to health and property for users and nonusers associated with nonconforming tobacco products; and (3) facilitating the investigation and identification of causes and root causes of consumer complaints and other reports of adverse events.						
Costs	Annualized Monetized $millions/year	$27.0	$13.3	$41.1	2020	7%	10 years	Annualized total costs of compliance with the proposed rule. Range of estimates captures uncertainty.
		$28.2	$13.7	$43.0	2020	3%	10 years	
	Annualized Quantified					7%	10 years	
						3%	10 years	
	Qualitative						10 years	
Transfers	Federal Annualized Monetized $millions/year					7%	10 years	
						3%	10 years	
	From/ To	From:			To:		10 years	
	Other Annualized Monetized $millions/year					7%	10 years	
						3%	10 years	
	From/To	From:			To:			
Effects	State, Local or Tribal Government:							
	Small Business:	One-time costs per small entity are between 0.06% and 0.11% of their average revenue. Due to many missing values from Census data, average small-entity impacts are likely subject to large variability, due to the significant amount of heterogeneity in small-entity impacts across manufacturers of different sizes. (See Section III.C.)						
	Wages:							
	Growth:							

II. Preliminary Regulatory Impact Analysis

A. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was signed into law, amending the FD&C Act. The Tobacco Control Act gives FDA authority to regulate the manufacture, distribution, and marketing of tobacco products. The provisions include, among other things, the authority to issue regulations relating to current good manufacturing practice or hazard analysis and critical control point (HACCP) methodology, hereinafter tobacco product manufacturing practice (TPMP), to assure that public health is protected, and that finished and bulk tobacco products are in compliance with the requirements of the FD&C Act.

As with other FDA-regulated products, we expect that tobacco products meet manufacturing standards; and that products manufactured and commercially distributed are not adulterated under Section 902 of the FD&C Act or misbranded under section 903 of the FD&C Act. FDA believes it is important that all manufacturers meet certain requirements regarding the methods used in, and facilities and controls used for, the manufacture, preproduction design validation, packing, and storage of tobacco products to assure that the public health is protected, such as to help protect against the manufacturing and distributing of contaminated or otherwise nonconforming product, and that the tobacco products are in compliance with the FD&C Act. The proposed rule requires the establishment and maintenance of procedures for various aspects of finished and bulk tobacco product manufacturing, preproduction design validation, packing, and storage to ensure that finished and bulk tobacco products conform to established product specifications and other requirements.

The requirements set forth in the proposed rule affect all aspects of production and would require that manufacturers control their manufacturing, packing, storage, and distribution activities. For example, process and acceptance activity controls would help manufacturers catch manufacturing deviations during the production process and acceptance activities, nonconforming tobacco product, and corrective and preventive action controls would reduce the likelihood that nonconforming tobacco products are manufactured and distributed. The result of such controls is decreased potential for commercially distributing adulterated and misbranded products. Less consumer exposure to adulterated or misbranded tobacco products is expected to decrease health risks to consumers that are not normally associated with tobacco product consumption.

B. Market Failure Relevant to Analysis of this Federal Regulatory Action

Market failure occurs when individual profit maximizing decisions are misaligned with an efficient allocation of resources from society's perspective. In this case, a market failure exists because consumers in the current marketplace may be unable to identify non-conforming tobacco products or may lack awareness of related health risks beyond those normally associated with consumption of tobacco products. Such consumer identification, awareness and appreciation of risk, and feedback on nonconforming products is a necessary incentive for firms to make socially beneficial choices about manufacturing processes, distribution, and sale of tobacco products. Without consumer awareness and appreciation of non-conforming products risks, firms may have reduced incentives to invest in a socially optimal level of prevention.[4]

[4] As discussed in Section II.C. of the Preamble, FDA's proposal is similar to industry proposed GMPs but also deviates from industry GMP recommendations in several ways. For example, the industry recommendations do not propose requirements for design and development activities generally, returned tobacco product, and warning plans, as discussed throughout this preamble. Such provisions are critical to ensure that the public health is protected and for the efficient enforcement of the FD&C Act.

Since consumers' perceived risk may not align with the actual risks, this may reduce the incentives for profit-maximizing manufacturers to invest in the socially optimal level of safety across the supply chain, from the raw tobacco and other ingredients through production of a finished tobacco product, distribution to retailers, and use by consumers. In real markets, risk information attributed to nonconforming tobacco products may be overshadowed by greater well-known risks associated with use of tobacco products, and therefore be overlooked by consumers, retailers, and producers alike.[5] The lack of awareness and appreciation by consumers of these risks suggests that demand may be unduly high for tobacco products that are not produced using adequate measures to prevent non-conforming products from entering the market. The entities involved in tobacco product manufacturing, processing, packing and holding make many decisions about what investments to make in choosing a level of quality for their customers (including retailers and consumers). According to classic economic theory, when doing so, firm managers may adjust their behavior to take into account the expected damage to the firm, which is the product of: (1) the probability that their practices will introduce a non-conforming product into the market, (2) the probability that they will be found legally responsible for damages caused by the sale of the non-conforming product, and (3) the maximum damage the event would cause to their firm if they are discovered to be responsible.

The maximum damage that selling a non-conforming product can cause for a manufacturing establishment includes the value of the recalled products, the value of the company's reputation to partners, and any individual or corporate liability that may be established. If the expected damage to the firm is equal to or greater than the cost of prevention, then the firm is more likely to invest

[5] A real market exists when the price that is asked for a product corresponds to the amount that a consumer is willing to pay for said product. The actual value of the product is not a necessary consideration in a real market.

in prevention. However, if the probability of detection is lower than 100 percent, firm managers will invest less in prevention than is socially optimal.

The potential social damage caused by the sale of a non-conforming tobacco product, in many cases, includes more than the private damage incurred by the specific manufacturing establishments who could have invested in preventing the nonconformance. Such social damage may also include consumer health impacts and spillover effects to the goods and services provided by other entities. These negative externalities associated with tobacco product recalls or market withdrawals may be larger in the aggregate than the losses to the producer of the recalled product itself (Refs. R1, R2).

The probability of a nonconforming product multiplied by the value of the firm's lost revenue may be less than the cost of prevention, while the probability multiplied by the total social damage is greater than the cost of prevention. In this case, if the external costs of recalling a non-conforming product are larger than the private costs, it is not rational for profit-maximizing managers to invest in the socially optimal levels of prevention.

This rule protects public health by addressing these situations. We assume that consumers are unable to distinguish between firms that have invested in producing conforming products at socially desirable levels from those that have not. Firms that invest in socially desirable levels of conformity may incur higher production costs causing them to compete at a disadvantage with firms that do not. When driven solely by consumer demand, establishments facing such diminished market incentives may not voluntarily invest sufficiently in product conformity, choosing to forego investments in preventive controls (including supplier approval and verification programs, or product testing when needed).

Imperfect information about the risks associated with tobacco products use and risks not normally associated with tobacco product use means that neither the legal system nor the marketplace may be able to provide adequate economic incentives for the production of conforming tobacco products. Predicting the consequences of having inadequate or insufficient controls is difficult as well. The Government may therefore be able to improve social welfare through targeted regulation. As explained in section D.1, and in section F, many provisions of this rule (e.g., written procedures, recordkeeping requirements) increase the probability of detection of a non-conforming product.

While all tobacco products have inherent risks to the public health, FDA is proposing TPMP requirements to minimize or prevent tobacco product design and manufacturing problems, as well as risks not normally associated with use of a tobacco product. Without a regulation that requires manufacturers to have adequate TPMP controls, FDA inspections data suggest that it is likely that some manufacturers would have inadequate controls to address risks associated with the tobacco product, its design and packaging, and its production process, packing, and storage. Inadequate TPMP controls may result in insanitary and environmentally inappropriate conditions, or improper handling and storage of finished and bulk tobacco products. Such poor manufacturing practices increase the probability that a tobacco product is contaminated or otherwise nonconforming and may generate or increase risks of illness, serious injury, or death that are not normally associated with tobacco product consumption, including biological, chemical, and physical hazards. A misbranded tobacco product may also result from poor manufacturing practices, such as an inaccurate statement of the quantity of content in terms of weight, measure, or numerical count. The commercial distribution of such nonconforming tobacco products may lead to product recalls.

FDA has identified several recalls of tobacco products since 2011 which may have been mitigated or avoided had TPMP controls been in place.

Further, as explained in the preamble of this proposed rule, if such nonconforming tobacco products are commercially distributed, consumers would face risks not normally associated with the use of tobacco products. For example, consumers may be harmed by consuming products containing a greater concentration of nicotine than expected due to labeling. Such exposure may result in health harms not normally associated with the use of nicotine-containing products.

The proposed manufacturing controls are intended to minimize or prevent contaminants and other risks. For example, the cleaning and sanitation activities in the proposed buildings, facilities, and grounds requirements are intended to ensure that the buildings and facilities are maintained in an appropriate condition to prevent tobacco product contamination. The proposed acceptance activities requirements would also ensure that tobacco products are not contaminated with physical hazards such as metal or plastic nontobacco related materials (NTRMs). Also, the proposed design and development requirements would help assure that the public health is protected by helping to prevent risks not normally associated with the use of the tobacco product, including risks to users and nonusers, such as environmental storage conditions that may result in mold growth on tobacco and tobacco products. The current high level of variability in tobacco product manufacturing practices makes it difficult for consumers to know whether a given tobacco product was produced using adequate manufacturing controls. Other than for obvious signs of adulteration (e.g., visible physical contamination, etc.) it may be difficult for even the most informed consumers to determine whether a product is adulterated or misbranded. Consumers, in many cases, are unable to distinguish, before consumption, between adulterated tobacco products (potentially carrying additional risks) and unadulterated tobacco products. The proposed regulation would help to

reduce this uncertainty by requiring TPMP for all finished and bulk tobacco product manufacturers.

As with products in any other industry, consumer knowledge and understanding of a given product (based on the product's established specifications) increases over time. Product specifications, however, may be changed by tobacco product manufacturers in ways that may go unnoticed by consumers. According to the FD&C Act (as amended by the Tobacco Control Act), a new tobacco product includes any product that was not commercially marketed in the United States as of February 15, 2007 or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. Unless such a product meets certain criteria, it may not be legally marketed in the United States unless FDA has issued an order authorizing its marketing. The proposed rule contains several requirements, including the establishment and maintenance of a master manufacturing record and production record, which would also help FDA ensure compliance with requirements of the FD&C Act. For example, these requirements would allow the Agency to determine if the finished or bulk tobacco product conforms to the specifications described in its marketing application under sections 905, 910 and 911 or required under section 907. If finalized, the proposed rule would help FDA ensure that a tobacco product's specifications are in accord with those described in its marketing application or, for grandfathered products, that they are manufactured consistent with their original specifications.

While product recalls are an important way for manufacturers and regulators to address nonconforming tobacco products that are discovered after distribution and sale, the costs of a recall due to inadequate or insufficient controls and records could spill over beyond the owner of the

firm conducting the recall (Refs. R1, R2). In this way, recalls may be associated with additional market failure. In a seminal work, Jarrell and Peltzman (1985) found that the capital market penalizes producers (whose costs are internalized) and their competitors of recalled products (whose costs are external) more than direct costs of recalls (Ref. R2). The authors state: "The capital market effects seem so great that they may exceed a plausible independent estimate of the relevant social costs." Not all recall costs are internalized and, therefore, the market may not provide sufficient deterrence against the sale of nonconforming products. Any recall, regardless of size, is followed by industry-wide asset loss (Ref. R2). However, Jarrell and Peltzman do not offer a clear way to separate social (external) costs from internal costs. We request comment and additional studies on the external costs of recalls.

C. Baseline Conditions

1. Number of Affected Entities

The requirements in the proposed rule apply to both domestic and foreign manufacturers of finished and bulk tobacco products. We use estimates from the Tobacco Registration and Product Listing Module within FDA's Unified Registration and Listing System,[6] and FDA tobacco import data,[7] we show our estimate of the number of affected entities, by major tobacco product group and size of operation group. We estimate that there is a total of 1,935 domestic entities and 3,273 foreign entities that would be affected by the proposed rule, as shown in Table 2.

[6] Under current guidance, FDA is enforcing the registration and listing requirements for manufacturers of finished tobacco products. For this reason, it is possible that this number is an underestimation because it does not include bulk manufacturers. However, this number may also be overestimated because it may include other manufacturers of tobacco products for further manufacturing (FFMs).

[7] The estimated number of foreign facilities is derived from data on tobacco product shipments from FY 2016 to FY 2018 prepared by U.S. Food & Drug Administration – Import Compliance Systems Branch – Minneapolis District Office, prepared on March 26th, 2018.

Of the 1,935 domestic entities, 102 are manufacturers that produce cigarettes, smokeless tobacco, and roll-your-own-tobacco; 223 produce cigars, pipes and pipe tobacco, waterpipes and waterpipe tobacco; 1,294 produce electronic nicotine delivery systems (ENDS) and e- liquids; and 315 are manufacturers that produce other nicotine delivery systems.[8]

Of the 3,273 foreign entities, 394 are manufacturers that produce cigarettes, smokeless tobacco, and roll-your-own-tobacco; 432 produce cigars, pipes and pipe tobacco, waterpipes and water pipe tobacco; 2,514 produce ENDS and e- liquids; and 32 are manufacturers that produce other nicotine delivery systems. We acknowledge that the market for ENDS remains in a state of flux. Larger firms or manufacturers continue to enter this market and may absorb smaller manufacturers and products. Any entry, exit, and consolidation occurring related to the Deeming rule is likely to be considerable, yet is difficult to forecast. The entry or exit of individual products is only loosely related to the number of physical manufacturing establishments. Identifying any trends in entry or exit of manufacturing establishments attributable to this proposed rule is especially difficult to predict and would be highly speculative. However, costs of entry under the proposed rule for new manufacturing locations are likely to be higher than they would be under the baseline. We are uncertain if these higher costs may substantially impact future market trends.[9]

[8] The estimated number of 1,294 domestic ENDS and e-liquids manufacturers reflects tobacco establishment registration counts as of June 2018. This number does not include manufacturers that identified as vape shops when registering with FDA. In the Deeming Final Rule, FDA assumed that ENDS Retailers/Vape Shops would continue to register and list until the compliance deadline for ENDS products to apply for marketing authorization, at which time these establishments were expected to convert to a retail-only business model. If finalized, the compliance date for this proposed rule would be later than the premarket authorization submission deadlines. As a result, we exclude Vape Shops from the count of establishments expected to comply with the requirements of this rule. However, we request comment on the extent to which Vape Shops should be included in this analysis.

[9] PMI Global Trends in Nicotine https://www.smokefreeworld.org/wp-content/uploads/2021/12/Global%20Trends%20in%20Nicotine%20Report%20December%202021.pdf viewed on 2-2-2022.

For purposes of this analysis, we assume small domestic establishments are entities with less than 350 employees.[10, 11] As explained in Section III of this analysis, about 89% of manufacturing establishments have less than 250 employees and about 93% have less than 500 employees. We estimate that 91 percent (the median between 89 and 93 percent) of domestic tobacco manufacturing entities or 1,764 would have less than 350 employees.

We currently do not have information to help define or characterize small tobacco product manufacturers in foreign countries; therefore, the number of small foreign tobacco product manufacturers is estimated using the same fraction (91 percent) used for domestic manufacturers. As illustrated in Table 2, we estimate that 2,984 foreign manufacturers would be considered small (3,273 foreign manufacturers *0.91= 2,984 small foreign manufacturers). We request comment on this estimate.

[10] In Section 900(16) of the FD&C Act, a small tobacco product manufacturer is defined as "a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer." As later referenced in Section III, Economic Census data provides a count of employees per establishment. Therefore, we categorize manufacturers using only the 350-employee threshold here and do not include an analysis of total employment for entities "under common control" with such manufacturers.

[11] We use the terms entities, establishments and manufacturers interchangeably. We also use the U.S. Census definition for an establishment. According to the Census, an establishment is a single physical location at which business is conducted or services or industrial operations are performed. An establishment is not necessarily equivalent to a company or enterprise, which may consist of one or more establishments. A single-unit enterprise owns or operates only one establishment.

Table 2.— Estimated Number of Affected Domestic and Foreign Tobacco Product Manufacturers*

Major Tobacco Group	Domestic Establishments			Foreign Establishments			Total
	<350 Employees	>= 350 Employees	Subtotal Domestic	<350 Employees	>= 350 employees	Subtotal Foreign	
Cigarettes, Cigarette Tobacco, Smokeless and Roll-your-own Tobacco	93	9	102	359	35	394	496
Cigars, pipes and pipe tobacco, waterpipes and waterpipe tobacco	203	20	223	394	38	432	655
ENDS	1,180	114	1,294	2,292	222	2,514	3,809
Other	287	28	315	29	3	32	347
Establishments	1,764	171	**1,935**	2,984	289	**3,273**	5,208

** Columns may not necessarily add up because some manufacturers are associated with more than one major tobacco group.*

2. Baseline Practices

2.1. FDA Inspections Data

For the proposed TPMP regulation, we have estimated the total burden of compliance with the provisions recognizing that many of the provisions of this proposed rule are consistent with quality control and manufacturing practices that have already been voluntarily adopted by a number of manufacturers. Therefore, it is expected that some manufacturer practices would already be aligned with the provisions of this proposed rule. To determine the extent of this baseline alignment, we rely upon a review of inspection reports collected between 2012 and 2015 for registered domestic manufacturing establishments of originally regulated tobacco products

(cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco) and deemed tobacco products.[12]

According to information from FDA inspections, some tobacco product manufacturers produce both originally regulated and deemed tobacco products.[13] Further, data provided by the U.S. Department of the Treasury - Alcohol and Tobacco Tax and Trade Bureau (TTB) regarding the total number of permitted tobacco product manufacturers and importers (excluding ENDS) for 2017 noted that many tobacco product manufacturers and importers were associated with multiple tobacco product categories.[14] For these reasons, we extrapolate the inspection information available to cover all domestic and foreign manufacturers of tobacco products. We request comment on this assumption, including any studies or research on the baseline manufacturing practices of domestic and foreign cigar, pipe and pipe tobacco, waterpipe and waterpipe tobacco, and ENDS manufacturers, and how they may compare to the manufacturing practices of originally regulated products.

FDA's establishment inspection reports for domestic manufacturing establishments include a total of 87 domestic establishments, including 53 establishments that manufacture only finished and bulk tobacco products, 28 establishments that manufacture tobacco products only for further manufacturing (FFM), and six establishments that manufacture both finished tobacco products and

[12] Data from establishment inspections from 2012-2015 is the most comprehensive review available at the time of the analysis, and FDA believes that subsequent reports are consistent with this data.
[13] While FDA did not inspect manufacturing establishments that only manufacture deemed tobacco products during the 2012-15 time period, we inspected manufacturers of originally regulated products who also produced deemed tobacco products at the same establishment.
[14] In the 2017 TTB data, the number of Employer Identification Numbers (EINs) with a tobacco product manufacturing permit when summed across all tobacco product categories (excluding ENDS) is 208, which is greater than the number of total active manufacturers 147). This indicates that some permitted manufacturers produce tobacco products in more than one category. The same is true of permits for importers – 213 permits are held by 184 active tobacco product importers.

FFM tobacco products. The survey consists of inspection data collected over four fiscal years—FY 2012 through FY 2015—for a total of 142 establishment inspection reports (EIRs).

FDA's inspection procedures primarily focus on an establishment's compliance with the provisions of the FD&C Act currently in effect and generally cover the establishment's manufacturing activities and procedures. The inspections do not specifically cover alignment with the proposed TPMP requirements. Collected inspection reports and associated data were reviewed by staff in FDA's Center for Tobacco Products (CTP) to determine whether sufficient information was collected to consider an establishment tentatively in alignment with the provisions of this proposed rule for purposes of establishing a baseline nonalignment estimate for this analysis. Accordingly, the inspection survey data contain information relevant to these proposed TPMP requirements for all registered, domestic establishments of originally regulated tobacco products, both finished and bulk tobacco product manufacturing establishments, and FFM manufacturing establishments.

FDA has inspected a wide variety of domestic tobacco manufacturers (e.g., cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, ENDS) and sizes of manufacturers. Experience with foreign pre-authorization inspections for tobacco products, site visits, facility visits, and listening sessions indicates that the baseline alignment assumptions used for domestic manufacturers (overall, small, and non-small) are generally applicable to foreign manufacturers. Further, FDA has observed on inspections that many different types of tobacco manufacturers employ the International Organization for Standardization (ISO) 9001 standard, which includes a Quality Management System approach that is similar to the requirements of this proposed rule. This standard covers all organizations, both domestic and foreign, and is not industry- or product-

specific. For these reasons, we extrapolate from our understanding of domestic establishments' overall baseline alignment with TPMP provisions to estimate foreign alignment at the baseline.

2.2. Computation of Alignment Estimates

During FY 12-15, FDA inspected a total of 87 tobacco product manufacturing establishments. Approximately 58 (or 67 percent) of the establishments are under the control of small tobacco manufacturers while 29 (or 33 percent) are not. EIRs and inspection documents allow us to estimate baseline practices; that is an estimate of the state of the current tobacco product manufacturing practices before the proposed regulation. The proposed rule would require that tobacco product manufacturers conduct certain activities, establish and maintain procedures for these activities, and keep records related to these activities, if such practices are not already part of their manufacturing practices. To determine the economic impact of the proposed rule, information on baseline practices is coupled with information on the number of entities covered by the rule.

Based on FDA's review of inspections reports and exhibits, baseline alignment for each manufacturing practice (i.e., activity, procedure, or record) was assessed in the following way:[15]

- Yes (Y) is used when the EIR makes explicit in writing that the element is present. When a manufacturer does not make explicit/provide evidence of completing an activity, but the manufacturer's related procedure requires them to take that action, the activity is also marked as "Y." For example, if the baseline question asks whether a manufacturer conducts training for personnel, a "Y" would be entered if the EIR stated that "Training for

[15] In Process (IP) is entered when the EIR explicitly states that the manufacturer is in the process of completing or implementing that activities/procedures/records. For example, if the baseline question asks whether a manufacturer conducts training for personnel, an "IP" would be entered if the EIR stated, "According to management, they do not conduct employee training at this time, however, they are in the process of developing an employee training program". However, this option is rarely selected for the provisions set forth in this proposed regulation.

new employees consists of on-the-job and classroom GMP training," or the manufacturer has a personnel procedure that states, "New personnel would receive on-the-job GMP training for their position."

- No (N) is used when the EIR explicitly states that the manufacturer is not conducting an activity/does not have a procedure/is not keeping a record. For example, if the baseline question asks whether a manufacturer conducts training for personnel, a "N" would be entered if the EIR stated, "According to management, they do not conduct employee training."
- Unknown (UNK) is used when a "Y" or "N" is not made explicit in the EIR. For example, the manufacturer may not have been asked to provide a record, but that does not necessarily mean that the manufacturer does not keep that record. When information about activities/procedures/records is not made explicit in the tagged documents, it is marked as "UNK." "UNK" is also used when no tags were identified for topics associated with a TPMP section.
- Not Applicable (NA) is used when: 1) the provision or baseline question does not apply to a manufacturer or 2) there was no need to provide an answer because the question contained no information to cite.

To account for the uncertainty regarding alignment with the TPMP requirements set forth in the proposed regulation, we computed the following 3 possible alignment rates and estimate likely nonalignment rates using a triangular distribution[16]:

- Minimum alignment rate: $\frac{Y+NA}{Y+N+UNK+NA}$, which assumes "UNK" = "N"

[16] A triangular distribution is a continuous probability distribution with a probability density function shaped like a triangle. It is defined by three values: the minimum value a, the maximum value b, and the peak value c. This is useful in situations where we can often estimate the maximum and minimum values, and the most likely outcome, even if we don't know the mean and standard deviation.

- Most Likely alignment rate: $\frac{Y+NA}{Y+N+NA}$
- Maximum alignment rate: $\frac{Y+NA+UNK}{Y+N+UNK+NA}$, which assumes "UNK" = "Y"
- Estimated nonalignment rate = 1−Triangular Distribution (Minimum, Most Likely, Maximum)

So, for example, if for a certain TPMP requirement there are 4 manufacturers with a "Y" response, 2 with a "N" response, 12 with a "UNK" response, and 1 with a "NA" response, the calculations are as follows:

- Minimum alignment rate: $\frac{4+1}{4+2+12+1} = \frac{5}{19} \cong 26\%$
- Most Likely alignment rate: $\frac{4+1}{4+2+1} = \frac{5}{7} \cong 71\%$
- Maximum alignment rate: $\frac{4+1+12}{4+2+12+1} = \frac{17}{19} \cong 89\%$
- Estimated nonalignment rate = 1−Triangular Distribution (26%, 71%, 89%) = 38%

This exercise is repeated for each provision of the proposed rule by size of operation (also explained in Appendices A and B). As described in greater detail below, we aggregate each provision into subparts to estimate the number of covered entities. The number of covered entities by subpart is equal to the sum of the two products:

1. Estimated nonalignment rate among small manufacturers × total number of small manufacturing establishments.
2. Estimated nonalignment rate among non-small manufacturers × total number of non-small manufacturing establishments.

3. Coverage of the Proposed Regulation

As discussed in section 2.1, this proposed rule would affect an estimated 1,935 domestic and 3,273 foreign tobacco manufacturing establishments. To the extent that a number of these

manufacturing establishments already meet some of the proposed requirements, costs of this proposed rule would be based on the estimated number of establishments that would have to change current practices to align with the proposed requirements. At a minimum, manufacturers who already meet the proposed requirements would incur costs to learn about the rule or to ensure that their practices in fact align with the proposed requirements. Others may find that only a small percentage of their practices align with the proposed requirements and may need to make substantial changes to their operations in order to meet the proposed requirements. While all manufacturers may be affected by this rule, some may be affected more (or less) than others. To obtain an overall snapshot of the extent in which tobacco product manufacturing establishments would be affected by the proposed rule, we calculated the percentage of manufacturers that are not currently aligned with proposed requirements by subpart. Each subpart of the proposed rule is composed of one or more sections and each section is composed of one or more provisions. We averaged the estimated non-alignment rate for each provision to generate an average nonalignment rate by subpart.

We then calculated the number of nonaligned establishments by multiplying the total number of manufacturing establishments by the average nonalignment rate by subpart. Table 3a summarizes our estimates for the average percentage and number of domestic manufacturers that would need to take action to become fully compliant with the proposed rule, if finalized, by subpart and size of operation.[17]

There are two noteworthy points. First, the number of manufacturers that have practices that are aligned with the proposed provisions in each subpart varies. Second, according to baseline

[17] Section 900 of the FD&C Act defines "small tobacco product manufacturers." However, the Small Business Administration's definition of small is applicable to the small entity analysis required under the Regulatory Flexibility Act.

information drawn from FDA inspection reports and exhibits, non-small manufacturers would be more likely than small manufacturers to have formal and comprehensive manufacturing practices in place before the regulation is finalized.

Table 3a.— Estimated Average Nonalignment Percentage and Number of Domestic Manufacturers Affected by the Proposed Regulation, by Subpart and Size of Operation

Subpart of the proposed rule	Small (< 350 Employees)		Non-Small (≥ 350 Employees)	
	1,764		171	
	Average nonalignment %	Number	Average nonalignment %	Number
Learn about the rule	100%	1,764	100%	171
Subpart B	40%	714	13%	23
Subpart C	40%	701	30%	51
Subpart D	73%	1,296	43%	74
Subpart E	43%	752	34%	57
Subpart F	31%	543	27%	46
Subpart G	32%	559	16%	28
Subpart H	65%	1,147	15%	26

Columns are not additive as some manufacturer's practices may not be aligned with more than one subpart.

In estimating the number and percentage characterizing affected foreign manufacturers, we applied the same fractions per subpart used for domestic establishments to foreign manufacturers (Table 3b). For example, of the estimated 2,984 small foreign manufacturers covered by this proposed rule, on average, 40 percent or 1,207 are estimated not to be in alignment with the provisions in subpart B of this proposed rule at baseline and would thus incur costs.

Table 3b.—Estimated Average Nonalignment Percentage and Number of Foreign Manufacturers Affected by the Proposed Regulation, by Subpart and Size of Operation

Subpart of the proposed rule	Small (< 350 Employees)		Non-Small (≥ 350 Employees)	
	2,984		289	
	Average nonalignment %	Number	Average nonalignment %	Number
Learn about the rule	100%	2,984	100%	289
Subpart B	40%	1,207	13%	39
Subpart C	40%	1,185	30%	86
Subpart D	73%	2,191	43%	125
Subpart E	43%	1,272	34%	97
Subpart F	31%	918	27%	77
Subpart G	32%	945	16%	47
Subpart H	65%	1,939	15%	43

Columns are not additive as some manufacturer's practices may not be aligned with more than one subpart.

The estimated total number and average percentage of affected domestic and foreign manufacturers by subpart is illustrated in Table 3c.

Table 3c.— Estimated Average Nonalignment Percentage and Number of Manufacturers Affected by the Proposed Regulation, by Subpart and Size of Operation

Subpart of the proposed rule	Small (< 350 Employees)		Non-Small (≥ 350 Employees)	
	4,775		433	
	Average nonalignment %	Number	Average nonalignment %	Number
Learn about the rule	100%	4,748	100%	459
Subpart B	40%	1,921	13%	62
Subpart C	40%	1,886	30%	136
Subpart D	73%	3,487	43%	199
Subpart E	43%	2,024	34%	154
Subpart F	31%	1,461	27%	123
Subpart G	32%	1,504	16%	75
Subpart H	65%	3,086	15%	69

Columns are not additive as some manufacturer's practices may not be aligned with more than one subpart.

D. Benefits of the Proposed Rule

1. Market Withdrawals and Recalls

Among the estimated benefits of this rule are the avoided external costs associated with conducting recalls. Market withdrawals and recalls are expensive, and commercial distribution of contaminated and otherwise nonconforming tobacco products can result in physical harm to consumers. Implementation of the proposed regulation would likely reduce the number of nonconforming—i.e., adulterated, contaminated, or misbranded—tobacco products distributed to the public, resulting in a potential reduction of the number of recalled or withdrawn products. The manufacturing practices outlined in the proposed regulation would help manufacturers to identify and correct manufacturing deviations or problems, as well as to ensure that tobacco products conform to established specifications before they are released for commercial distribution. Nonconforming tobacco products that are not distributed and used by consumers do not need to be recalled or withdrawn from the market. However, if nonconforming tobacco products are distributed, the records required by the proposed regulation would enable manufacturers and FDA to identify the nonconforming products, determine the root cause and scope of the problem, and take appropriate corrective actions, including recalls and market withdrawals. Product recalls are an important way for manufacturers and regulators to deal with nonconforming tobacco products that are discovered after sales and distribution took place. Conducting a product recall usually consists of a two-part process: 1) the detection of the problem and 2) the actual recall of a nonconforming product. If either of these two processes are not properly conducted, the costs of a recall due to having inadequate or insufficient controls could spill over beyond the owner of the firm conducting the recall. (Refs. R1, R2). Costs of conducting a recall or market withdrawal include lost sales (lost retail value of product), expenses associated with notifying retailers and consumers,

collection and shipping costs, disposal costs, and legal costs, among others. In addition to costs of conducting a recall, aggregate costs include spillover costs to shareholders, competitors, wholesalers, retailers, and customers. (Refs. R1, R2). Because not all members of the supply chain are reimbursed by the manufacturer, this spillover or negative externality associated with the costs of conducting a recall may be larger in the aggregate than the losses to the producer of the recalled product itself. We therefore estimate a reduction in social costs due to reduced recalls as a benefit of this rule. We request comments on this approach.

Prior to the enactment of the Tobacco Control Act, FDA did not regulate tobacco products or have a role in recalls or market withdrawals conducted by tobacco product manufacturers. As a result, FDA does not have a complete historical account of corrective actions taken by tobacco product manufacturers to voluntarily recall or withdraw their nonconforming products from the market. Nevertheless, FDA is aware of numerous voluntary actions undertaken by manufacturers to remove billions of contaminated and otherwise nonconforming tobacco products from the market that may have caused or contributed to user injury or illness both before and after the enactment of the Tobacco Control Act.

Three non-small tobacco manufacturers—Philip Morris, R.J. Reynolds, and Lorillard (prior to being purchased by R.J. Reynolds American)—have previously issued voluntary recalls. In 1995, Philip Morris issued a recall involving 36 cigarette product lines—approximately eight billion cigarettes—because some products had defective filters that had an odor and initial reports indicated that they may "result in temporary discomfort, including eye, nose and throat irritation, dizziness, coughing and wheezing (Ref. R3 and R4). "The President and Chief Executive Officer of Philip Morris at the time estimated that the recall itself "would cost about $100 [million] and

lost sales could cost a further $100 [million]," or about $309 million in 2020 dollars.[18] In 2011, Lorillard voluntarily recalled some Newport Non-Menthol cigarettes because of a discovery that they could contain small pieces of plastic (Ref. R5). And in 2015, R.J. Reynolds's American Snuff Company issued a voluntary recall of some Grizzly and Kodiak moist snuff products because their packaging may have become damaged during the manufacturing process and the product could, as a result, contain pieces of plastic.[19]

Table 4a shows a partial account of recent actions taken by tobacco product manufacturers to recall or withdraw nonconforming products from the market since 2011. Between 2011 and 2019, at least three million cans of smokeless tobacco and 62 million cigarettes have been recalled or withdrawn. The last four recalls in Table 4a include all FDA classified recalls since 2011 revealing that a nontrivial number of nonconforming products may be commercially distributed before a firm informs FDA of the product issue or institutes a voluntary recall. TPMP controls could have directly or indirectly averted the need for these recalls.[20, 21, 22, 23]

[18] The newspaper article discussing the anticipated financial impact of the voluntary recall can be found here: https://industrydocuments.library.ucsf.edu/tobacco/docs/hsjc0036, last accessed May 10, 2016.
[19] The recall notice provided by R.J. Reynolds Tobacco Company can be found here: http://www.eby-brown.com/sites/default/files/u3/American%20Snuff%20Company%20LLC.pdf, last accessed May 10, 2016.
[20] In 2015, a Class II recall of 2,321,100 cans of smokeless tobacco product were recalled due to the presence of small pieces of plastic due to a manufacturing defect. TPMP's production process controls as well as equipment and CAPA requirements could have helped to address or minimize the contamination that resulted in this recall.
[21] In 2017, a Class II recall of approximately 28 million cans of smokeless product were recalled due to the presence of foreign metal objects. TPMP's acceptance activities requirements, which may include metal/optical detectors (which are described in the preamble Section III.E) to identify product contamination, could help identify the presence of foreign metal objects.
[22] In 2018, a market withdrawal of approximately 2.6 million ENDS products was initiated due to complaints about malfunctioning batteries which may cause the power unit to overheat and create a fire risk. TPMP's design and development controls and CAPA requirements could help to address design or manufacturing defects that could result in malfunctioning batteries.
[23] In 2019, a Class II recall of approximately 7,100 100 ml bottles of e-liquid were recalled following consumer complaints and testing that indicated higher than labeled concentration of nicotine. TPMP's production process controls, acceptance activities, and laboratory controls could help to ensure that the concentration of nicotine in e-liquids conforms to established MMR specifications.

Table 4a.— Estimated Retail Value of Recall Actions Taken by Tobacco Product Manufacturers to Recall or Withdraw Nonconforming Products (2011-2019)

Year	Product and units Recalled	Volume Recalled	Retail Value of Recall	Annual value of Recalls (2020 USD)
2011	smokeless (cans)	40,000	$78,000	
2011	smokeless (cans)	143,000	$278,852	
2011	cigarettes	176,640	$39,512	
2011	cigarettes	4,068,000	$909,957	
Sum 2011				$1,306,321
2013	cigarettes	58,044,000	$12,983,669	$12,605,503
2014	smokeless (cans)	750,850	$3,359,103	$3,261,265
2015	smokeless (cans)	2,318,400	$10,371,903	
2015	cigarettes	564,000	$126,159	
2015[1]	smokeless (cans)	2,321,100	$4,526,170	
2015[1]	smokeless (cans)	28,000,000	$54,600,300	
Sum 2015				$69,624,532
2018[1]	Batteries	2,600,000	$26,780,000	$26,780,000
2019[1]	E-liquid (100 ml bottles)	7,105	$87,923	$87,923
Sample Sum - Retail Value Recalled				**$114,141,548**
Sum of retail value of FDA classified recalls				**$85,994,393**

[1] Denotes FDA classified recalls and market withdrawals.

Table 4b shows the steps we use in estimating average costs of recalls and market withdrawals potentially associated with insufficient TPMP controls. We first estimate the annual average retail value and the estimated annual maximum retail value of all recalls and market withdrawals. Of these recalls and market withdrawals, we estimate the total and average annual retail value of voluntarily initiated recalls and market withdrawals handled and classified by FDA since 2011 (lines a through e).

Table 4b.— Calculated Values Used in Estimating Benefits from Avoiding External Costs of Recalls and Market Withdrawals

Calculations	Calculation Description	Value
a	Sample Sum - Retail Value Recalled *(From Table 4a)*	$114,053,625
b = a / 9	Annual average retail value	$12,672,625
c	Annual maximum *(From Table 4a, Sum 2015)*	$69,624,532
d	Sum of retail value of FDA classified recalls *(From Table 4a)*	$85,994,393
e = d / 9	Annual average classified retail value	$9,554,933

*The sum of FDA classified recalls and market withdrawals in Table 4a.

There have also been several smaller-scale cases involving voluntary recalls of e-cigarettes and e-liquids, which suggest that manufacturers of newly deemed tobacco products may not have adequate controls in place to prevent contaminated or otherwise nonconforming product. For an example from a foreign manufacturer, in 2014, Flavour Crafters recalled 5,000 bottles of "Groovy Grape" e-liquid across Canada because a chemical analysis revealed that it contained a chemical linked to a respiratory disease (Ref. R6).

The retail value excluding taxes—in 2020 dollars—of the nonconforming products that were recalled or withdrawn from the market during the time period shown in Table 4a is about $114 million or about $12.7 million per year.[24,25] However, the total cost of conducting a recall or

[24] The average retail price of a pack of 20 cigarettes including federal and state excise taxes, ranged from $4.62 in Missouri to a high of $10.67 in New York, as of November 2017. We use the estimated median price of 7.79 minus the average 44.3% of Federal and State excise tax to arrive at an estimated average price of $4.34 per pack. Average retail prices of a pack of cigarettes and average Federal and State excise tax information for cigarettes can be found here: https://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/index.htm#anchor_1548357749071, last accessed November 22, 2019.
The average retail price of a can of smokeless tobacco used in the analysis is $3.15 (including taxes) can be found here: http://www.nidcr.nih.gov/oralhealth/Topics/SmokelessTobacco/SmokelessTobaccoAGuideforQuitting.htm, last accessed May 10, 2016. We estimate an average price per can without taxes to be $1.89 (3.15-(3.15 x .40)). Average State and Federal tax for smokeless tobacco products and e-cigarette tax estimated at 40% based on average parallel tax rate based on the cigarette tax and the taxable wholesale price of cigarettes versus other tobacco products found at https://www.tobaccofreekids.org/assets/factsheets/0169.pdf, last accessed November 22, 2019.
[25] Also, in 2014, "eGo" voluntarily recalled an e-cigarette kit because the "cut-off device of battery charger fails to work to prevent lithium battery from overcharging…which could cause the device to overheat and explode or catch on fire." See the European Commission's report for more information http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.notification&search_term=A11/0037/14&exclude_search_term=0&search_year=2014, last accessed May 10, 2016.

market withdrawal includes expenses associated with notifying tobacco retailers and consumers, collection and shipping costs, disposal costs, lost sales, among others. The manufacturing controls required by the proposed rule would help to reduce the potential for the production and commercial distribution of nonconforming products which, in turn, would likely reduce the probability that a manufacturer would need to conduct a recall or market withdrawal. Furthermore, the records requirements set forth in the proposed rule may help to reduce the length and scope of potential recalls and market withdrawals. Taken together, FDA expects that the proposed rule would decrease the costs associated with recalled or withdrawn nonconforming tobacco products.

Compliance with a recall affects all members in the supply chain of a tobacco product. While the entities most directly affected by a recall would be the manufacturers of a nonconforming finished tobacco product, wholesalers and retailers also incur costs beyond their foregone sales. In the event of a recall, retailers and wholesalers would need to quickly remove recalled products from their inventory, incurring foregone sales and storage costs for products they can no longer sell. In addition to inventory removal costs, retailers would incur additional costs in dealing firsthand with customers with questions about refunds. If retailers can not properly handle a recall, they risk incurring civil penalties or increasing risks to their customers, which could lead to reputational harms. In addition to potential health-related costs, it is possible that customers would also incur costs by having to throw away the product and would need to deal with retailers or manufacturers about refunds or replacements. Depending on the nature of a recall, retailers may choose to withdraw similar products from competing manufacturers or complementary products because of perceived risks associated with the recalled product. In other situations, retailers may choose to withdraw all products from a single manufacturer beyond the recalled product. Both situations are sometimes referred to as conducting a "shelf sweep" which retailers sometimes do

to protect their brand and reputation. Depending on existing contractual relationships between manufacturers and retailers, some of these costs may be partially or wholly reimbursed by the recalling manufacturer. Thus, total costs of recalls to wholesalers and retailers would include a portion of the forgone retail value of the recalled and withdrawn products plus other costs associated with conducting recalls. The general assumption is that direct costs would fall mostly on the manufacturer rather than the wholesaler or retailer.[26] Retailers on the other hand, may incur significant indirect costs in the administration of a recall.[27] We consider the costs of recalls to a recalling manufacturer (including reimbursement costs paid to retailers) to be private costs and the costs of recalls to manufacturers of competing and complementary products, along with any *unreimbursed* costs to wholesalers, retailers and consumers to be external costs.[28]

To estimate manufacturers, wholesalers', and retailers' private costs of conducting recalls, we first estimate the costs of recorded recalls of tobacco products and assign the estimated proportion of costs to be the same as the estimated revenue share corresponding to manufacturers, wholesalers, and retailers of finished tobacco products.

[26] Manpreet Hora, Hari Bapuji, Aleda V. Roth, Safety hazard and time to recall: The role of recall strategy, product defect type, and supply chain player in the U.S. toy industry, Journal of Operations Management, Volume 29, Issues 7–8, 2011, Pages 766-777, ISSN 0272-6963, https://doi.org/10.1016/j.jom.2011.06.006

[27] John Z. Ni, Barbara B. Flynn, F. Robert Jacobs, Impact of product recall announcements on retailers′ financial value, International Journal of Production Economics, Volume 153, 2014, Pages 309-322, ISSN 0925-5273, https://doi.org/10.1016/j.ijpe.2014.03.014.

[28] We consider costs to manufacturers to be private costs because well-established, profit-maximizing tobacco product manufacturers may be able to consider in their decisions the costs associated with recalling a nonconforming tobacco product beyond the value of recalled units, to include expenses associated with notifying tobacco retailers and consumers, collection, shipping, disposal and legal costs. However, from Jarrell and Peltzman any recall, regardless of size, is followed by industry-wide asset loss. Their findings "help shed light on the degree to which the capital market might sub optimally deter production of faulty products," and show that large costs exist in cross-company effects (Ref. R2).

We estimate that the manufacturer's portion of the retail value (excluding taxes) to be approximately 68% of the total retail value of cigarettes (excluding taxes) in the U.S. market.[29]

Of the remaining 32% of total retail value (excluding taxes) attributable to both wholesalers and retailers, we estimate approximately 11% corresponds to wholesalers and approximately 22% to retailers.[30] In addition to the estimated value of recalled product, recalls also impose "spillover" costs on competing manufacturers of non-recalled products, in the form of financial losses and reputational harm, among others. Further discussion of "spillover" costs can be found in Appendix D. To estimate the percent external cost share of recalls for manufacturers, wholesalers, and retailers, we apply the estimated percent range for the share of external recall costs by sector using data from the FDA's Requirements for Additional Traceability Records for Certain Foods (Final Rule) Regulatory Impact Analysis (hereinafter referred to as the Food Traceability Rule RIA)[31], as a proxy to estimate the percent share of external recall costs (Ref. R7). We estimate the middle percentage for external cost share by revenue share and by sector (column c, Table 4c) as the product of both columns (a) Percent Revenue Share for cigarette products and (b) Percent External Cost Share from the Food Traceability Rule RIA. We addressed inherent uncertainty and variability in the Percent External Cost Share (column b, Table 4c) using Monte Carlo simulations.

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[29] This percentage is derived from the price breakdown for a pack of a prominent brand of cigarettes with a 20% share of retail value corresponding to manufacturer operating profit, 18% to components, 4% to "other," 17% to both wholesaler and retailer markup and 42% share of the retail value corresponding to State and Federal Excise tax. The estimated percentage of the manufacturer operating profit over sales without taxes is about 34% = 20% ÷ (100% - 42%)], components 31% =[18% ÷ (100% - 42%)] and other 7% [4% ÷ (100% - 42%)] . We assume that the estimated 7% category for other is divided equally between wholesaler and retailers. We further estimate manufacturers share of total retail value as 68% [(34% profit share + 31% components + (7% other x 50%). We also estimate the share of both wholesaler and retailer markup without taxes is 32% =[17% ÷ (100% - 42%)+ (7% other x 50%)]. *Against All Odds, the U.S. Tobacco Industry Is Rolling in Money,* Wall Street Journal - April 23, 2017, https://www.wsj.com/articles/u-s-tobacco-industry-rebounds-from-its-near-death-experience-1492968698.

[30] We estimate the percent markup share for wholesalers as 11% = (32% x 33%) and retailers as 22% = (32% x 67%). The percentage markup between retailers (33%) and wholesalers (66%) is estimated using information from "Total Cigarette Markup Across Standard Distribution Chain in Pricing States 2015) https://tobacconomics.org/research/total-cigarette-markup-across-standard-distribution-chain-in-pricing-states-2015/

[31] (87 FR 70910, November 21, 2022)

A more detailed discussion and rationale behind these calculations, as well as the full range of estimates and simulation results, can also be found in Appendix D. The central estimates displayed in column (c) of Table 4c are also used in Table 5a to illustrate the estimated value of external recall costs in columns (B), (C) and (D).

Table 4c.— Estimated Share of Internal and External Recall Costs Across Standard Tobacco Distribution Chain (Middle Estimate)

Sector	Percentage of Revenue Share (a)	Percent External Cost Share (b)	Percent External Cost Share by Revenue Share and by Sector (c) = (a) x (b)
Manufacturer Share	68%	51%	34%
Wholesaler Share	11%	5%	0.6%
Retailer Share	22%	6%	1.4%

In the event of a recall or market withdrawal for an imported product, we assume the recall will be initiated by the domestic importer and, thus, depending on existing contracts, a portion of all associated costs of conducting a recall or market withdrawal due to a foreign manufacturer defect would fall on the importer.[32] We request comment on this assumption.

We estimate benefits of this rule as the avoided external cost of recalls. We estimate a range of potential external costs as the cumulative percentage of total potential recall costs not internalized by the recalling manufacturer (costs to competing manufacturers of non-recalled products and uncompensated losses to wholesalers and retailers). In Table 5, we estimate benefits from avoided recalls and market withdrawals due to the implementation of TPMPs using the percent external cost shares by revenue and by sector from Table 4c.

[32] Some importers are also manufacturers and may initiate recalls. However, some importers may also be wholesalers who typically wouldn't initiate a recall.

Table 5a.— Calculations for Low, Middle, and High Benefits Estimates from Avoided Recalls and Market Withdrawals, 2011-2019 (2020 U.S. Dollars, using GMA fraction)*

Calculation	Calculation Description		(A) Value	Percent External Cost Share by Revenue Share by Sector			(E) External Costs due to Recalls or Market Withdrawals = B + C + D
				(B) Manufacturing Share = A x (34%)	(C) Wholesaler Share = A x (0.6%)	(D) Retailer Share = A x (1.4%)	
f	Retail value of tobacco products sold by sector in U.S.		$128,474,990,000	$369,522,489	$712,234,061	$1,772,218,847	$46,646,149,172
g	Fraction of recall costs over retail value per sector		**0.29%**				
h= f x g	Annual costs of tobacco recalls per sector		$369,522,489	$127,018,807	$2,048,543	$5,097,293	$134,164,643
i = h / c	Multipliers for estimating other recall associated costs	*low*	**5**				
j = k - ((k-i)/2)		*middle*	**17**				
k = h / b		*high*	**29**				
e	Annual average classified retail value from Table 4b		$9,554,933	$3,284,390	$52,970	$131,803	$3,469,164
l = e x i	**Estimated Annual Costs of FDA classified recalls from TPMP**	***low***	**$50,711,471**	**$17,431,444**	**$281,132**	**$699,528**	**$18,412,104**
m = e x j		***middle***	**$164,555,101**	**$56,563,790**	**$912,253**	**$2,269,918**	**$59,745,962**
n = e x k		***high***	**$278,398,732**	**$95,696,137**	**$1,543,375**	**$3,840,308**	**$101,079,819**

*This table presents an example calculation using the GMA fraction. See Tables 6 through 10 in Appendix D for additional calculations using a range of 50% and 150% of the GMA fraction and the full range of results.

In order to account for other recall associated costs beyond the retail value of recalled products and due to FDA's limited record of tobacco product recalls and market withdrawals, we extrapolate from food manufacturers' recall costs as a proportion of annual revenues to estimate total recall costs incurred by tobacco manufacturers (line g in Table 5a) (Refs. R2, R8, R9, R10, R11, R12, R13, R14, R15).[33,34] The general steps for processing food and tobacco products share certain similarities. For example, cigarette, cigar, and roll-your-own-tobacco processors and food manufacturers may have comparable manufacturing processes because these tobacco products, like many food products, are agricultural products that are grown and harvested and distributed as ingredients for further processing and refinement including heat and moisture treatment before final processing and packaging. We request comments on this approach.

Table 5a does not show the full simulated range of estimated benefits from avoiding recalls taking into account variability and uncertainty around two key cost components, specifically the GMA fraction (line g) and the potential share of manufacturers' private costs (percentage in Column B). While Table 5b shows the full simulated range of estimated benefits from avoiding recalls taking into account variability and uncertainty around two key cost components, we use

[33] As stated in Jarrell and Peltzman (Ref. R2), recalls, regardless of their size or who initiated them, are generally followed by industry wide asset losses and that the capital market penalizes producers (whose costs are internalized) and their competitors of recalled products (whose costs are external) more than direct costs of recalls. While we are unable to extrapolate the estimated social losses from this paper and apply to this analysis, the authors state: "The capital market effects seem so great that they may exceed a plausible independent estimate of the relevant social costs".

[34] We use data on recall costs among a sample of 36 food manufacturers from a 2011 study from Grocery Manufacturers Association -GMA (Ref 4). From page 4 in the GMA study we estimate an average of 2.16 recalls in the past 5 years at an average cost per recall of $25.8 million (page 3). Over a five-year period, the product of the average 2.16 recalls in 5 years x $25.8 million x 36 manufacturers represents approximately $2,005 million USD lost to recalls by the whole sample or $400 million USD in lost recalls by the whole sample per year. To characterize uncertainty, we estimate the GMA sample's recall costs as a fraction of sales (revenues) of 0.0029 with a lower bound estimate of 50% and an upper bound estimate of 150% of the GMA fraction or approximately 0.0014 and 0.0043 respectively. We characterize the range as a triangular distribution to characterize the variability about our uncertainty about how this estimate affects recall costs. (Refs. R8-15). We then multiply this proportion by tobacco manufacturers' annual revenue of $128 billion from 2018 Euromonitor International data for the US Market to obtain an estimate of total recall costs of $370 million ≈ 0.0029 x $128 billion).

Table 5a to show the steps in our calculations using single point estimates of the mean expected values for Column A. We estimate that tobacco manufacturers that sell within the U.S. incur recall costs of approximately $370 million per year (line h which is the product of line g and line f of revenues of roughly $128 billion, based on available 2018 market data). Of the approximately $370 million per year in estimated tobacco recalls, we calculate a range of costs that could have potentially been averted if manufacturers followed TPMP. To partially address variability and/or uncertainty, we estimate three multipliers (lines i, j, and k) to account for the total value of recall-associated costs that would occur in addition to the retail value of recalled products. Our low multiplier of 5 (line i) is the result of dividing $370 million (line h) by annual maximum retail value of recalls of $69.6 million (line c, Table 4b). Our high multiplier of 29 (line k) is the result of dividing $370 million (line h) by the average annual retail value of $12.7 million (line b in Table 4b). The middle estimate of 17 (line j) is the median between 5 (line i) and 29 (line k).

The mean range of benefits of avoided recalls avoided under TPMP are calculated as the product of the annual average classified retail value (line e) and each estimated multiplier to account for other recall associated costs (i, j, and k).

We estimate the mean external domestic undiscounted costs of conducting recalls and market withdrawals may fall by between $18 and $101 million per year (Table 5a) lines l, m, and n in column E). We multiply the values in Column A by 34% to make Column B which also represents manufacturers estimated share of external recall costs (the 34% estimate is explained in more detail in Appendix D). Columns C and D represent the percent external costs share to wholesalers and retailers. We estimate benefits of this rule as the external costs of recalls that could be avoided by

adding columns B, C and D into column E. Mean undiscounted benefits from avoided recalls in Column E would range between $18 million to $101 million per year.

We are uncertain about whether these estimates would include potential avoided or mitigated losses to capital markets (manufacturers shareholders or shareholders of manufacturers of competing and complementary tobacco products) and we request comments on this topic.

Table 5a shows the full simulated range of estimated benefits from avoiding recalls taking into account variability and uncertainty around two key cost components, specifically the GMA fraction (line g, Table 5a) and the potential percentage share of external costs by revenue share and by sector (column c, Table 4c). We characterize variability about our uncertainty using probabilistic techniques representing the GMA fraction of 0.29% (line g) as a triangular distribution with parameter estimates 0.15%, and 0.42% representing the lower and upper bound around 0.29%. To approximate the share of external costs associated with a recall across the supply chain, we use information on external costs of recalls from the Food Traceability Rule RIA (Ref. R7). In the Food Traceability Rule RIA, we estimated the benefits from avoiding overly broad recalls by estimating the forgone external costs associated with conducting a recall when following an FDA advisory. We use the estimated share of external recall costs applied to food industry sectors covered under the traceability rule as a proxy to estimate the share of external recall costs incurred by tobacco industry sectors affected under the TPMP proposed rule. Appendix D provides a more detailed explanation of this methodology and these results.

Due to the overlap between the Minimum, Mean and Maximum (columns) across the Low, Middle and High results in rows, we use as a primary estimate the Middle/Mean of $60 million with $4 million (Min/Low) and $164 million as the lower and upper bound estimates respectively. Full simulation results can be found in Appendix D. We request comment on these assumptions

and estimates, including any information/data/research on additional tobacco product recalls and external recall costs.

Table 5b.— Simulation Results for Potential Low, Middle and High External Cost Estimates due to Recalls or Market Withdrawals (Full Range of Results for Table 5, Column E)

Simulated Calculation Range*		Range	Minimum	Mean	Maximum
Column E, Row l	Simulated Range of Annual Social Benefits from TPMP Implementation	**Low**	**$4,230,726**	$18,383,910	$38,758,660
Column E, Row m		**Middle**	$13,728,400	**$59,654,480**	$125,769,100
Column E, Row n		**High**	$23,226,080	$100,925,100	**$212,779,500**

* Simulated Calculation Range taken from model results corresponding to Table 5b, Column E, rows l, m, and n. See Appendix D for more detail.

2. Potential for Reduction in Adverse Events Associated with Adulterated, Contaminated, or Misbranded Tobacco Products

An assessment of the public health benefit of the proposed rule is complicated by the inherently harmful and deadly nature of tobacco product consumption. Tobacco use causes mortality attributable to many diseases including cancer, cardiovascular disease, respiratory disease, and perinatal conditions (Ref. R16). In the case of cigarettes, at least 250 of the 7,000 chemicals in tobacco smoke are known to be harmful to human health, including hydrogen cyanide, carbon monoxide, and ammonia (Ref. R17). However, as in the cases discussed above suggest, other hazards not normally associated with tobacco products could increase the health risk of tobacco product consumption. Additional examples include:

- A review of the literature investigating the question of whether lung inflammation is associated with microbes and microbial toxins in cigarette tobacco smoke concluded

that "microbial elements may pose an additional and previously unidentified health risk to the smoker (Ref. R18)."

- Another study analyzed samples of a product of the R.J. Reynolds Tobacco Company marketed under the name Eclipse and found that the filters were contaminated with glass fibers and glass dust, concluding that contamination of Eclipse filters with glass fibers and glass dust poses a potential and unnecessary health hazard to uninformed consumers (Ref. R19)."

The controls required by the proposed rule aim to ensure, among other things, that filthy, putrid, decomposed, poisonous, or otherwise harmful substances are not added or incorporated into tobacco products during the manufacturing process.

Information about the health risk of certain tobacco products is, in part, communicated to the user through required warnings on tobacco product packaging. The packaging and labeling controls in the proposed rule would help to ensure that required warnings regarding the risk of tobacco use are communicated to consumers, adherence to approved warning plans, as applicable, and that packaging and labeling operations protect against the adulteration and misbranding of tobacco products. If a mislabeled tobacco product is commercially distributed, it is possible that consumption of such a product could cause unexpected harm to the user.

A potential benefit of this proposed rule is a decrease in the incidence of injuries and illnesses caused by tobacco products that are adulterated or misbranded. For example, studies have shown that the actual nicotine concentration level in e-liquids can vary from its labeled nicotine concentration level. One 2017 study analyzed brands of refill liquids that dominate the market and found that the difference between the nicotine content and the labeled nicotine value ranged from negative 8 percent to 30 percent (–8% to +30%) (Ref. R20). The manufacturing controls

established by this proposed rule—such as those outlined in sections covering personnel, buildings, facilities, and equipment, acceptance activities, and process controls—can help a manufacturer identify and minimize or prevent the adulteration or misbranding of tobacco products. When adulterated or misbranded tobacco products are commercially distributed and consumed, use of such a product may result in injury and illness and the consumer may also file a complaint with the manufacturer and/or report an adverse event to FDA or a poison control center.[35]

FDA has observed during inspections of tobacco product manufacturers that many manufacturers receive complaints every year that relate to adulteration, misbranding, or user illness or injury. For example, complaints may relate to nonconforming product such as incorrectly packaged or mislabeled tobacco products, irregular and improper burning of cigarettes, or brand or flavor mix-ups. Examples of other potential contamination or adulteration issues include finding non-tobacco related materials such as glass or hard plastics in a tobacco product, mold in the tobacco product, experienced chemical tastes, and tobacco beetles or other type of insect infestation. Tobacco product manufacturers have also received complaints alleging personal injury and property damage from tobacco product-related materials, fires, and explosions.

A tobacco product manufacturer may also become aware of nonconforming products through complaints. Under the proposed requirements, a complaint that could be related to a nonconforming product, a product design issue, or a reportable adverse experience must be investigated to determine its scope and cause, the risk of illness or injury, and whether any follow-

[35] For example, in 2019 a manufacturer recalled more than 7,000 bottles of e-liquid product that contained a higher concentration of nicotine than the label indicated due to inadequate manufacturing controls that could cause immediate and potentially serious adverse health effects. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/drip-more-lp-voluntarily-recalls-four-lots-candy-king-worms-3-mg-100-ml-due-elevated-nicotine#recall-announcement.

up action is necessary, including a corrective and preventative action (CAPA). If a manufacturer determines that a CAPA is necessary, it must investigate the cause of the nonconformity and take appropriate action to correct and prevent recurrence of nonconformities, which may include a recall or reassessment of the product's design under its design and development activities.

For example, if an ENDS manufacturer becomes aware of complaints regarding batteries in its ENDS product, it must perform an investigation to determine if the issue is related to a nonconformity or design problem. If the issue relates to a nonconforming battery, the manufacturer would be required to initiate a CAPA to investigate the cause of the nonconformity and take appropriate action, which can include a recall and change of battery supplier or redesign of the battery.

The proposed TPMP requirements would address nonconforming tobacco products by requiring the investigation of all potential nonconforming tobacco products, and for products that are nonconforming, a determination of the scope and cause of the nonconformity and the risk of illness or injury it poses. This would help a manufacturer identify the scope of nonconforming products and take appropriate corrective action, such as preventing its distribution or facilitating its reprocessing or rework.

FDA receives voluntary reports of adverse events through its Safety Reporting Portal. These include reports of personal injuries from product malfunctions such as exploding e-cigarette batteries, as well as serious adverse events such as acute toxicity poisoning from e-liquids and allergic reactions to tobacco products.

As discussed in greater detail below, we lack information that would allow us to draw a concrete link from deviations from manufacturer-established specifications that occur during manufacturing operations to any adverse events that are experienced by users of such products.

It is difficult to assess the potential health and economic impacts of the proposed rule because we are unable to determine the total number of adverse events that are directly attributable to inadequate manufacturing controls. FDA inspections data provide us with a measure of the fraction of tobacco manufacturers that have inadequate manufacturing controls. However, to be able to estimate the health and economic effects of adverse events associated with inadequate manufacturing controls, we need to know the fraction of nonconforming tobacco products that are released for commercial distribution. This percentage is likely to vary widely by type of tobacco product manufacturer and size of operation.

Note that, even if we knew the fraction of nonconforming tobacco products that are released for commercial distribution, it is difficult for consumers to separate symptoms that are brought on by a contaminated tobacco product from those that are brought on by a non-contaminated tobacco product. The symptoms produced from smoking a cigarette containing a potentially harmful foreign object may not appear to a smoker as a special cause for concern, even if those symptoms are not normally associated with consumer the tobacco product. That is, in this example, a smoker of contaminated and non-contaminated tobacco products may not be able to link specific symptoms to the consumption of contaminated tobacco products, which is why we are unable to measure the effects of consuming contaminated tobacco products. Due to the health effects normally associated with consumption of tobacco products, many adverse events associated with consumption of contaminated tobacco products are likely to go unnoticed and unreported.

Below, Figure 1 further illustrates the data deficiency by showing a very simple representation of tobacco product manufacturing and commercial distribution. Although we can consult surveillance systems that track adverse events associated with tobacco product consumption, without knowing the parameters δ, β_1, or β_2, it is difficult to know how many adverse events

observed are directly attributable to tobacco products that were produced in manufacturing facilities that had inadequate TPMP. For this reason, we expect that the proposed regulation would minimize the likelihood of the manufacture and distribution of nonconforming tobacco products, which would in turn reduce the number of adverse events attributable to additional harms not normally associated with tobacco consumption, e.g., risks associated with nonconforming batteries in electronic cigarettes and product hazards such as mycotoxin contamination.

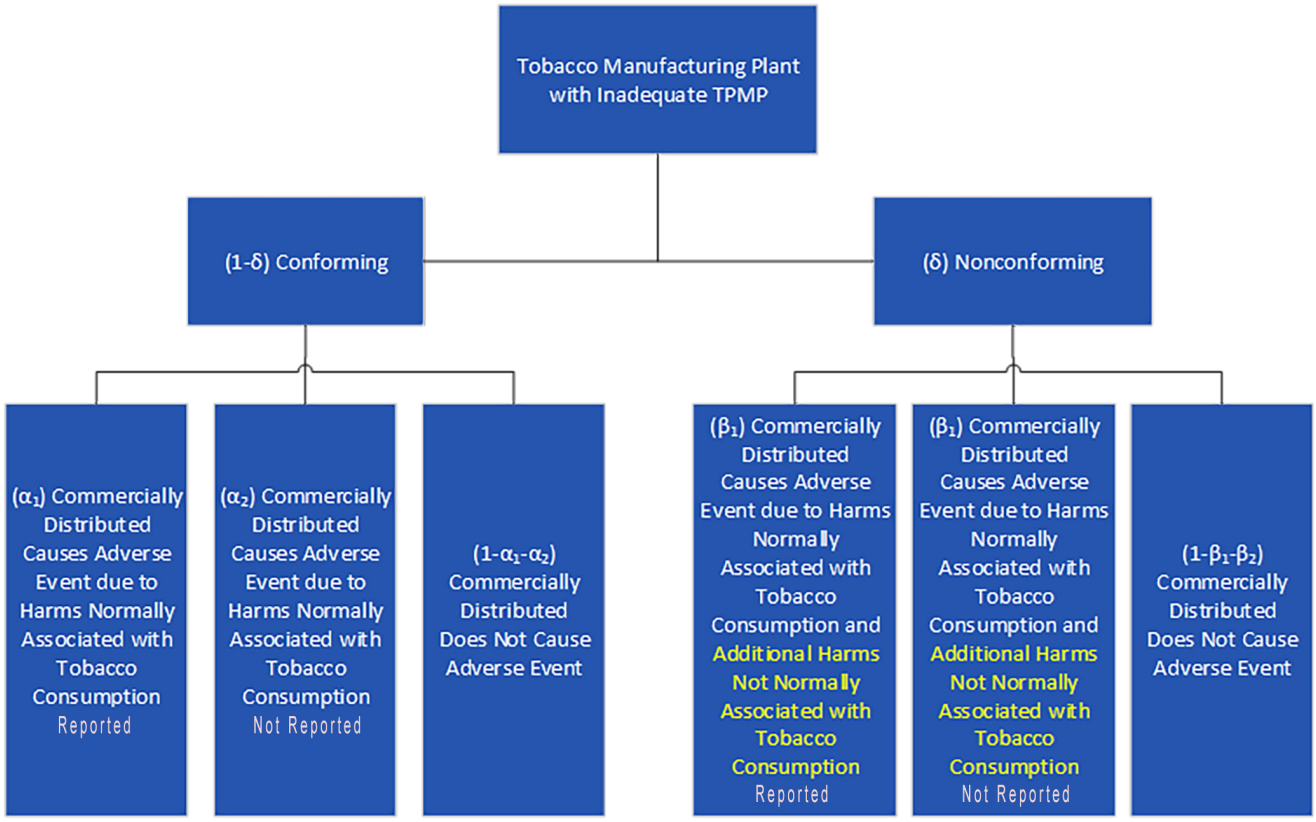

Figure 1.

To shed light on the potential health benefits of the TPMP proposed rule, we analyzed data on the number of calls to U.S. poison control centers (PCs) that were attributed to exposure to

possibly contaminated tobacco products.[36] These data were drawn from the National Poison Data System (NPDS), which is owned and managed by the American Association of Poison Control Centers (AAPCC). The NPDS provides information on human exposure calls to PCs across the U.S. and its territories. Since its inception in 1983, the NPDS has collected information on more than 57 million human poison exposure cases related to a broad spectrum of products, with more than two million records added annually (Ref. R21).

Telephone calls received at U.S. PCs are managed by healthcare professionals. These Specialists in Poison Information (SPIs)—primarily registered nurses, Doctors of Pharmacy, and pharmacists—have received specialized training in toxicology and managing exposure emergencies. Additionally, PCs use follow-up calls to monitor case progress and medical outcome. Information is recorded for each call received by a PC, including fields such as "reason for exposure" and "medical outcome of exposure."

During 2001-2017, there were 159,416 exposure calls involving tobacco products.[37,38] Of these, 434 exposure calls were identified as being possibly associated with "contamination" or "tampering" or both.[39] SPIs coded "contamination/tampering" as the reason of exposure if the patient was deemed to be an "unintentional victim of a substance that has been adulterated (either

[36] Such exposure calls represent a subset of reported adverse events associated with consumption of a potentially contaminated tobacco product, which is β_1 or the fraction of nonconforming product that cause an adverse event and are reported to surveillance systems in Figure 1.

[37] The number for 159,416 tobacco exposure calls is the sum of calls reported in each NPDS annual report beginning with the 2001 annual report to the most recent 2017 annual report (Ref. R21).

[38] Other sources have also recorded adverse events associated with possibly adulterated or misbranded/mislabeled tobacco products (e.g., FDA FACTS Consumer Complaint Reports, FDA MedWatch, FDA Safety Reporting Portal, U.S. Consumer Product Safety Commission, Center for Tobacco Products (CTP) Ombudsman, CTP Call Center, and News Reports). Between 2009 and the first half of 2014, we calculated that there were 168 adverse events recorded by these sources, averaging 28 per year over this period. Out of the 168 adverse events, 57 were categorized as serious: 6 of these adverse events resulted in deaths and 26 resulted in hospitalizations. We are unable to determine whether a subset of these adverse events is also reported to Poison Control Centers.

[39] Note that "contamination/tampering" as a reason for human exposure cases is low in general, not only for human exposure cases involving tobacco products. For example, Table 6a of the NPDS Annual Reports from 2001 through 2017 show that on average of the 2001-2017 total number of human exposure cases only 0.3% were associated with "contamination/tampering".

maliciously or unintentionally) by the introduction of an undesirable substance".[40] Illnesses or injuries associated with the consumption of contaminated tobacco products are likely to be under-reported because of difficulty with diagnosis, incomplete reporting to poison control centers, or symptoms not being recognized as a poisoning.[41] Another explanation for under reporting is that not everyone knows or chooses to call a poison control center when experiencing a poison event.[42] A 2012 Poison Help Campaign Report to Congress by the U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA) found that 30% of people who were looking for help or information to manage poisoning events called a poison control center. Other respondents reported using resources such as hospitals emergency rooms, health care professionals, 911, product labels or manufacturers, etc.[43] We are not aware of peer-reviewed research on the under-reporting rate of adverse events with, or reactions to, contaminated tobacco products. We assume that our estimate of tobacco exposures associated with contamination or tampering account for only 10 percent of the actual number, which is based on the literature on under-reported adverse drug reactions (Ref. R22).[44] More specifically, to correct for likely under-reporting in exposure calls due to contaminated tobacco products, we multiply our estimate of

[40] Exposure calls that involved more than one consumer product (often cigarette + alcohol) with tobacco ranked as the primary or #1 product were included. We acknowledge that the NPDS data for calls related to "contamination" or "tampering" has limitations including data deficiencies such as (1) when, where, and how the contamination occurred; (2) whether the contamination occurred during the manufacturing process; and (3) whether the contamination was accidental or intentional.

[41] This is due, in part, to the inherent nature of the tobacco products which carry a normally associated risk profile. Certain adverse events may not be recognized because of the normally occurring baseline risk. For example, a contaminate in the tobacco product that causes acute respiratory distress and coughing or wheezing may not be separated from the respiratory distress and coughing or wheezing that may occur from chronic use of the product.

[42] There are many reasons why a person may choose to report or not report an adverse event. The reasons may include but are not limited to lethargy. https://pubmed.ncbi.nlm.nih.gov/19132802/. However, the actual number of reports related to a non-conforming product issue would only be a fraction of any of the reasons a person may choose to report or otherwise.

[43] From https://poisonhelp.hrsa.gov/sites/default/files/poisonhelp/about-us/2012-ph-report-to-congress.pdf, Figure 1 page 17 (viewed on June 13, 2019).

[44] A 2006 review article finds that the under-reporting rate of adverse drug reactions (ADRs)—defined as the percentage of known, suspected, or expected ADRs that were not reported to the relevant reporting systems for a population and time period similar to those in the study—is likely over 90% (Ref. R22).

tobacco exposures associated with contamination or tampering by ten (10) to arrive at adjusted counts. We request comment on this method of adjusting for under-reporting. Table 6 shows the estimated number of observed exposure calls associated with contamination of tobacco products, as well as the adjusted numbers by year.

Table 6.— Exposure Calls Associated with Contaminated Tobacco Products, by Year

Year	Tobacco Exposure Calls	Calculated % of Total Exposures Associated with Contamination or Tampering*	Tobacco Exposures Associated with Contamination or Tampering	Exposures (Adjusted for under-reporting)
2001	7,710	0.24%	18.82	188
2002	7,866	0.22%	17.64	176
2003	7,806	0.20%	15.57	156
2004	7,671	0.19%	14.44	144
2005	7,398	0.21%	15.18	152
2006	6,883	0.24%	16.24	162
2007	7,453	0.27%	20.36	204
2008	8,069	0.22%	17.89	179
2009	8,457	0.24%	20.35	203
2010	8,500	0.34%	29.19	292
2011	8,276	0.27%	22.01	220
2012	8,804	0.28%	24.53	245
2013	10,179	0.32%	32.78	328
2014	13,252	0.35%	45.73	457
2015	14,649	0.34%	50.21	502
2016	13,319	0.36%	47.47	475
2017	13,124	0.34%	45.06	451
Total	159,416	0.27%	434.22	4,535

Source: American Association of Poison Control Centers' National Poison Data System.

* Percent of Total Associated with Contamination or Tampering = Number of Human Exposure Cases where the reasons are listed as "Contamination / Tampering" divided by Number of Total Human Exposure Cases, e.g., 2017 (Ref 20, Table 6A) 0.3% = 7,262 ÷ 2,115,186.

Of the 159,416 exposure calls from 2001-2017 involving tobacco products for which information on the medical outcome of exposure is available:

- 33 percent reported no effect (i.e., the patients did not develop any signs or symptoms as a result of the exposure).
- 21 percent reported a minor effect (i.e., the patient developed some signs or symptoms as a result of the exposure, but they were minimally bothersome and generally resolved rapidly with no residual disability or disfigurement); and
- 2 percent reported a moderate effect (i.e., the patient exhibited signs or symptoms as a result of the exposure that were more pronounced, more prolonged, or more systemic in nature than minor symptoms).

We estimate the number of clinical effects from associated exposure calls for 2001 through 2017 by extrapolating the clinical effects estimated from epidemiological trends in electronic cigarette exposures from Vakkalanka, et al, (2014) in which the authors characterize the trends in e-cigarette exposures to users of all ages reported to U.S. Poison Centers between June 1, 2010 and September 30, 2013 (Ref. R23); from Chatham, et al (2016) on characterizing exposures calls involving electronic cigarettes and conventional cigarettes using NPDS data between September 2010 and December 2014 (Ref. R24); Wang, et al (2017) on tobacco related poison events in young children using NPDS data for the years 2001 to 2016 (Ref. R25) and from a study from Kamboj, et al, (2016) in which the authors, using NPDS data from January 2012 through April 2015 to characterize clinical effects from pediatric exposures to different types of tobacco products (Ref. R26). Table 7 shows the list of estimated reported clinical effects associated with the 2001-2017

exposure calls.[45] As with the number of exposure calls, we multiply the number of reports by ten to account for the likely under-reporting associated with PC data. The most frequently reported clinical effects include vomiting, nausea, dizziness/vertigo, throat irritation, abdominal pain, and headache.

Table 7.— List of Reported Clinical Effects and Adjusted, Extrapolated Number of Reports, 2001-2017

Clinical Effect	*Type of Illness*	*Number of Reports (Adjusted, Extrapolated)*
Vomiting	Gastrointestinal	979
Nausea	Gastrointestinal	53
Abdominal pain	Gastrointestinal	9
Diarrhea	Gastrointestinal	8
Cough or choke	Respiratory	98
Dyspnea	Respiratory	5
Eye irritation or pain	Other	88
Drowsiness/lethargy	Other	78
Other	Other	54
Oral irritation	Other	53

[45] We estimated clinical effects for 159,416 exposure calls to the AAPCC between January 1, 2001 to December 31, 2017 by extrapolating from N=1700 calls and 1381 clinical effects between June 11, 2010 and September 30, 2013 from Table 6 in Vakkalanka (2014); N=123,876 calls involving young children with clinical effects during the years 2001 -2016 from Table 3 in Wang (2017); N= 27,076 calls reporting clinical effects from September 2010 through December 2014 from Table 4 in Chatham (2016) and N=29,141 calls to the AAPCC and 21,288 clinical effects between January 2012 through April 2015 from Table 3 in Kamboj, et al (2016). In all studies one exposure call may be associated with more than one clinical effect.

Clinical Effect	*Type of Illness*	*Number of Reports (Adjusted, Extrapolated)*
Agitated or irritable	Other	50
Red eye/conjunctivitis	Other	47
Pallor	Other	42
Tachycardia	Other	26
Ocular irritation or pain	Other	24
Dizziness/vertigo	Other	22
Diaphoresis	Other	17
Headache	Other	16
Irritation/pain	Other	14
Throat irritation	Other	9
Ataxia	Other	7
Tremor	Other	7
Erythema/flushed	Other	7
Chest pain (noncardiac)	Other	7
Blurred vision	Other	6
Dermal–irritation/pain	Other	6
Total		***1,732***

Source: American Association of Poison Control Centers' National Poison Data System.

Since Table 6 shows an apparent trend of increasing exposure calls, and therefore health losses over the observed 2001-2017 time period, we use a simple linear regression to project baseline clinical effects over the time period of the analysis (2021-2030). We use the ratio of the future period's (2021-2030) projected yearly average exposure calls over the historical rate as a multiplier of 1.69 on historical clinical effects, which we assume continue to occur in the same proportions. We request comments about the range of years used in estimating a trend for the extrapolation.

To quantify the potential health benefits associated with the proposed rule, we calculate the reduction in quality-adjusted life days (QALD) caused by exposures to contaminated tobacco products and then monetize the health losses.[46] Quality-adjusted life years (QALYs) are a measure of health in units of a year for a given health state. QALDs are QALYs divided by 365 days. In Table 8, to facilitate quantification of the health losses, the clinical effects associated with exposure to contaminated tobacco products are categorized as being related to three types of illnesses: "gastrointestinal", "respiratory", or "other".

Preference-based health-related quality of life (HRQoL) measures such as QALDs measure health states on a scale of 0 to 1, where 0 represents death and 1 represents perfect health. The EuroQol 5 Dimensions (EQ-5D) scale measures HRQoL on five domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression).

To compute QALD losses, we require a value for the average health of individuals in the U.S., as well as health losses associated with the clinical effects associated with exposure to contaminated tobacco products. Estimates for these values are taken from peer-reviewed research in the relevant literature. We also require information on the duration of clinical effects. Because this information is absent in the PC data, we assume that the duration of clinical effects in the data

[46] To compute QALD losses associated with exposure calls and monetize the losses, we borrow from the methodology outlined in a peer-reviewed research article analyzing losses associated with foodborne illnesses (Ref. R27).

ranges from a minimum of 0 to a maximum of two days. The assumptions underlying the QALD loss computations are as follows:

i. We start with the baseline estimate of average health in the U.S. population of 0.870, as measured by the EQ-5D and estimated in the literature (Ref. R27).

ii. Food allergy symptoms usually include gastrointestinal effects such as vomiting, nausea, and diarrhea. Since these symptoms are also very prevalent in other forms of gastrointestinal distress, we use the average QALD loss (0.200) associated with a food allergic reaction, as estimated in the literature (Ref. R28).

iii. For respiratory-related clinical effects, we use the average QALD loss (0.123) for chronic respiratory system diseases, as estimated in the literature (Ref. R29).[47] We request comments on the association between contaminated/nonconforming tobacco products and chronic respiratory system disease, including any data or research that could be used to separate the effects of contaminated/nonconforming tobacco products from the general health risk from tobacco products.

iv. For other clinical effects, we used the median QALD health loss of (0.162) which is the median (0.2) given in (ii) and (0.123) given in (iii).

v. Although a single exposure call may report more than one clinical effect, we treat each reported clinical effect as an individual health event; i.e., health losses associated with multi-effect cases are treated as additive.

vi. We assume a duration for clinical effects that range from a minimum of 0 to a maximum of two days and use a triangular distribution function to account for uncertainty (triangular

[47] We conservatively use these values to apply to short term conditions that have similar effects on a day to day basis as a chronic illness. The mean EQ-5D values for emphysema, asthma, other lung diseases, and other respiratory system diseases were 0.663, 0.797, 0.714, and 0.816 or an average of 0.748 (Ref. R27). Thus, the estimated QALD loss resulting from a respiratory disease is 0.87-0.748=0.123.

distribution; minimum, most likely, maximum). In particular, (triangular distribution; 0, 0.5, 1) was used for "minor effect"; (triangular distribution; 0, 1, 2) was used for "moderate effect"; and 0 days was used for "no effect".

Table 8, 9, and 10, break down the analysis by type of illness, using $1,589 as the value per QALD calculated with a three percent discount rate (Ref. R30).[48] We estimate the QALD losses to range from 0 to 0.2 per gastrointestinal-related clinical effect, 0 to 0.123 per respiratory-related clinical effect, and 0 to 0.162 per other clinical effect. We monetize these QALD losses by multiplying them by $1,589, which produces ranges of $0-318, $0-195, and $0-257 per case, respectively.

Table 8.— Projected Baseline Health Loss from Gastrointestinal Related Clinical Effects of Exposure to a Contaminated Tobacco Product, 2021-2030

Severity of Clinical Effect	QALDs Lost per Case	Number of Cases	Monetized Health Loss Per Case (QALD – 3%)	Monetized Health Loss Per Case (QALD – 7%)	Monetized Health Loss (QALD – 3%)	Monetized Health Loss (QALD – 7%)
"no effect"	0	340.97	$0	$0	$0	$0
"minor"	0.1	215.43	$79	$133	$17,116	$28,626
"moderate"	0.2	21.95	$318	$532	$6,976	$11,667

*These estimates are based on a value per quality-adjusted life day (QALD) of $1,589 calculated with a three percent discount rate and $2,658 calculated with a seven percent discount rate.

[48] This value per QALD is given by the Value of Statistical Life (VSL) of $11.42 million (2020 dollar value) using a 3% discount rate divided by 365 (Ref. R27). Other values per QALD are used in Table 12.

Table 9.— Projected Baseline Health Loss from Respiratory-Related Clinical Effects of Exposure to a Contaminated Tobacco Product, 2021-2030

Severity of Clinical Effect	QALDs Lost per Case	Number of Cases	Monetized Health Loss Per Case (QALD – 3%)	Monetized Health Loss Per Case (QALD – 7%)	Monetized Health Loss (QALD – 3%)	Monetized Health Loss (QALD – 7%)
"no effect"	0	33.48	$0	$0	$0	$0
"minor"	0.062	21.15	$49	$82	$1,034	$1,729
"moderate"	0.123	2.16	$195	$327	$421	$705

*These estimates are based on a value per quality-adjusted life day (QALD) of $1,589 calculated with a three percent discount rate and $2,658 calculated with a seven percent discount rate.

Table 10.— Projected Baseline Health Loss from Other Clinical Effects of Exposure to a Contaminated Tobacco Product, 2021-2030

Severity of Clinical Effect	QALDs Lost per Case	Number of Cases	Monetized Health Loss Per Case (QALD – 3%)	Monetized Health Loss Per Case (QALD – 7%)	Monetized Health Loss (QALD – 3%)	Monetized Health Loss (QALD – 7%)
"no effect"	0	188.52	$0	$0	$0	$0
"minor"	0.08	119.11	$64	$107	$7,642	$12,781
"moderate"	0.162	12.14	$257	$429	$3,115	$5,209

*These estimates are based on a value per quality-adjusted life day (QALD) of $1,589 calculated with a three percent discount rate and $2,658 calculated with a seven percent discount rate.

The total estimated health loss over the period 2021-2030 is $36,304 or $3,630 per year when the value per QALD is $1,589 (Tables 8, 9, and 10). We also use $740 and $2,411 as values per QALD, which corresponds to a VSL of $5.3 million and $17.47 million (Ref. R27), respectively. In these cases, the total monetized health loss is $16,900 (or $1,690 per year) and $55,082 (or $5,508 per year), respectively (Table 11).

Table 11.— Total Projected Monetized Health Loss from Clinical Effects of Exposure to Contaminated Tobacco Products, 2021-2030

	Low value per QALD (3%) = $740	Medium value per QALD (3%) = $1,589	High value per QALD (3%) = $2,411	Low value per QALD (7%) = $1,233	Medium value per QALD (7%) = $2,658	High value per QALD (7%) = $4,027
Total Monetized Health Loss	$16,900	$36,304	$55,082	$28,166.84	$60,715	$92,012
Annual Monetized Health Loss	$1,690	$3,630	$5,508	$2,817	$6,072	$9,201
Annual Monetized Health Loss Prevented by the Proposed Rule (Estimated): 25% of Health Loss Prevented	$423	$908	$1,377	$704	$1,518	$2,300
Annual Monetized Health Loss Prevented by the Proposed Rule (Estimated): 75% of Health Loss Prevented	$1,268	$2,723	$3,744	$2,113	$4,554	$6,901

It is likely that the numbers of avoided tampering and contamination incidents, and their attendant health costs are subject to considerable uncertainty and variability making it difficult to determine, with certainty, the number of adverse events that are directly attributable to the consumption of nonconforming products resulting from inadequate controls in manufacturing facilities. It is, however, likely that a subset of the exposure calls to poison control centers is associated with inadequate controls in manufacturing plants. The requirements in the proposed rule, if finalized, would reduce the number of adverse events associated with nonconforming

products; however, we lack information that would allow us to estimate how much of (monetized) health loss would be avoided. Given this lack of information, we assume that at least 25 percent and at most 75 percent of the (monetized) health loss would be avoided if the proposed rule is finalized. We request comment on this assumption. If the proposed rule is finalized, we estimate, based just on PC call data, that monetized health losses associated with exposure calls brought on by a contaminated tobacco product may be reduced by between $908 and $2,723 per year (Table 12). These health estimates may be low because they do not take into account doctor or emergency room visits.

As noted above, exposure calls associated with contaminated tobacco products are likely to be systematically under-reported. We have accounted for this assumption by inflating our exposure call counts by a factor of ten. However, we may have still underestimated the potential health benefits resulting from the proposed rule. It is important to note that, in addition to tobacco products that are tampered with or contaminated, other nonconforming tobacco products may cause or contribute to injury or illness. For example, batteries in electronic cigarettes may explode during use because of product design flaws or nonconformity. Such events could harm users and non-users who are located near users when the explosion occurs. Lack of reliable information, such as records of complaints highlighting these potentially important adverse events, may cause us to underestimate the potential health benefits of the proposed rule. This is discussed further in subsection 4. Additional Potential Benefits, following the next subsection.

3. Summary of Total Quantified Benefits

In Table 12, we show a summary of the **two quantified benefits**: (1) cost saving due to avoided recalls and market withdrawals and (2) avoided adverse health effects associated with contaminated or other nonconforming tobacco products. We estimate that the undiscounted

benefits accruing to tobacco companies and consumers totals between $4.2 million and $212.8 million per year if the proposed rule is finalized. Below, we discuss other non-quantified benefits.

Table 12.— Summary of Total Quantified Benefits

	Low	Middle	High
(1) Estimated Annual Reduction in the Costs Associated with Recalls and Market Withdrawals*	$4,230,726	$59,654,480	$212,779,500
(2) Estimated Annual Prevented (Monetized) Health Loss of the Proposed Rule**	$908	$1,815	$2,723
Total	$4,231,634	$59,656,295	$212,782,223

*See Appendix D for low and high calculations.

**These estimates are based on calls to Poison Control Centers and use a value per quality-adjusted life day (QALD) of $1,589. In the benefits section, estimates based on values per QALD of $740 and $2,411 are also presented. 2020 U. S. Dollars.

As non-small and small manufacturers represent a respective eight and 92 percent of all manufacturers affected by this rule, we assume that 92 percent of estimated benefits correspond to small manufacturers and eight percent of benefits correspond to non-small manufacturers. [49] Because non-small and small manufacturers are assumed to begin working towards compliance with the requirements of this rule in year one and year five respectively, we estimate that benefits from non-small and small manufacturers begin to accrue on year two and year six respectively. We request comment on these assumptions. In Table 13, using the middle estimate for benefits of $60 million (while still noting that the cost avoidance method likely yields a potential lower, middle and upper bound), we show that about $5 million in annual benefits from non-small

[49] As explained in Sections II.C.1 and III. of this analysis, according to the U.S. Census data, about 89% of manufacturing establishments have less than 250 employees and about 95% have less than 500 employees. We estimate that 92 percent (the median between 89 and 95 percent) of domestic tobacco manufacturing entities or 1,774 would have less than 350 employees and be considered small.

manufacturers begin to accrue in year two and about $60 million from small manufacturers will begin to accrue in year six.

Table 13.— Annual Accrual of Benefits, Middle Estimate of Range, Present Value and Annualized Benefits over a Ten-year Period

Year	Recurring Annual Benefits (Undiscounted)	Discount Rate (3 percent)	Discount Rate (7 percent)
1	$0	$0	$0
2	$5,263,791	$4,961,628	$4,597,599
3	$5,263,791	$4,817,114	$4,296,821
4	$5,263,791	$4,676,810	$4,015,721
5	$5,263,791	$4,540,592	$3,753,010
6	$59,656,295	$49,961,208	$39,751,508
7	$59,656,295	$48,506,027	$37,150,942
8	$59,656,295	$47,093,230	$34,720,507
9	$59,656,295	$45,721,583	$32,449,072
10	$59,656,295	$44,389,886	$30,326,235
Present Value		**$254,668,079**	**$191,061,416**
Annualized		**$29,854,868**	**$27,202,847**

(2020 U.S. Dollars)

4. Additional, Unquantified Potential Benefits

The rule has several further potential benefits that we do not monetize. First, the requirements proposed in this rule would help support the implementation and enforcement of other provisions of the FD&C Act (as amended by the Tobacco Control Act). As regulations are promulgated, TPMP would help make them more effective by verifying that tobacco products are manufactured in conformance to those requirements.

- FDA's premarket authorities under sections 905(j) and 910 of the FD&C Act will authorize the marketing of new tobacco products with certain specifications and, where appropriate, labels, labeling, packaging, and advertising, as well as other information. TPMP's proposed recordkeeping requirements (such as MMRs and production records) would be used to confirm through inspection that the tobacco product's specifications and other

information are consistent with those described in the tobacco product application authorized by FDA. In addition, TPMP's records would assist FDA in identifying whether there are any changes to the specifications or other information that would make the product a new tobacco product requiring FDA premarket review.

- FDA may promulgate a tobacco product standard under section 907 of the FD&C Act. TPMP's recordkeeping requirements (e.g., MMR, acceptance activities, production record subparts) may be used to confirm that tobacco products are manufactured to meet the specifications established by a tobacco product standard.
- Under section 904 of the FD&C Act, tobacco product manufacturers are required to submit a listing of ingredients for each tobacco product to FDA. TPMP's proposed recordkeeping requirements (such as MMR recordkeeping requirements) may be used to confirm whether the tobacco product's ingredients are consistent with those reported to FDA.
- TPMP's recordkeeping requirements (such as those on complaint records, nonconforming product records, corrective and preventive action records, design and development activities records, acceptance activity records, production records, and distribution records) may be used to determine if distribution of the tobacco product should cease and whether a tobacco product should be recalled under 908(c) of the FD&C Act. TPMP's proposed recordkeeping requirements (such as complaint, corrective and preventive actions records) can help FDA determine if a required report of a serious unexpected adverse event or any removal or correction action needs to be reported to FDA under sections 909(a) and (b), respectively.

Second, the proposed rule, if finalized, may further reduce losses to health and property for users and nonusers associated with nonconforming tobacco products, beyond those estimated in

the quantified benefits. For example, FDA is aware of cases of fires and explosions associated with ENDS products that have been reported through various sources such as the news media. A U.S. Fire Administration report published in October 2014 counts 25 separate incidents of explosion or fire involving ENDS products reported in U.S. news media between 2009 and August 2014, resulting in ten injuries, including several burns and two instances of serious injury when devices exploded in users' mouths (Ref. R31). Although the report does not estimate the amount of property damage associated with these incidents, it does estimate that 32 percent of these incidents resulted in "moderate fire spread" to nearby materials while 52 percent resulted in "minor fire spread" (Ref. R31). The proposed rule would help reduce the incidence and severity of harm from contaminated and/or malfunctioning products, such as nonconforming batteries, by requiring design validation to assess the performance of the tobacco product, production process controls, as well as manufacturer evaluation and investigation of complaints regarding nonconforming tobacco products.

A third potentially unquantified benefit of the proposed rule (in at least a portion of the estimated range) is that its risk assessment, CAPA, tobacco product complaints and related provisions may facilitate investigation and identification of causes and root causes of consumer complaints and other reports of adverse events. For example, an increase of reported frequency or severity of respiratory distress from use of an ENDS product may help detect a previously unidentified risk of metallic particles in the cartomizer aerosol due to defective solder joints from the cartomizer (Ref. R32). Similarly, increased complaints of pneumonia, exacerbation of asthma, bronchitis, chronic obstructive pulmonary disease, eosinophilic pneumonitis, and laryngitis may be associated with chemical contamination of a tobacco product (Ref. R4).

Other ***potential*** benefits include avoided spillover costs to capital markets.[50] Jarrell and Peltzman measured losses in capital markets using cumulative excess returns (CERs). While the authors found that average stockholder losses beyond costs to the specific recalled product can range between 3% and 6% of market value, they do not specifically distinguish effects on recalling firm stockholders from competing firm stockholders (Ref. R2). We are uncertain whether any of these effects on capital markets would be captured in our estimated benefits. We request comment on these additional, unquantified potential benefits.

E. Costs of the Proposed Rule

1. Measurement of Costs

The proposed rule would subject finished and bulk tobacco product manufacturers to new manufacturing requirements that are specific to tobacco product manufacturers. When we lacked data on costs to write or update a procedure, conduct an activity, or train an employee specific to tobacco manufacturers, we relied on data for comparable requirements for a comparable industry, which was most often data associated with food manufacturers. The general steps for processing food and tobacco products share certain similarities. For example, cigarette, cigar, and roll-your-own-tobacco processors and food manufacturers may have comparable manufacturing processes because these tobacco products, like many food products, are agricultural products that are grown and harvested and distributed as ingredients for further

[50] Researchers contend that any recall, regardless of size, is followed by an industry-wide asset loss (Refs. R1, R2). Estimated quantified benefits of avoided recalls include reduced external costs in the supply chain of the recalled or withdrawn products (or they exclude reduced recall costs to manufacturers). Estimated external costs of conducting a recall or market withdrawal include lost sales to retailers and wholesalers, expenses associated with notifying tobacco retailers (for wholesalers) and consumers, removal and storage of inventory costs collection and shipping costs, disposal costs, and legal costs, among others. Estimated benefits do not include avoided spillover costs to capital markets.

processing and refinement including heat and moisture treatment before final processing and packaging. We ask for comment on our assumptions in this section.

Our analysis closely follows the analytical methods used in the recently published Final Regulatory Impact Analysis for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Foods (PCHF RIA) (80 FR 55907) published on September 17, 2015. The PCHF RIA analysis relied on a survey of a random sample of food manufacturers to determine how many conducted a hazard analysis; have process controls, sanitation controls and written procedures; how many conduct corrective actions; and how many perform verification activities and have written procedures before the adoption of the rule (Ref. R33). Numerous experts in safe food handling practices, GMPs, and risk-based preventive controls were also consulted for the development of the PCHF RIA. The consultation took place in the form of 3 formal expert elicitations, where the experts were asked a series of wide-ranging questions in a structured format relevant to the time and effort to develop the written procedures and to perform the other activities to adopt GMPs and preventive controls. When we lacked data specific to the tobacco product industry, we also relied on these expert elicitations (Refs. R34, R35).

There are significant differences between tobacco manufacturers and food manufacturers that we try to note here. There is a very wide range of food products that are made in food facilities. As identified by the North American Industrial Classification System (NAICS), covered food products span the codes from 311211 to 312112 including over 40 different categories of processed foods, comprising for example, milled flour, dry cereals, infant foods, low and high acid canned foods, milk and milk powders, pet foods, refrigerated foods and beverages, frozen fruit, fruit and vegetable canning, retail bakeries, dry pasta manufacturing soft drink manufacturing, and perishable prepared foods. In contrast, there is only one NAICS code for

tobacco manufacturing, 312230, which may not reflect the breadth of variety of manufacturing practices in the industry, particularly those practices of small tobacco product manufacturers. With this in mind, we applied the results for food processors that are most similar to tobacco product manufacturers as we adopted the GMP and expert elicitation results for the food industry in the analysis.

Because there are many more categories of food manufacturers and because food manufacturing often involves more raw materials and ingredients, sometimes with 40 or more different raw materials and ingredients, it may appear that food manufacturing steps are more complex that tobacco manufacturing steps. However, with the more recent development of electronic and novel tobacco products, it is difficult to ascertain the number of steps or the degree of complexity of tobacco product manufacturing processes relative to food manufacturing processes. For purposes of this analysis, we treat combustible tobacco product manufacturing as being less complex than food manufacturing. For example, cigarette manufacturing involves fewer ingredients than some food products such as the cut tobacco rod, the cigarette paper, the filter material, adhesives and sometimes flavoring. The processing involves the stemming and re-drying of the tobacco, cutting the leaves into fine strands with a specified moisture content, and wrapping of the filler and cutting before processing into the final products and packaging. Consequently, we assume that the processes in the combustible tobacco manufacturing industry are in general less diverse and at most equal in complexity to food processing plants. Comparatively, the manufacturing of e-cigarettes most often involves the assembly of electronic parts, including a vaporizer or atomizer, rechargeable batteries, heating coils, sometimes LED indicators, voltage controls, an on/off switch among other electrical or mechanical parts that have been pre-manufactured as well as a mix of flavorings in the e-liquid. Consequently, e-

cigarette manufacturers have attributes that might be analogous to consumer electronics manufacturers rather than to food manufacturers, while the manufacturing of e-liquids has attributes that may align with food manufacturers.

As with the PCHF RIA, FDA may develop additional TPMP guidance materials. We anticipate that tobacco industry trade groups would also develop model TPMP SOPs or offer their support to the tobacco industry, and GMP consultants would offer their professional experience to individual manufacturers, all of which would reduce the burden on the tobacco industry to comply, by in part reducing the hours needed to develop the written procedures and to train their staff to comply with the new requirements.

The estimates of the labor hours needed to write the procedures for most provisions in this regulation are reported under the cost explanation for each subpart and are based on Eastern Research Group's (ERG) expert elicitation for food plants.[51] The amount of time needed to develop establishment-specific procedures increases by establishment size as larger establishments have more areas to address and often have a greater number and more complex processes. The expert elicitation indicates that on average it would take six to eight hours to write GMP procedures. Specifically, the experts estimated the time necessary to write a procedure for a small food facility is about seven hours, a medium-sized food facility is about ten hours, a large food facility is about thirteen hours, and a very large food facility is about sixteen hours.

[51] ERG used a modified Delphi technique for this study. The Delphi method is the first structured method for eliciting and combining expert opinion. The method requires indirect interaction among experts through a moderator. Although different variations of the method exist, in a typical Delphi study, experts make individual judgments. Next, these judgments are shared anonymously with the whole group of experts. After viewing other experts' judgments, each expert is then given the opportunity to revise his or her own judgments, and the process is repeated. Theoretically, the goal of the Delphi is to reach a consensus after a few rounds. In reality this rarely happens. Thus, at the end of the Delphi rounds, the experts' final judgments are typically combined mathematically. Thus, the estimated labor hours from ERG's expert elicitation are basically the final expert judgements that were later combined mathematically.

To reflect the lesser complexity for tobacco manufacturers, we generally scale the food GMP estimates downward since small and non-small tobacco manufacturers are likely to have fewer and simpler processes than small and non-small food manufacturers, respectively. For the cost of preparing written procedures, we generally used two to six hours for small tobacco product manufacturers and four to twelve hours for non-small tobacco product manufacturers. For some provisions we estimated that more hours might be necessary to develop written procedures, such as those for cleaning because manufacturers might have a varied set of procedures for different areas of their manufacturing plants. The food manufacturing experts interviewed by ERG estimated the amount of time needed to develop equipment-specific procedures, including what sanitizers and cleaning tools to use, as between six to eight hours per piece of equipment. This includes the time to develop an initial draft, hold internal meetings, and edit. The experts judged that the hours necessary to develop the SOPs to perform the calibration functions should not be included in the hours necessary to write the procedures for the often-complicated equipment. We, therefore, assume that the equipment already comes with the necessary technical instructions. The written procedures that would be necessary to comply with the proposed rule would be to train the quality control (QC) personnel to perform the calibration checks and to establish how and how often to report the calibration results.

We request comment on the applicability of food processor data and estimates to the tobacco product manufacturers covered by the proposed regulation. Additionally, we request comments, data, and research on how the hours necessary for tobacco-specific manufacturers to comply with TPMP provision may differ from those estimated for food manufacturers.

To estimate the number of personnel that would have to conduct specific activities we first estimate the average number of personnel in tobacco manufacturing establishments using

information from the 2017 Economic Census[52]. From the Census data, we estimated the average number of personnel for tobacco manufacturing establishments and for tobacco and tobacco product merchant wholesalers.[53] We examined the Census data for tobacco establishments as classified under the North American Industry Classification System (NAICS) codes 312230 for tobacco manufacturing establishments and 424940 for tobacco and tobacco product merchant wholesalers. For each NAICS code, we derived estimates for the average number of employees per establishment for small (less than 350 employees) and non-small (350 or more employees) enterprises.[54] As illustrated in Table 14, the overall average number of employees per establishment for small and non-small tobacco enterprises is 13 and 210 respectively.

Table 14.— Average Number of Employees by NAICS Code and Employee Size Category

NAICS code	NAICS code description	Average number of employees per establishment in enterprises with less than 350 employees	Average number of employees per establishment in enterprises with 350 or more employees
312230	Tobacco Manufacturing	22	326
424940	Tobacco and Tobacco Product Merchant Wholesalers	13	191
Overall average number of employees per establishment		**13**	**210**

To estimate the costs for conducting many of the activities required by the TPMP rule, including the costs of conducting the manufacturing activities and training personnel in their new

[52] United States Census Bureau. Economic Census (2017). The economic Census is the U.S. government's official five year measure of American businesses and the economy. 2017 is the most recent year for which data are currently available. https://www.census.gov/programs-surveys/economic-census.html.

[53] According to Census data manufacturers of tobacco products that could be affected by this proposed rule would be designated under the North American Industry Classification System (NAICS) as "tobacco product manufacturers." Importers may be designated as wholesalers or retailers. Most tobacco product-importing wholesalers would be classified as "tobacco and tobacco product merchant wholesalers.

[54] The U.S. Census Statistics of U.S. Businesses gathers employment and receipt data for establishments by first grouping each establishment into an enterprise size category. An enterprise may consist of a single establishment or multiple establishments. Our derived average number of employees per establishment is less than the enterprise size category because of the presence of multi-unit enterprises.
https://www.census.gov/programs-surveys/susb/technical-documentation/methodology.html

tasks, we assumed that QC staff or a small, specialized team of Technical Services personnel would perform most of the distinct new requirements; not every production worker would be expected to perform or be trained in every requirement of the rule.

According to information from ERG's expert elicitation for food plants, about four to fifteen employees typically comprise a "core HACCP team" of QC or Technical Services employees, with an average of ten employees for smaller food facilities (Ref. R34). From Table 14, considering that a small tobacco product manufacturing establishment has on average 13 employees, we scale the average number of QC or technical service staff in tobacco establishments to two employees in a small tobacco establishment (<350 employees). Also, from Table 14 a large tobacco product manufacturing establishment has on average 210 employees. We therefore estimate the average number of QC or technical service staff to 10 employees in a large tobacco product manufacturing establishment (roughly five percent of 210 employees). For example, an average of two employees would need to perform a production activity and be trained by each manufacturer in the monitoring, controlling, and minimizing the presence of animals and pests in the buildings, facilities, and grounds of smaller establishments to protect against contamination, including the establishment of any threshold criteria for animals and pests. In general, we estimate the two employees would need to be trained for each new provision for small tobacco product manufacturers and that it would take an average of two to four hours per employee to train for each provision. We also estimate that about ten QC or Technical Services employees would need to perform a production activity and be trained for each provision for non-small tobacco product manufacturers, which is likely to have more production processes and that it would generally take an average of two to four hours to train each employee for each provision. We assumed it would take an average of one manager to

conduct the training for every ten employees. For some functions we assumed more hours of training might be necessary, such as for label controls, because plants might have several varieties of labels. Another important exception is for cleaning activities. From Table 14 we assumed that 13 employees or almost all production workers would have to be trained in the procedures for cleaning, preventing contamination, etc., for small tobacco product manufacturers and 210 employees would have to be trained for non-small tobacco product manufacturers.

The survey results show that monitoring of the preventive control activities including cleaning and sanitation, labeling and supplier ingredients among the other activities that require monitoring is already conducted for almost all food processing plants. We interpret monitoring to include those required activities that require managerial oversight of QA/QC function, investigation, visual inspection, review of check sheets, evaluation of testing results, and review of written records and other forms of documentation. In the PCHF RIA (80 FR 55907), it was estimated that it would take small and medium-sized (large and very large) food processing plants two hours per month (four hours per month) to conduct manufacturing activities such as the review of records, review and assessment of audit reports, and review and assessment of testing results. In our analysis, to estimate the time that it would take to perform the additional monitoring by production managers or QC staff to comply, we assumed the task would be conducted throughout the year on a weekly basis, and that ten percent of establishments currently do not perform the additional monitoring activity. For those establishments, because many of the provisions require review plus additional activities, we generally assume that small establishments would need one to three hours per week and non-small establishments would need an additional two to six per week.

As discussed above, our estimates of the time required to perform the activities outlined in the proposed regulation are derived from estimates developed for food processing manufacturers. We have adjusted the estimates to reflect the fact that tobacco product manufacturers generally engage in fewer processes or less complex processes than do food manufacturers. We provide a range of cost estimates to account for the uncertainty in the costs specific to the tobacco product manufacturing industry.

Tobacco product manufacturers have a private incentive to control the consistency of their products and that their manufacturing operations remain in a state of control. Throughout the analysis, it is important to note that our working assumption is that, while tobacco product manufacturers are conducting many of the types of activities required by the proposed regulation, on average they would have to exert some additional effort to achieve alignment with the proposed TPMP requirements. Our general approach is to estimate the time required to make existing manufacturing activities and practices conform to the requirements in the proposed rule.

The following list shows our wage and cost conventions, which are used throughout the cost analysis.

- Domestic wage rates come from the Bureau of Labor Statistics, (May 2017 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 312200 - Tobacco Manufacturing, https://data.bls.gov/oes/#/home)
- Foreign wage rate estimates for foreign tobacco manufacturing establishments are from historical occupational and industry-level wages in the 20 foreign countries exporting the largest amount of tobacco products to the United States by total dollar value (Appendix C). We use these wage estimates to calculate a single weighted average wage rate for estimating costs to foreign manufacturers.

- We estimate costs using costs per hour for four types of labor: general and operations management, industrial production management, production operations occupations, and legal occupations. Nominal mean hourly wages are increased by 100 percent to account for benefits and overhead (Table 15).

Table 15.— Mean Hourly Wages for Domestic and Foreign Workers by Occupation Rates

Occupation (SOC code)	Mean Hourly Wage	Wage Plus Benefits and Overhead	Source
Domestic Manufacturers			
Production Occupations (510000)	$24.45	$48.90	Bureau of Labor Statistics (2020). May 20208 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312200 - Tobacco Manufacturing https://www.bls.gov/oes/current/naics4_312200.htm
Industrial Production Managers (113051)	$63.08	$126.16	
General and Operations Managers (111021)	$51.29	$147.72	
Legal Occupations (231011)	$73.86	$147.72	Bureau of Labor Statistics (2018). May 2020 National Industry-Specific Occupational Employment and Wage Estimates for NAICS 541100- Legal Services https://www.bls.gov/oes/current/naics4_541100.htm
Foreign Manufacturers			
Production Occupations	$3.23	$6.46	(See Appendix C)
Industrial Production Manager	$5.45	$10.89	
General and Operations Manager	$6.99	$13.98	
Legal Occupations	$6.37	$12.75	

2020 wages - Domestic Manufacturers SOC code: Standard Occupational Classification code -- see http://www.bls.gov/soc/home.htm.

- To estimate the number of domestic and foreign manufacturers that would be covered by our rule, we use data from FDA's Tobacco Registration and Listing System and FDA

tobacco product import data in combination with FDA inspection reports and exhibits. To estimate the number of manufacturers that would be expected to perform an activity or procedure to comply with the proposed rule, we multiply the total number of tobacco product manufacturers by the percentage of manufacturers that currently would not be in alignment with requirements set forth in the proposed rule, if finalized. This is done separately for each quantified provision for every subpart of the proposed rule and for two sizes of operation groups (small tobacco product manufacturers with < 350 employees and non-small manufacturers with ≥ 350 employees).

- Our basic method for estimating average alignment costs is to multiply an estimate for the average time it takes to prepare a written procedure and/or conduct an activity by the average wage rate of the workers that are performing the activity. Hourly estimates in the analysis are based on hourly estimates developed for food GMP regulations (Refs. R33-R34). This is done on a provision-by-provision basis for each subpart.[55]
- For estimating costs associated with learning about the requirements of this proposed rule, and also with costs of setting up procedures to make available certified English translations of documents to FDA when requested, we adjust time estimates for foreign establishments to account for potential differences in time due to differences in English language proficiency and internet accessibility for all foreign facilities who offer tobacco products for sale in the U.S. covered under this proposed rule. We estimate the average number of equivalent hours for all foreign establishments to be 2.13 hours. This estimate is the product of an estimated English proficiency weighted average of 1.8 hours and an

[55] Costs attributable to written procedures may include costs to define, document in writing, and update each procedure. Additionally, they may include the costs of creating and maintaining records to document the performance of activities in writing. Where applicable, the marginal costs to implement the procedures and conduct the specific activities required in each subpart are estimated separately.

estimated internet usage weighted average of 2.4 hours. To account for language proficiency differences, we use information from a report titled "Education First English Proficiency Index" (EF EPI) published in November of 2018 (Ref. R36). This report ranks countries by the average level of English language skills amongst adults using data collected via English tests available over the internet. To account for country differences in internet accessibility, we use 2018 internet user percentage estimates by country (Ref. R37). Table 16 shows establishment counts from countries scaled according to the country's English proficiency index (EPI). We estimate that for every hour used by an establishment with high to very high EPI score, that establishments in countries with low and very low EPI score would require two to three hours respectively. Similarly, we estimate that for each hour used by an establishment with high to very high EPI score, that establishments in countries with a moderate EPI score would require one and a half hours. We estimate 1.8 proficiency weighted hours as the sum of the product of the establishment percentage (A) and the hourly equivalent (B) within each proficiency index range.

Table 16.— Number of Establishments in Countries According to their English Proficiency

English Proficiency Index (Range)	Number of Establishments	Percent Establishments (A)	Hourly equivalent (B)	Proficiency Weighted Hours (A X B)
Very High (63.2 - 100)	276	8%	1.00	0.08
High (58.14 - 63.1)	93	3%	1.00	0.03
Moderate (52.82 - 58.13)	701	21%	1.50	0.32
Low (48.78 - 52.81)	2,022	62%	2.00	1.24

English Proficiency Index (Range)	Number of Establishments	Percent Establishments (A)	Hourly equivalent (B)	Proficiency Weighted Hours (A X B)
Very Low (0 - 48.77)	181	6%	3.00	0.17
Sum	3,273	100%	-	**1.8**

Table 17 shows the estimated number of establishments from countries scaled according to their country's internet access. We estimate that for every hour used by an establishment with high to very high internet access, establishments with moderate, low, and very low internet usage would require 1.5, two and three hours respectively. We estimate that for every hour used by an establishment with high to very high internet usage, that establishment in countries with low and very low internet usage would require two to three hours respectively. Similarly, we estimate that for every single hour used by an establishment with high to very high internet usage, that establishments in countries with a moderate EPI score would require one and a half hours. We estimate 2.4 internet weighted hours as the sum of the product of the establishment percentage (A) and the hourly equivalent (B) within each internet access index range.

Table 17 .— Number of Establishments in Countries According to Percent Internet Access

Internet Use (Scale)	Number of Establishments	Percent Establishments (A)	Hourly equivalent (B)	Internet Weighted Hours (A X B)
Very High (90%-100%)	330	10%	1.00	0.10
High (71% - 89%)	470	14%	1.00	0.14
Moderate (59% - 70%)	824	3%	1.50	0.04

Internet Use (Scale)	Number of Establishments	Percent Establishments (A)	Hourly equivalent (B)	Internet Weighted Hours (A X B)
Low (57% - 58%)	165	5%	2.00	0.10
Very Low (0 - 56%)	2,225	68%	3.00	2.04
Total	3,273	100%	-	**2.4**

The average of both weighted sums of 1.8 hours to account for differences in English proficiency and of 2.4 hours to account for differences in internet usage give us a single estimate of 2.13 ((1.8 hours + 2.4 hours)/2) for foreign establishments as equivalent to one hour for domestic establishments. We acknowledge that there is uncertainty associated with using this data and request comment on our time estimates.

- Most of the provisions in the proposed rule require tobacco manufacturers to define, document in writing, implement, follow, and update procedures. For each provision of the proposed rule, information from FDA inspection reports and exhibits is used to estimate the number of affected entities by size of operation (small tobacco product manufacturers with <350 employees and manufacturers with ≥350 employees). The total labor cost of compliance for each section of the proposed rule is calculated by taking the product of three cost components:
  a. estimated number of entities affected by the provisions in the section
  b. estimated value of time of the employee likely to carry out the activity; and
  c. estimated time, which includes the time needed to develop and write-up the procedures, to comply with the provisions in a section.

The proposed rule may also result in manufacturers having to incur nonlabor costs (e.g., the purchase of tracking software, testing or other types of equipment) to ensure compliance with the proposed rule. Estimated costs for these and other requirements (e.g., training or establishing risk management process) are calculated in a similar fashion. The values or distribution of values used in the calculation of costs vary by subpart and a summary of these values will be provided, in turn, in the discussion of the analysis for each subpart below.

2. Costs Associated with Learning about the Proposed Rule

Each tobacco product manufacturer covered under this proposed rulemaking will incur costs to learn about the requirements in the proposed rule. For domestic manufacturers, average reading speed ranges between 200 and 250 words per minute (Ref. R34). The preamble is approximately 60,000 words, so given this reading speed range, it would take a qualified worker between four and five hours to read the preamble. However, it would take additional time for the qualified worker to understand the rule as it relates to a specific manufacturer and its manufacturing plants. Given the complexity of rules involving GMPs, we assume that it would take a domestic manufacturers total of 40 hours to read and understand the proposed rule (Eastern Research Group Refs. R33 - R34). For foreign manufacturers we estimate that it would take about 85 hours (40 hours x 2.13 hours to account for internet access and English proficiency as explained under Table 17) to read and understand the proposed rule. We assume that to read and understand the rule both small and non-small domestic manufacturers would require a General and Operations Manager with a wage rate of $103 per hour, and, in addition, would require eight hours of services from a worker in the Legal Occupations field with a wage rate of $148 per hour. For foreign manufacturers we estimate that to read and understand the rule both small and non-small domestic manufacturers would require a General and Operations Manager with a wage rate of $14 per hour,

and in addition, would require 17 hours of services from a worker in the Legal Occupations field with a wage rate of $13 per hour. Table 18 provides a detailed breakdown of the values and calculations used to estimate the compliance costs associated with learning about the rule. We estimate that these actions would impose a total one-time cost of about $10 million to domestic manufacturers and $4.6 million to foreign manufacturers (Table 18).

Table 18 .— One-time Cost of Learning About the Rule (2020 U.S. Dollars)

Row	Cost Calculations Item	Domestic Manufacturers			Small Manufacturers		
		Small	Non-Small	Total	Small	Non-Small	Total
a	Number of Entities	1,764	171	1,935	2,984	289	3,273
b	General and Operations Manager Total Hourly Wage	*$103*	*$103*	-	*$14*	*$14*	-
c	Time reading and learning rule (hours)	*$40*	*$40*	-	*$85*	*$85*	-
d	Legal Occupations Worker Total Hourly Wage	*$148*	*$148*		*$13*	*$13*	-
e	Time reading and learning rule (hours)	*$8*	*$8*		*$17*	*$17*	-
f	One Time Cost to Learn about the Rule	*$,9,324,068*	*$902,329*	$10,226,398	$4,199,645	$406,417	$4,606,062
g	Per Establishment Learning Cost	$5,285	$5,285		$1,408	$1,408	$1,408

a.- From Table 2 Estimated Number of Affected Domestic and Foreign Tobacco Product Manufacturers &
b & d.- From Table 15 Estimated Domestic and Foreign Hourly Wage Rates
c & e.- Eastern Research Group (Refs.33-34) for domestic hours and as explained under Table 16 & Table 17 for foreign hours
f (One-time costs to learn about the rule) = a x (b x c +d x e)

3. Subpart B Costs

Subpart B prescribes the proposed requirements pertaining to finished and bulk tobacco product manufacturers' management systems that cover a manufacturer's organization and

personnel, tobacco product complaints, and corrective and preventive actions. The tasks outlined in subpart B include the following items:

- Proposed § 1120.12 would require manufacturers to establish and maintain an organizational structure; designate, in writing, appropriate responsibility for all personnel who perform an activity subject to part 1120 and designate, in writing, management with executive responsibility who have the duty, power, and responsibility to implement the requirements under part 1120; establish and maintain training procedures for identifying training needs; maintain records of personnel qualifications and training records;.
- Proposed § 1120.14 would require manufacturers to establish and maintain procedures that aim to document and evaluate complaints, and investigate, and determine whether follow-up is necessary for complaints that could be related to a nonconforming tobacco product, a design issue, or an adverse experience required to be reported under a regulation promulgated under section 909(a) of the FD&C Act.
- Proposed § 1120.16 would require manufacturers to establish and maintain procedures for implementing corrective and preventive actions (CAPA). These procedures are to require review of various sources of data for identifying and investigating existing and potential causes of nonconformities and design problems, acting to correct and prevent nonconformities and design problems, verifying or validating the CAPAs, implementing and documenting the changes needed, and disseminating that information to specified personnel. Manufacturers must maintain records of all activities conducted under this section.

We summarize estimated one-time and annual costs per proposed requirement in Table 19a. Domestic one-time and annual costs range from $1.5 to $3.7 million and $3.1 to $9.4 million

respectively. Foreign one-time and annual costs range from $0.3 to $0.8 million and $0.5 to $1.5 million respectively.

Table 19a.— Costs to Domestic & Foreign Manufacturers of Subpart B: Management System Requirements (2020 U.S. Dollars)

Requirement	One Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Domestic Establishments						
§1120.12 - Organization and personnel	$376,085	$752,169	$1,128,254	$150,037	$314,698	$479,359
§1120.14 - Tobacco product complaints	$573,551	$953,887	$1,334,223	$1,481,843	$2,963,687	$4,445,530
§1120.16 - Corrective and preventive actions (CAPA)	$538,915	$897,080	$1,255,246	$1,476,473	$2,952,945	$4,429,418
Subpart B- Domestic Costs	***$1,488,550***	***$2,603,136***	***$3,717,722***	***$3,108,353***	***$6,231,330***	***$9,354,307***
Foreign Establishments						
§1120.12 - Organization and personnel	$86,661	$173,321	$259,982	$34,573	$72,515	$110,458
§1120.14 - Tobacco product complaints	$109,969	$187,090	$264,212	$224,878	$449,755	$674,633
§1120.16 - Corrective and preventive actions (CAPA)	$103,092	$175,613	$248,134	$223,640	$447,280	$670,920
Subpart B- Foreign Costs	***$299,721***	***$536,025***	***$772,328***	***$483,091***	***$969,551***	***$1,456,011***
Total Costs Subpart B	**$1,788,271**	**$3,139,161**	**$4,490,050**	**$3,591,443**	**$7,200,881**	**$10,810,318**

Table 19b provides a detailed breakdown of the values or distribution used to estimate the compliance costs of subpart B, along with sources for this information. Unless identified differently, values used for domestic establishments are the same values used for foreign establishments.

Table 19b.— Value or Distribution Used in Cost Calculations—Subpart B

Cost Calculation Item	*Value or Distribution Used*	*Source*
Hourly Wage Rate	Domestic: General and Operations Manager ($103), Production Manager ($126), Production Operations ($49) Foreign: General and Operations Manager ($14), Production Manager ($11), Production Operations ($6)	*See Table 15*
Additional Time for Manufacturing Activities such as Review, Investigation, Evaluation, or Implementation	Small Manufacturers (1 to 3 hours per week) Non-Small Manufacturers (2 to 6 hours per week)	*Eastern Research Group (Refs. R33-R35)*
Time for Training	2 to 4 hours	*Eastern Research Group (Refs. R33-R35)*
Time for Records	0.05 hours (or 3 minutes)	*Eastern Research Group (Refs. R33-R35)*
Set-up Time for Procedures	Small Manufacturers (2 to 6 hours) Non-Small Manufacturers (4 to 12 hours)	*Eastern Research Group (Refs. R33-R35)*
Annual Time Required for Procedures	Small Manufacturers (0 to 3 hours) Non-Small Manufacturers (2 to 6 hours)	*Eastern Research Group (Refs. R33-R35)*

Using FDA inspection reports and exhibits we estimate that, depending on the requirement, 21-56% of small manufacturers and 6-18% of non-small manufacturers lack procedures that are aligned with proposed subpart B. We estimate one-time labor hours to comply with the proposed requirements for this subpart to range from two to six hours for small manufacturers and four to 12 hours for non-small manufacturers. We estimate annual labor hours to comply with the requirements for this subpart to range from zero to three hours for small manufacturers and two to six hours for non-small manufacturers.

Costs of this subpart would be incurred by an estimated 737 domestic and 1,246 foreign establishments. Tables 19c and 19d summarize costs to domestic and foreign manufacturers, respectively. Both tables break down the costs of this subpart by written procedure requirements, training requirements and complaint processing requirements. Costs are also broken down by costs incurred to small and non-small manufacturers. Costs estimates are laid out in detail in Table 2 in Appendix A for domestic manufacturers and Table 2 in Appendix B for foreign manufacturers. We request comment on the methods and estimates in this section.

Estimated one-time costs to domestic establishments for proposed written procedure requirements in this subpart range between $0.8 and $2.3 million; estimated annual costs range between $0.3 million and $1 million. The one-time cost for the training requirements in this subpart is estimated to be between $0.7 million and $1.4 million (Table 19c).

We estimate that, in addition to written procedure and training costs, some domestic manufacturers may need to exert additional effort beyond current practice, specifically for those activities related to the processing of complaints (§ 1120.14) and implementing corrective and preventive actions (CAPA) (§ 1120.16). The annual cost for these tasks is estimated to be between $2.7 million and $8.3 million (the sum of Complaint processing and CAPA processing in Table 19c).

Table 19c provides a summarized breakdown of the components used to estimate the one-time and annual costs to domestic manufacturers of proposed subpart B. We estimate that for domestic establishments one-time costs range from $1.5 million to $3.7 million and annual costs range from $3.1 million to $9.3 million (Table 19c). The activities to establish (write and put into place) complaint and CAPA processing are covered in the One-Time Costs for Written Procedure and Training. The costs to implement Complaint Processing and CAPA Processing are covered in the

Annual Costs for these activities moving forward. Accordingly, the costs estimates are not minimal and are expected to yield the public health and other benefits as described, including fewer recalls and market withdrawals and potential for reduction of adverse events associated with adulterated, contaminated, or misbranded tobacco products.

Table 19c.— Subpart B Management System Requirements: Costs to Domestic Establishments (n=737 establishments) (2020 U.S. Dollars)

Activity	One-time Cost			Annual Cost		
	L	M	H	L	M	H
Written Procedure	$766,998	$1,533,995	$2,300,993	$345,493	$705,611	$1,065,729
Employee Training	$227,760	$341,639	$455,519	$0	$0	$0
Training by Manager	$467,417	$701,126	$934,834	$0	$0	$0
Record of Training	$26,376	$26,376	$26,376	$0	$0	$0
Complaint Processing	$0	$0	$0	$1,381,430	$2,762,859	$4,144,289
CAPA Processing	$0	$0	$0	$1,381,430	$2,762,859	$4,144,289
Non-Small (n=23)	*$111,875*	*$187,519*	*$263,163*	*$469,574*	*$934,769*	*$1,399,964*
Cost/Non-Small Est. (714)	*$4,882*	*$8,182*	*$11,483*	*$20,489*	*$40,788*	*$61,086*
Small (n=737)	*$1,376,675*	*$2,415,617*	*$3,454,559*	*$2,638,779*	*$5,296,561*	*$7,954,343*
Cost/ Small Est.	*$1,929*	*$3,384*	*$4,839*	*$3,697*	*$7,420*	*$11,143*
Total	**$1,488,550**	**$2,603,136**	**$3,717,722**	**$3,108,353**	**$6,231,330**	**$9,354,307**

Table 19d provides a summarized breakdown of the components used to estimate the costs of proposed subpart B to foreign manufacturers. We estimate that one-time costs range from $0.3 million to $0.8 million and annual costs range from $0.5 million to $1.5 million. For both domestic and foreign manufacturers, we estimate that on average 93 percent of one-time costs and 86 percent of annual costs associated with this subpart would be incurred by small tobacco product manufacturers.

Table 19d.— Subpart B Management System Requirements: Costs to Foreign Establishments (n=1,246 establishments) (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Written Procedure	$176,738	$353,477	$530,215	$79,612	$162,593	$245,575
Employee Training	$50,871	$76,306	$101,741	$0	$0	$0
Training by Manager	$68,260	$102,390	$136,520	$0	$0	$0
Record of Training	$3,852	$3,852	$3,852	$0	$0	$0
Complaint Processing	$0	$0	$0	$201,739	$403,479	$605,218
CAPA Processing	$0	$0	$0	$201,739	$403,479	$605,218
Non-Small n=39	$23,976	$40,660	$57,344	$70,393	$139,777	$209,161
Cost/Non-Small Est.	$619	$1,049	$1,479	$1,816	$3,606	$5,396
Small n=1,207	$275,745	$495,365	$714,985	$412,698	$829,774	$1,246,850
Cost/ Small Est.	$228	$410	$592	$342	$687	$1,033
Total	**$299,721**	**$536,025**	**$772,328**	**$483,091**	**$969,551**	**$1,456,011**

4. Subpart C Costs

Subpart C of the proposed rule involves proposed requirements that are specific to personnel practices (§ 1120.32), building, facilities, and grounds (§ 1120.34), equipment (§ 1120.36), and environmental controls (§ 1120.38). The tasks outlined in subpart C include the following items:

- Proposed § 1120.32 would require manufacturers to establish and maintain procedures for the cleanliness, personal practices, and apparel, which must include requirements to ensure that contact between personnel and the tobacco product or environment would not result in contamination of the tobacco product.
- Proposed § 1120.34 would require manufacturers to ensure each building, facility, and grounds is maintained in appropriate condition to prevent contamination and ensure that buildings and facilities are of suitable construction, design, and location to facilitate

sanitation, maintenance, and proper operation. The provision also would require controls for water quality, and record keeping, as well as require manufacturers to establish and maintain procedures for cleaning and sanitation and animal and pest control.

- Proposed § 1120.36 would require manufacturers to ensure that equipment used in manufacturing operations is appropriately designed, constructed, and suitable for its intended use, and must establish and maintain procedures for the routine cleaning, calibration, maintenance, as well as testing, monitoring, and measuring of equipment to ensure proper performance. The provision also would require identification of major equipment and processing lines.
- Proposed § 1120.38 would require manufacturers to establish and maintain procedures to adequately control environmental conditions, where appropriate, and maintain and monitor environmental control systems to verify that the system is adequate and functioning properly.

We estimate that one-time costs range from $6.9 million to $19.9 million and annual costs range from $1.7 to $22.7 million. A more detailed layout of the costs estimates can be found in Appendix A, Table 3 (domestic) and Appendix B Table 3 (foreign). We request comment on the methods and estimates in this section. We summarize estimated one-time and annual costs per proposed requirement in Table 20a. One-time and annual costs to domestic manufacturers range from $5.7 to $16.5 million and $1.3 to $15.2 million respectively. One-time and annual costs to foreign manufacturers range from $1.2 to $3.4 million and $0.4 to $7.5 million respectively.

Table 20a.— Costs to Domestic and Foreign Manufacturers of Subpart C: Buildings, Facilities and Equipment (2020 U.S. Dollars)

Requirement	One Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Domestic Manufacturers						
§1120.32 Personnel	$711,048	$1,312,077	$2,395,681	$59,227	$113,724	$168,222
§1120.34 Buildings, facilities and grounds	$1,863,995	$3,013,265	$4,457,937	$832,714	$7,349,191	$13,865,668
§1120.36 Equipment	$2,265,138	$4,418,293	$7,171,518	$263,206	$526,412	$789,618
§1120.38 Environment controls	$854,772	$1,683,987	$2,513,202	$126,568	$253,136	$379,704
Subpart C - Domestic Costs	***$5,694,953***	***$10,427,621***	***$16,538,338***	***$1,281,715***	***$8,242,464***	***$15,203,213***
Foreign Manufacturers						
§1120.32 Personnel	$144,059	$272,050	$500,739	$13,648	$26,205	$38,763
§1120.34 Buildings, facilities and grounds	$413,163	$664,453	$970,279	$317,982	$3,751,200	$7,184,418
§1120.36 Equipment	$450,480	$884,607	$1,441,331	$60,650	$121,301	$181,951
§1120.38 Environment controls	$168,026	$332,320	$496,613	$29,165	$58,330	$87,495
Subpart C - Foreign Costs	***$1,175,728***	***$2,153,430***	***$3,408,962***	***$421,445***	***$3,957,036***	***$7,492,627***
Total Costs - Subpart C	***$6,870,680***	***$12,581,051***	***$19,947,299***	***$1,703,160***	***$12,199,500***	***$22,695,840***

Table 20b provides a detailed breakdown of the values or distribution used to estimate the costs of subpart C, along with sources for this information.

Table 20b.— Value or Distribution Used in Cost Calculations—Subpart C

Cost Calculation Item	*Value or Distribution Used*	*Source*
Hourly Wage Rate	Domestic: General and Operations Manager ($103), Production Manager ($126), Production Operations ($49) Foreign: General and Operations Manager ($14), Production Manager ($11), Production Operations ($6)	*See Table 15*
3rd Party Pest Control	Small Manufacturers ($3,000 to $120,000 per year) Non-Small Manufacturers ($15,000 to $230,000 per year)	*FDA Inspections*
Time for Training	0.5 to 6 hours	

Cost Calculation Item	*Value or Distribution Used*	*Source*
Time for Records	0.05 hours (3 minutes)	*Eastern Research Group (Refs. R33-R35)*
Set-up Time for Procedures	Non-Small Manufacturers (4 to 40 hours) Small Manufacturers (2 to 40 hours)	
Annual Time Required for Procedures	Small Manufacturers (1 to 10 hours) Non-Small Manufacturers (2 to 10 hours)	

Using FDA inspection reports and exhibits we estimate that, depending on the requirement an average of 40 percent, (20-70%) of small manufacturers and an average of 40 percent (13-70%) of non-small manufacturers lack procedures that are aligned with subpart C. We estimate one-time labor hours to comply with the requirements for this subpart to range from two to 40 hours for small manufacturers and four to forty hours for non-small manufacturers. We estimate annual labor hours to comply with the requirements for this subpart to range from one to ten hours for small manufacturers and two to ten hours for non-small manufacturers.

Costs of this subpart would be incurred by an estimated 769 domestic and 1,344 foreign establishments. Tables 20c and 20d summarize costs to domestic and foreign establishments, respectively. Both tables break down the costs of this subpart by requirements, training requirements and third-party pest control requirements. Costs are also broken down by costs incurred to small and non-small manufacturers. A more detailed layout of the cost estimates can be seen in Table 33 in Appendix A. We request comment on the methods and estimates in this section.

The one-time cost to domestic establishments for the written procedure requirements for this subpart is estimated to be between $2.4 million and $5.9 million; the annual cost is estimated to be between $0.9 million and $2.3 million (Table 20c).

We assume that for all proposed written procedure requirements, training would also be needed. We estimate that, for each proposed requirement where additional training is necessary, one manager would be required to conduct training for every ten workers who are trained. For the proposed requirements where additional training is necessary, there would also be costs associated with training records. We estimate the cost of preparing a training record at 0.05 hours (three minutes). We estimate one-time labor hours to comply with the training requirements for this subpart range from 0.5 to six hours. The one-time cost to domestic manufacturers for the training requirements for this subpart is estimated to be between $3.3 million and $10.6 million (in Table 20c, sum of employee training, training by manager and record of training)

We estimate that, in addition to written procedure and training costs, some manufacturers may need to exert additional effort beyond current practice, especially in those activities related to pest control (§ 1120.34). In our food expert elicitation, it was estimated that roughly 95 percent of all food processing facilities contract out pest control (Ref. R34). We assume that five percent of the tobacco product manufacturers do not already conduct pest control activities as outlined in the proposed rule and would have to start conducting these activities on a regular basis. We estimate that the pest control activities can be outsourced to a 3rd party at an annual cost of $3,100 to $123,600 ($15,500 to $236,900) per small and non-small domestic manufacturers, respectively (Refs. R34, R35).

Table 20c. — Costs to Domestic Manufacturers of Subpart C: Buildings, Facilities and Equipment (n=752 establishments) (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Written Procedure	$2,433,164	$4,185,033	$5,936,902	$875,934	$1,576,816	$2,277,698
Employee Training	$1,794,150	$3,588,299	$6,372,976	$0	$0	$0

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Training by Manager	$1,186,650	$2,373,299	$3,947,471	$0	$0	$0
Record of Training	$280,989	$280,989	$280,989	$0	$0	$0
3rd Party Pest Control	$0	$0	$0	$405,781	$6,665,648	$12,925,515
Non-Small (n=51)	$1,244,477	$2,336,615	$4,063,667	$216,157	$1,232,841	$2,249,526
Cost/Non-Small Est.	$24,568	$46,129	$80,225	$4,267	$24,339	$44,410
Small (n=701)	$4,450,476	$8,091,006	$12,474,671	$1,065,558	$7,009,623	$12,953,687
Cost/ Small Est.	$6,349	$11,543	$17,797	$1,520	$10,000	$18,480
Total	$5,694,953	$10,427,621	$16,538,338	$1,281,715	$8,242,464	$15,203,213

In estimating costs of written procedure and training requirements to foreign manufacturers, we use the same assumptions used in estimating costs for domestic establishments (except for wages) in Table 20b.

In estimating pest control costs for foreign countries, we assume that the costs for pest control services are 80 percent labor and 20 percent capital costs. Our foreign wage estimates across four different occupations are on average about 15 percent of domestic wages. We therefore estimate that for $3,100 in pest control services, that about 20 percent (or $620) are capital costs but labor costs would be proportional to the difference in our average wage estimates. Adjusting for the difference in wages, we estimate costs for 3rd party pest control services as ($3,100 x 0.2 in capital costs) + ($3,100*0.8 x 0.15 in labor costs) would be equivalent to $992 or approximately $1,000. We therefore estimate that pest control activities in foreign countries can be outsourced to a 3rd party at an annual cost of $1,000 to $40,000 ($5,000 to $74,000) for small and non-small foreign manufacturers, respectively. The annual cost to foreign establishments for the pest-control-related requirements for this subpart is estimated to be between $0.2 million and $7.0 million (Table 20d).

Table 20d.— Costs to Foreign Manufacturers of Subpart C: Buildings, Facilities and Equipment (n=1,271 establishments) (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Written Procedure	$560,671	$964,353	$1,368,034	$201,841	$363,344	$524,847
Employee Training	$400,727	$801,454	$1,423,418	$0	$0	$0
Training by Manager	$173,294	$346,589	$576,476	$0	$0	$0
Record of Training	$41,035	$41,035	$41,035	$0	$0	$0
3rd Party Pest Control	$0	$0	$0	$219,604	$3,593,692	$6,967,780
Non-Small (n=86)	$255,244	$485,729	$847,981	$90,928	$605,195	$1,119,462
Cost/Non-Small Est.	$2,980	$5,670	$9,899	$1,061	$7,065	$13,068
Small (n=1,185)	$920,483	$1,667,701	$2,560,981	$330,516	$3,351,841	$6,373,166
Cost/ Small Est.	$776	$1,407	$2,160	$279	$2,827	$5,376
Total	**$1,175,728**	**$2,153,430**	**$3,408,962**	**$421,445**	**$3,957,036**	**$7,492,627**

5. Subpart D Costs

Subpart D of the proposed rule involves requirements for design and development activities (§ 1120.42) and master manufacturing records (§ 1120.44). The tasks outlined in subpart D include the following items:

- Proposed § 1120.42 would require manufacturers to establish and maintain procedures to control the design and development of each finished and bulk tobacco product and its package, including the control of risks associated with the product, production process, packing, and storage. To control for risks, manufacturers would be required to conduct a risk assessment – risk identification of all known or reasonably foreseeable risks associated with the tobacco product and its package, production process, packing, and storage,

including risks normally associated with the use of the tobacco product; risk analysis of the nature and level of risk for each identified known or reasonably foreseeable risk; and risk evaluation of each identified risk to determine the significance of the risk and the type of risk treatment needed. In addition, manufacturers would be required to perform risk treatment to significantly minimize or prevent risks identified that are reasonably likely to occur and that may cause serious illness, injury, or death not normally associated with the use of the tobacco product, or that the manufacturer determines constitutes an unacceptable level of risk as well as to address risks for any applicable tobacco product standards to ensure that the tobacco product will conform to the specifications and requirements established in the tobacco product standard. Finally, manufacturers would be required to conduct a risk reassessment whenever the manufacturer becomes aware of new information that could change the risks assessment and risk treatment, including information about previously unidentified risks or the adequacy of risk treatment measures. Manufacturers would also be required to perform design verification and validation of all finished and bulk products first commercially marketed or modified after the rule's effective date. Manufacturers would maintain records of all activities required under this section.

- Proposed § 1120.44 would require that manufacturers establish and maintain a master manufacturing record for each tobacco product manufactured. Manufacturers would also establish and maintain procedures for the review and approval of the master manufacturing record.

We summarize estimated one-time and annual costs per proposed requirement in Table 21a. Domestic one-time and annual costs range from $2.7 to $5.6 million and $0.8 to $1.7 million respectively. Cost estimates are laid out in more detail in Table 4 of Appendix A and Table 4 of

Appendix B for domestic and foreign costs, respectively. We request comment on the methods and estimates in this section.

Table 21a.— Costs to Domestic and Foreign Manufacturers of Subpart D: Design and Development Controls (2020 U.S. Dollars)

Requirement	One Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Domestic Manufacturers						
§1120.42 Design and development activities	$2,094,419	$3,122,844	$4,151,269	$640,689	$961,034	$1,281,378
§1120.44 Master manufacturing record	$642,422	$1,063,515	$1,484,609	$139,960	$272,044	$404,128
Subpart D - Domestic Costs	**$2,736,840**	**$4,186,359**	**$5,635,878**	**$780,649**	**$1,233,077**	**$1,685,506**
Foreign Manufacturers						
§1120.42 Design and development activities	$449,588	$671,638	$893,689	$147,633	$221,450	$295,267
§1120.44 Master manufacturing record	$131,370	$220,886	$310,402	$30,009	$58,385	$86,760
Subpart D - Foreign Costs	$580,958	$892,524	$1,204,091	$177,642	$279,835	$382,027
Total Costs - Subpart D	***$3,317,798***	***$5,078,884***	***$6,839,969***	***$958,291***	***$1,512,912***	***$2,067,533***

Table 21b provides a detailed breakdown of the values or distribution used to estimate the compliance costs of subpart D, along with sources for this information.

Table 21b.— Value or Distribution Used in Cost Calculations—Subpart D

Cost Calculation Item	*Value or Distribution Used*	*Source*
Hourly Wage Rate	Domestic General and Operations Manager ($103) Production Manager ($125) Production Operations ($49) Foreign General and Operations Manager ($14) Production Manager ($11) Production Operations ($6)	*See Table 15*

Cost Calculation Item	*Value or Distribution Used*	*Source*
Additional Time for Manufacturing Activities such as Review	Small Manufacturers (1 to 3 hours per week) Non-Small Manufacturers (2 to 6 hours per week)	*Eastern Research Group (Refs. R33-R35)*
Time for Training	2 to 4 hours	*Eastern Research Group (Refs. R33-R35)*
Time for Records	0.05 hours (3 minutes)	*Eastern Research Group (Refs. R33-R35)*
Set-up Time for Procedures	Small Manufacturers (2 to 6 hours) Non-Small Manufacturers (4 to 12 hours)	*Eastern Research Group (Refs. R33-R35*
Annual Time Required for Procedures	Small Manufacturers (1 to 3 hours) Non-Small Manufacturers (2 to 4 hours)	*Eastern Research Group (Refs. R33-R35)*

Using FDA inspection reports and exhibits we estimate that, depending on the requirement, 25-56% of small manufacturers and 11-31% of non-small manufacturers lack the requirements set forth in subpart D. We estimate one-time labor hours to comply with written procedure requirements for this subpart to range from two to six hours for small manufacturers and four to twelve hours for non-small manufacturers.

Costs of this subpart would be incurred by an estimated 1,370 domestic and 2,316 foreign establishments. Tables 21c and 21d summarize costs to domestic and foreign establishments, respectively. Both tables break down the costs of this subpart by requirements, training requirements and master manufacturing record requirements. Costs are also broken down by costs incurred to small and non-small manufacturers. A detailed explanation of these costs estimates is laid out in Table 44 in Appendix A (domestic costs) and Table 4 in Appendix B (foreign costs). We request comment on the methods and estimates in this section.

We estimate annual labor hours for this subpart to range from one to three hours for small manufacturers and two to four hours for non-small manufacturers. The one-time cost to domestic manufacturers for the written procedure requirements for this subpart is estimated to be between

$1.5 million and $3.2 million; the annual cost is estimated to be between $0.7 million and $1.6 million (Table 21c).

We assume that for most proposed written procedure requirements, training would also be needed. We estimate that, for each proposed requirement where additional training is necessary, one manager would be required to conduct training for every ten workers who are trained. We estimate one-time labor hours to comply with the training requirements for this subpart range from two to four hours. For the proposed requirements where additional training is necessary, there would be costs associated with training records. We estimate the cost of preparing a training record at 0.05 hours. The one-time cost to domestic manufacturers for the training requirements for this subpart is estimated to be between $1.2 million and $2.4 million (Table 21c).

We estimate that, in addition to written procedure and training costs, some manufacturers may need to exert additional effort beyond current practice, especially for those activities related to the review and approval of the master manufacturing record (§1120.44). Our food GMP survey indicates that approximately 90% of all food processing facilities maintain production records (Ref. R34). We use this as a proxy for the percent of manufacturers that already review and approve master manufacturing records and assume that 10% of tobacco product manufacturers would have to start doing so on an annual basis. We estimate that these tasks would take between one and three hours annually for small manufacturers and between two and four hours annually for non-small manufacturers. The annual cost for these tasks is estimated to be between $26,000 and $75,000 (Table 21c). We request comment on the frequency in which tobacco manufacturers would need to update, review, and approve master manufacturing records.

Table 21c.— Subpart D Costs- Domestic Manufacturers: Design and Development Controls including Risk Management (n= 1,370 establishments) (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Written Procedure	$1,508,165	$2,371,788	$3,235,412	$754,083	$1,182,099	$1,610,116
Employee Training	$698,455	$1,047,683	$1,396,910	$0	$0	$0
Training by Manager	$473,337	$710,005	$946,673	$0	$0	$0
Record of Training	$56,883	$56,883	$56,883	$0	$0	$0
MMR Review and Approval	$0	$0	$0	$26,566	$50,978	$75,390
Non-Small (n=74)	$426,895	$640,610	$854,326	$81,331	$121,996	$162,662
Cost/Non-Small Est.	$5,775	$8,666	$11,557	$1,100	$1,650	$2,200
Small (n=1,296)	$2,309,945	$3,545,749	$4,781,552	$699,318	$1,111,081	$1,522,845
Cost/ Small Est.	$1,783	$2,736	$3,690	$540	$857	$1,175
Total	**$2,736,840**	**$4,186,359**	**$5,635,878**	**$780,649**	**$1,233,077**	**$1,685,506**

We summarize one-time and annual costs to foreign establishments according to written procedure, training and master manufacturing record requirements for this subpart in Table 21d. One-time and annual costs to foreign manufacturers range from $0.6 million to $1.2 million and $0.2 million and $0.4 million respectively (Table 21d). Detailed cost tables to foreign manufacturers of this subpart are laid out in Appendix B, Table 44.

Table 21d.— Subpart D Costs- Foreign Manufacturers: Design and Development Controls including Risk Management (n= 2,316 establishments) (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Written Procedure	$347,525	$546,529	$745,532	$173,762	$272,390	$371,017

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Employee Training	$156,001	$234,002	$312,003	$ -	$ -	$ -
Training by Manager	$69,125	$103,687	$138,249	$ -	$ -	$ -
Record of Training	$8,307	$8,307	$8,307	$ -	$ -	$ -
MMR Review and Approval	$ -	$ -	$ -	$3,880	$7,445	$11,010
Non-Small (n=125)	$91,368	$137,732	$184,096	$18,377	$27,566	$36,755
Cost/Non-Small Est.	$731	$1,102	$1,473	$147	$220	$294
Small (n=2,191)	$489,590	$754,792	$1,019,995	$159,265	$252,268	$345,272
Cost/ Small Est.	$223	$344	$465	$73	$115	$158
Total	$580,958	$892,524	$1,204,091	$177,642	$279,835	$382,027

6. Subpart E Costs

Subpart E of the proposed rule involves proposed requirements for purchasing controls (§ 1120.62), acceptance activities (§ 1120.64), production and process controls (§ 1120.66), laboratory controls (§ 1120.68), production records (§ 1120.70), sampling (§ 1120.72), nonconforming tobacco products (§ 1120.74), returned tobacco products (§ 1120.76), and reprocessing and rework (§ 1120.78). The tasks outlined in subpart E include the following items:

- Proposed § 1120.62 would require manufacturers to establish and maintain purchasing procedures, purchasing records, and procedures for qualifying its suppliers.
- Proposed § 1120.64 would require manufacturers to establish and maintain procedures for acceptance activities. The written procedures would also be required to contain procedures and records for ensuring that each accepted incoming tobacco product is designated by a unique identifier, which must be maintained throughout the manufacturing process and

documented in the production record. Any equipment costs associated with this section are included in the estimates for proposed §1120.66.

- Proposed § 1120.66 would require manufacturers to establish and maintain production and procedures that describe the process specifications and process controls used in the manufacturing of tobacco products. Process controls include monitoring and acceptance activities such as inspection, testing, evaluation, or other verification activities. The procedures should also address removal of manufacturing material if it could reasonably be expected to have an adverse effect on the product, if applicable; changes to a production process; and process validation procedures to demonstrate that the process will be maintained in a state of control to ensure that tobacco products conform to their established specifications and other requirements when it cannot be fully verified that tobacco product characteristic conforms to the MMR.
- Proposed § 1120.68 would require manufacturers to establish and maintain procedures for any laboratory controls employed to satisfy requirements in the proposed rule. The procedures are to require the use of scientifically valid laboratory methods that are accurate, precise, and appropriate for its intended use, sampling plans that comply with § 1120.72 of the proposed rule, and documentation of analytical control. Manufacturers would also be required to demonstrate the lab's competence to perform laboratory activities associate with the manufacturer of finished or bulk tobacco products.
- Proposed § 1120.70 would require manufacturers to establish and maintain procedures for the preparation of a production record for each manufactured tobacco product batch.
- Proposed § 1120.72 would require manufacturers to have an adequate sampling plan using representative samples.

- Proposed § 1120.74 would require manufacturers to establish and maintain procedures to control and disposition of nonconforming tobacco products. These procedures include identification and segregation of the nonconforming products; investigation of all potentially nonconforming products and determination of the scope and cause of the nonconformance and the risk of illness or injury posed by the nonconformance; and a determination of the disposition and needed follow up of all nonconforming products.
- Proposed § 1120.76 would require manufacturers to establish and maintain procedures for the control and disposition of returned products. These procedures should address identification, segregation, evaluation, and disposition of returned products. Returned products must be segregated in a manner that prevents mix-ups and use of returned products prior to evaluation and disposition. Returned product must be evaluated to determine if the product can be reworked or released for distribution.
- Proposed §1120.78 would require manufacturers to establish and maintain procedures for reprocessing and reworking tobacco products. These procedures require that a designated individual(s) evaluate to determine whether tobacco products may be reprocessed or reworked; processes used to ensure tobacco products containing reprocessed and reworked meet the specifications in the master manufacturing record; and that a record of any reprocessing or rework is kept in the production record.

We provide cost estimates of one-time and annual costs broken down by proposed requirement in Table 22a. One-time costs to domestic manufacturers range from $14.1 million to $26.2 million and annual costs range from $9.6 and $28.8 million. One-time costs to foreign manufacturers range from $9.4 million to $11.9 million and annual costs range from $1.5 and $4.5 million. Costs estimates for this subpart are laid out in more detail, in Appendix A, Table 5 and Appendix B

Table 5 for foreign manufacturers. We request comment on the methods and estimates in this section.

Table 22a.— Subpart E Costs- Purchasing Controls, Acceptance Activities and Process Controls (2020 U.S. Dollars)

Requirement	One Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Domestic Manufacturers						
§1120.62 Purchasing controls	$2,692,456	$4,128,586	$5,564,717	$220,910	$441,821	$662,731
§1120.64 Acceptance activities	$1,819,700	$2,973,641	$4,127,582	$1,652,430	$3,304,860	$4,957,290
§1120.66 Production processes and controls	$2,307,003	$3,522,764	$4,738,526	$1,662,043	$3,324,087	$4,986,130
§1120.68 Laboratory controls	$4,485,275	$4,738,095	$4,990,915	$1,440,569	$2,881,138	$4,321,706
§1120.70 Production record	$330,536	$640,621	$1,064,165	$1,479,742	$2,959,484	$4,439,225
§1120.72 Sampling	$1,028,272	$1,676,720	$2,325,167	$150,095	$300,190	$450,286
§1120.74 Nonconforming tobacco product	$461,604	$755,137	$1,048,671	$1,450,857	$2,901,714	$4,352,571
§1120.76 Returned tobacco product	$493,787	$806,039	$1,118,290	$1,454,230	$2,908,459	$4,362,689
§1120.78 Reprocessing and rework	$524,798	$856,569	$1,188,339	$77,295	$154,590	$231,886
Subpart E - Domestic Costs	**$14,143,431**	**$20,098,172**	**$26,166,372**	**$9,588,172**	**$19,176,343**	**$28,764,515**
Foreign Manufacturers						
§1120.62 Purchasing controls	$517,101	$800,711	$1,084,321	$50,904	$101,808	$152,712
§1120.64 Acceptance activities	$356,936	$593,920	$830,904	$264,186	$528,371	$792,557
§1120.66 Production	$1,019,595	$1,270,869	$1,522,144	$266,401	$532,802	$799,203

Requirement	One Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
processes and controls						
§1120.68 Laboratory controls	$6,988,753	$7,040,750	$7,092,748	$215,367	$430,734	$646,100
§1120.70 Production record	$69,320	$135,653	$223,012	$224,393	$448,787	$673,180
§1120.72 Sampling	$203,204	$337,088	$470,971	$34,586	$69,173	$103,759
§1120.74 Nonconforming tobacco product	$90,206	$150,329	$210,452	$217,738	$435,475	$653,213
§1120.76 Returned tobacco product	$97,223	$161,522	$225,822	$218,515	$437,029	$655,544
§1120.78 Reprocessing and rework	$103,366	$171,703	$240,040	$17,811	$35,622	$53,433
Subpart E - Foreign Costs	**$9,445,703**	**$10,662,546**	**$11,900,414**	**$1,509,900**	**$3,019,801**	**$4,529,701**
Total Costs - Subpart E	**$23,589,134**	**$30,760,718**	**$38,066,786**	**$11,098,072**	**$22,196,144**	**$33,294,216**

Table 22b provides a detailed breakdown of the values or distribution used to estimate the compliance costs of Subpart E, along with sources for this information.

Table 22b.— Value or Distribution Used in Cost Calculations—Subpart E

Cost Calculation Item	*Value or Distribution Used*	*Source*
Hourly Wage Rate	Domestic: General and Operations Manager ($103) Production Manager ($126) Production Operations ($49) Foreign: General and Operations Manager ($14) Production Manager ($11) Production Operations ($6)	*See Table 15*
Equipment—Production and Laboratory Materials	Small Manufacturers ($3,200—Process Controls; $38,800—Laboratory Controls) Non-Small Manufacturers ($8,000—Process Controls; $77,700 —Laboratory Controls)	*Various (Please see text)*

Cost Calculation Item	*Value or Distribution Used*	*Source*
Additional Time for Manufacturing Activities such as Review, Investigation, Evaluation, Implementation, Testing, or Monitoring	Small Manufacturers (1 to 3 hours per week) Non-Small Manufacturers (2 to 6 hours per week)	*Eastern Research Group (Refs. R33-R35)*
Time for Training	Small Manufacturers (2 to 8 hours) Non-Small Manufacturers (2 to 12 hours)	*Eastern Research Group (Refs. R33-R35)*
Time for Records	0.05 hours (3 minutes)	*Eastern Research Group (Refs. R33-R35)*
Set-up Time for Procedures	Small Manufacturers (2 to 6 hours) Non-Small Manufacturers (4 to 12 hours)	*Eastern Research Group (Refs. R33-R35)*
Annual Time Required for Procedures	Small Manufacturers (1 to 3 hours) Non-Small Manufacturers (2 to 6 hours)	*Eastern Research Group (Refs. R33-R35)*

In estimating the costs to both domestic and foreign manufacturers, we use FDA inspection reports and exhibits. Depending on the requirement, we estimate that 29-69% of small manufacturers and 11-72% of non-small manufacturers have not established procedures that meet the requirements set forth in subpart E. We estimate one-time labor hours to comply with the requirements for this subpart to range from two to six hours for small manufacturers and four to 12 hours for non-small manufacturers. We estimate annual labor hours for this subpart to range from one to three hours for small manufacturers and two to six hours for non-small manufacturers.

Costs of this subpart would be incurred by an estimated 809 domestic and 1,368 foreign establishments. Tables 22c and 22d summarize costs to domestic and foreign establishments respectively. Both tables break down the costs of this subpart by requirement; written procedures, training requirements, requirements for monitoring production operations, requirements involving investigating laboratory findings and nonconformities, reviewing production record requirements, and requirements involving the evaluation and disposition of returned tobacco products. Costs are also broken down by costs incurred to small and non-small manufacturers. Detailed cost estimates incurred by domestic and foreign manufacturers are laid out in Appendix A, Table 55, and

Appendix B, Table 5 respectively. We request comment on the methods and estimates in this section.

The one-time cost to domestic manufacturers for the proposed written procedure requirements for this subpart is estimated to be between $2.6 million and $7.8 million; the annual cost is estimated to be between $1.3 million and $3.9 million (Table 22c).

We assume that for all proposed written procedures requirements, training would also be needed. We estimate that, for each proposed requirement where training is necessary, one manager would conduct training for every ten workers who are trained. We estimate one-time labor hours for training activities related to requirements for this subpart range from 0.5 to 12 hours. For the proposed requirements where training is necessary, there would be costs associated with training records. We estimate the cost of preparing a training record at 0.05 hours (three minutes). The one-time cost for the training requirements to domestic manufacturers for this subpart is estimated to be between $7.1 million and $13.9 million (in Table 22c, sum of training activities).

We estimate that, in addition to establishing and maintaining procedures and training costs, some manufacturers may need to exert additional effort beyond current practice, especially for those activities related to monitoring production operations (§ 1120.66), investigating laboratory findings and nonconformities (§ 1120.68 and § 1120.74), reviewing production records (§ 1120.70), and evaluating and disposition of returned tobacco products (§ 1120.76). In our food GMP survey, it was estimated that all but 20 percent of the very smallest food facilities maintain production records and planned and unplanned process deviation records (Ref. R33). Because so few tobacco manufacturers are very small, we assume that fewer tobacco establishments or only ten percent of tobacco product manufacturers do not already conduct the above-mentioned production activities and would have to start conducting these tasks on a weekly basis. We

estimate that these the tasks would take between one and three hours per week. The annual cost to domestic manufacturers for these activity-related requirements for this subpart is estimated to be between $8.3 million and $24.9 million (in Table 22c, sum of line items 5, 7, 8, 9, 10, and 11).

To conduct activities related to sections § 1120.66 and § 1120.68, some tobacco product manufacturers may purchase capital equipment such as metal detectors, pH meters, thermometers, ultrasonic flow meters, scanners and densimeters. Our food expert elicitation indicates that there has been a trend away from acceptance testing by receiving food processing facilities towards verification procedures and purchasing records from suppliers (Ref. R34), so we assume that only 5% of tobacco product manufacturers will purchase equipment. We estimate that the cost of the equipment that would be purchased for § 1120.66 is $3,500 per small and $8,000 per non-small manufacturer;[56] the cost of the equipment that would be purchased for § 1120.68 is $38,800 per small and $77,700 per non-small manufacturer. The one-time capital cost to domestic manufacturers for this subpart is estimated to be $4 million (Table 22c).[57]

[56] These include the cost of metal detectors, pH meter, and thermometer; our estimates were derived from the following websites:http://www.coleparmer.com/Category/pH_Ion_Benchtop_Meters/7450 and http://www.kellycodetectors.com/catalog/topselling?utm_source=bing&utm_medium=cpc&utm_campaign=Metal%20Detectors%20%28Optimized%29&utm_term=where%20can%20i%20buy%20a%20%2Bmetal%20%2Bdetector&utm_content=Non%20Brand%20Terms-%20BMM%20%28Buy%29. Hyperlinks were last accessed on May 10, 2016.

[57] This includes the cost of laboratory equipment as outlined by B.T.S.(Business Tobacco Supplies) (please see https://www.businesstob.com/en/products/laboratory-equipments; our estimates were derived from the following websites: http://www.instrumentsdirect.com/categories/11490/ultrasonic-flow-meters, http://www.alibaba.com/showroom/densimeter.html, http://www.uline.com/Product/Detail/H-1670BL/Barcode-Equipment/Motorola-Symbol-LS-2208-Corded-USB-Laser-Barcode-Scanner-Black?pricode=WY223&utm_source=Bing&utm_medium=pla&utm_term=H-1670BLQ3&utm_campaign=Bar%2BCode%2BLabels, and http://www.firststreetonline.com/Home+Solutions/Lighting/Lighted+Full+Page+Magnifier.axd?gdffi=9a20428ec1d54934beee1c302c159b51&gdfms=80B9452E3C9846528094BBD8FB5171AD&utm_source=bing&utm_medium=cpc&utm_campaign=ROI+-+Shopping+-+Arts+and+Entertainment&utm_content=Hobbies+&+Creative+Arts&utm_keyword=51-150&utm_id=26143. Hyperlinks were last accessed on January 22, 2019.

Table 22c.— Subpart E Costs- Domestic Manufacturers: Purchasing Controls, Acceptance Activities, Equipment and Process Controls (n= 809 establishments) (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
1. Written Procedure	$2,599,186	$5,198,373	$7,797,559	$1,299,593	$2,599,186	$3,898,779
2. Employee Training	$3,424,057	$5,078,073	$6,789,726	$0	$0	$0
3. Training by Manager	$3,392,054	$5,093,591	$6,850,953	$0	$0	$0
4. Record of Training	$265,114	$265,114	$265,114	$0	$0	$0
5. Acceptance Activities	$0	$0	$0	$1,381,430	$2,762,859	$4,144,289
6. Equipment	$4,463,021	$4,463,021	$4,463,021	$0	$0	$0
7. Control and Disposition of Non-conforming Products.	$0	$0	$0	$1,381,430	$2,762,859	$4,144,289
8. Monitoring and Control	$0	$0	$0	$1,381,430	$2,762,859	$4,144,289
9. Conducting Laboratory Activities	$0	$0	$0	$1,381,430	$2,762,859	$4,144,289
10. Production Record Review	$0	$0	$0	$1,381,430	$2,762,859	$4,144,289
11. Evaluation of Returned Product	$0	$0	$0	$1,381,430	$2,762,859	$4,144,289
Non-small n=57	$2,366,754	$3,223,480	$4,102,787	$1,509,084	$3,018,167	$4,527,251
Cost/entity	$41,378	$56,356	$71,729	$26,383	$52,766	$79,150
Small n=752	$11,776,676	$16,874,691	$22,063,585	$8,079,088	$16,158,176	$24,237,264
Cost/entity	$15,662	$22,442	$29,342	$10,744	$21,489	$32,233
Total	$14,143,431	$20,098,172	$26,166,372	$9,588,172	$19,176,343	$28,764,515

Table 22d provides the same breakdown of the components used to estimate the compliance costs of proposed subpart E for foreign manufacturers as for domestic manufacturers in Table 22c. We estimate that one-time costs to foreign establishments range from $9.4 million and $11.9

million and annual costs range from $1.5 million and $4.5 million. We request comment on the methods and estimates in this section.

Table 22d.— Subpart E Costs- Foreign Manufacturers: Purchasing Controls, Acceptance Activities, Equipment and Process Controls (n=1368 establishments) (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
1. Written Procedure	$598,928	$1,197,855	$1,796,783	$299,464	$598,928	$898,391
2. Employee Training	$764,770	$1,134,198	$1,516,499	$0	$0	$0
3. Training by Manager	$495,364	$743,851	$1,000,490	$0	$0	$0
4. Record of Training	$38,716	$38,716	$38,716	$0	$0	$0
5. Acceptance Activities	$0	$0	$0	$201,739	$403,479	$605,218
6. Equipment	$7,547,925	$7,547,925	$7,547,925	$0	$0	$0
7. Control and Disposition of Non-conforming Products.	$0	$0	$0	$201,739	$403,479	$605,218
8. Monitoring and Control	$0	$0	$0	$201,739	$403,479	$605,218
9. Conducting Laboratory Activities	$0	$0	$0	$201,739	$403,479	$605,218
10. Production Record Review	$0	$0	$0	$201,739	$403,479	$605,218
11. Evaluation of Returned Product	$0	$0	$0	$201,739	$403,479	$605,218
Non-Small (n=97)	$1,580,719	$1,766,054	$1,956,074	$234,305	$468,611	$702,916
Cost/Non-Small Est.	$16,341	$18,257	$20,221	$2,422	$4,844	$7,266

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Small (n=1,272)	$7,864,984	$8,896,492	$9,944,340	$1,275,595	$2,551,190	$3,826,785
Cost/ Small Est.	$6,185	$6,996	$7,820	$1,003	$2,006	$3,009
Total	**$9,445,703**	**$10,662,546**	**$11,900,414**	**$1,509,900**	**$3,019,801**	**$4,529,701**

7. Subpart F Costs

Subpart F of the proposed rule involves proposed requirements for packaging and labeling activities (§ 1120.92), repacking and relabeling activities (§ 1120.94), manufacturing codes on the packaging or label of tobacco products (§ 1120.96), and warning plans for packaging (§ 1120.98). The tasks outlined in subpart F include the following items:

- Proposed § 1120.92 would require manufacturers to establish and maintain procedures to control packaging and labeling activities.[58]
- Proposed § 1120.94 would require manufacturers to establish and maintain procedures to control repackaging and relabeling activities for those establishments engaging in such activities.
- Proposed § 1120.96 would require manufacturers to apply a manufacturing code to the packaging or package label of tobacco products. We lack data on the percentage of manufacturers who apply such codes to the packaging and labeling of tobacco products but based on a cursory review of manufactured products it appears that many, if not all, manufacturers already apply a manufacturing code to their products. Because the code also supplies information that the manufacturer needs for internal quality and distribution purposes, any costs associated with this activity would be private or part of their business

[58] Establish and maintain means to define, document in writing or electronically, implement, follow, and update.

plan. For this reason, we assume that manufacturers are already conducting this activity. We request comment on this assumption.

- Proposed § 1120.98 would require finished tobacco product manufacturers, who are required to comply with a warning plan for tobacco product packaging, to establish and maintain procedures to implement the requirements of such warning plans.

There will be one-time and annual costs to domestic and foreign tobacco manufacturers whose practices are not already in alignment with the proposed requirements. We provide cost estimates of one-time and annual costs broken down by proposed requirement in Table 23a. One-time costs to domestic manufacturers range from $2.2 million to $6.6 million and annual costs range from $0.2 million and $0.6 million. One-time costs to foreign manufacturers range from $0.4 million to $1.3 million and annual costs range from $45,000 and $135,000. A more detailed cost layout can be found in Appendix A, Table 6 and Appendix B Table 6 for foreign manufacturers. We request comment on the methods and estimates in this section.

Table 23a.— Subpart F Costs - Packaging & Labeling Activities (2020 U.S. Dollars)

Requirement	One Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
§1120.92 Packaging and labeling controls	$807,332	$1,274,713	$2,392,896	$70,990	$141,980	$212,971
§1120.94 Repackaging and relabeling	$723,601	$1,141,775	$2,144,329	$62,992	$125,984	$188,976
§1120.98 Warning plans	$694,847	$1,097,139	$2,059,512	$61,125	$122,251	$183,376
Subpart F - Domestic Costs	$2,225,780	$3,513,627	$6,596,737	$195,108	$390,215	$585,323
§1120.92 Packaging and labeling controls	$154,997	$247,791	$460,740	$16,358	$32,716	$49,075
§1120.94 Repackaging and relabeling	$139,525	$222,837	$414,710	$14,515	$29,030	$43,546
§1120.98 Warning plans	$133,376	$213,235	$396,473	$14,085	$28,170	$42,255
Subpart F - Foreign Costs	$427,898	$683,863	$1,271,923	$44,958	$89,917	$134,875
Total	**$2,653,678**	**$4,197,489**	**$7,868,660**	**$240,066**	**$480,132**	**$720,198**

Table 23b provides a detailed breakdown of the values or distribution used to estimate the costs of subpart F, along with sources for this information.

Table 23b.— Value or Distribution Used in Cost Calculations—Subpart F

Cost Calculation Item	*Value or Distribution Used*	*Source*
Hourly Wage Rate	Domestic: General and Operations Manager ($103) Production Operations ($49) Production Manager ($126) Foreign: General and Operations Manager ($14) Production Operations ($11) Production Manager ($6)	*See Table 15*
Time for Training	4 to 12 hours	*Eastern Research Group (Refs. R33-R35)*
Time for Records	0.05 hours	*Eastern Research Group (Refs. R33-R35)*
Set-up Time for Procedures	Small Manufacturers (2 to 6 hours) Non-Small Manufacturers (4 to 12 hours)	*Eastern Research Group (Refs. R33-R35)*
Annual Time Required for Procedures	Small Manufacturers (1 to 3 hours) Non-Small Manufacturers (2 to 6 hours)	*Eastern Research Group (Refs. R33-R35)*

In estimating the costs to both domestic and foreign manufacturers, we use FDA inspection reports and exhibits. Depending on the requirement, we estimate that 29-34 percent of small manufacturers and 23-30 percent of non-small manufacturers lack practices corresponding to the proposed requirements set forth in subpart F. We estimate one-time labor hours to comply with the requirements for this subpart to range from two to six hours for small manufacturers and four to 12 hours for non-small manufacturers. We estimate annual labor hours to comply with the requirements for this subpart to range from one to three hours for small manufacturers and two to six hours for non-small manufacturers.

Costs of this subpart would be incurred by an estimated 588 domestic and 995 foreign establishments. Tables 23c and 23d summarize costs to domestic and foreign establishments

respectively. Both tables break down the costs of this subpart by written procedure requirements and training requirements. Costs are also broken down by costs incurred to small and non-small manufacturers. Detailed estimated costs incurred by domestic and foreign manufacturers are laid out in Appendix A, Table 6, and Appendix B Table 6, respectively. We request comment on the methods and estimates in this section.

The one-time cost to domestic manufacturers for the written procedure requirements for this subpart is estimated to be between $0.4 and $1.2 million; the annual cost is estimated to be between $0.2 million and $0.6 million (Table 23c).

Table 23c.—Subpart F Costs- Domestic Manufacturers: Packaging & Labeling Activities (n= 588 establishments) (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Written Procedure	$390,215	$780,430	$1,170,645	$195,108	$390,215	$585,323
Employee Training	$904,364	$1,356,546	$2,713,092	$0	$0	$0
Training by Manager	$890,899	$1,336,349	$2,672,698	$0	$0	$0
Record of Training	$40,302	$40,302	$40,302	$0	$0	$0
Non-Small (n=46)	$401,617	$625,709	$1,185,896	$28,022	$56,045	$84,067
Cost/Non-Small Est.	$8,821.04	$13,743	$26,047	$615	$1,231	$1,846
Small (n=543)	$1,824,163	$2,887,918	$5,410,841	$167,085	$334,170	$501,255
Cost/Small Est.	$3,360	$5,319	$9,966	$308	$615	$923
Total	**$2,225,780**	**$3,513,627**	**$6,596,737**	**$195,108**	**$390,215**	**$585,323**

We assume that for all proposed written procedure requirements, training would also be needed. We estimate that, for each proposed requirement where training is necessary, one manager would conduct training for every ten workers who are trained. We estimate one-time labor hours to comply with the training requirements for this subpart range from four to 12 hours. For the proposed requirements where training is necessary, there would be costs associated with training

records. We estimate the cost of preparing a training record at 0.05 hours. The one-time cost to domestic facilities for the training requirements for this subpart is estimated to be between $1.8 million and $5.4 million (Table 23c, sum of training activities including record of training)

Table 23d provides the same breakdown of the components used to estimate the compliance costs of proposed subpart F for foreign establishments as for domestic establishments in Table 23c. There would be one-time and annual costs to foreign tobacco manufacturers that are not already in alignment with the proposed requirements. We estimate that one-time costs to foreign establishments range from $0.5 million and $1.3 million and annual costs range from $45,000 to $135,000. We request comment on the methods and estimates in this section.

Table 23d.—Subpart F Costs- Foreign Manufacturers: Packaging & Labeling Activities (n= 995 establishments) ((2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Written Procedure	$89,917	$179,834	$269,751	$44,958	$89,917	$134,875
Employee Training	$201,992	$302,987	$605,975	$0	$0	$0
Training by Manager	$130,104	$195,156	$390,312	$0	$0	$0
Record of Training	$5,886	$5,886	$5,886	$0	$0	$0
Non-Small (n=77)	$84,037	$131,820	$249,342	$6,457	$12,914	$19,372
Cost/Non-Small Est.	$1,091	$1,712	$3,238	$84	$168	$252
Small (n= 918)	$343,861	$552,042	$1,022,581	$38,501	$77,002	$115,504
Cost/ Small Est.	$374	$601	$1,114	$42	$84	$126
Total	**$427,898**	**$683,863**	**$1,271,923**	**$44,958**	**$89,917**	**$134,875**

8. Subpart G Costs

Subpart G of the proposed rule involves proposed requirements for activities associated with handling and storage (§ 1120.102) and distribution (§ 1120.104). The tasks outlined in subpart G include the following items:

- Proposed § 1120.102 would require tobacco product manufacturers to establish and maintain procedures for the handling and storage of all tobacco products.
- Proposed § 1120.104 would require tobacco product manufacturers to establish and maintain procedures for the distribution of finished and bulk tobacco products and to keep distribution records and records of direct accounts.

We provide cost estimates of one-time and annual costs broken down by proposed requirement in Table 24a. One-time costs to domestic manufacturers range from $1.8 million to $3.6 million and annual costs range from $180,000 and $340,000. One-time costs to foreign manufacturers range from $0.9 million to $1.2 million and annual costs range from $40,000 and $79,000. A more detailed cost table showing how we derived these costs estimates can be found in Appendix A, Table 7 and Appendix B Table 7 for foreign manufacturers. We request comment on the methods and estimates in this section.

Table 24a.—Subpart G Costs - Handling, Storage and Distribution (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
§1120.102 Handling and storage	$1,037,348	$1,460,567	$1,883,787	$85,177	$124,087	$162,997
§1120.104 Distribution	$765,833	$1,228,556	$1,691,279	$93,116	$135,646	$178,176
Subpart G - Domestic Costs	**$1,803,181**	**$2,689,124**	**$3,575,066**	**$178,293**	**$259,733**	**$341,173**
§1120.102 Handling and storage	$717,291	$804,924	$892,558	$19,627	$28,593	$37,559
§1120.104 Distribution	$152,602	$248,416	$344,230	$21,457	$31,257	$41,057
Subpart G - Foreign Costs	**$869,893**	**$1,053,340**	**$1,236,787**	**$41,084**	**$59,850**	**$78,616**
Total	**$2,673,074**	**$3,742,464**	**$4,811,853**	**$219,377**	**$319,583**	**$419,789**

Table 24b provides a detailed breakdown of the values or distribution used to estimate the compliance costs of subpart G, along with sources for this information.

Table 24b.— Value or Distribution Used in Cost Calculations—Subpart G

Cost Calculation Item	*Value or Distribution Used*	*Source*
Hourly Wage Rate	Domestic: General and Operations Manager ($103) Production Manager ($126) Production Operations ($49) Foreign: General and Operations Manager ($14) Production Manager ($11) Production Operations ($6)	*See Table 15*
Equipment—Extra Storage Materials or Space	Small Manufacturers ($3,000) Non-Small Manufacturers ($6,000)	*Eastern Research Group (Refs. R34-35)*
Time for Training	2 to 4 hours	*Eastern Research Group (Refs. R34-35)*
Time for Records	3 minutes	*Eastern Research Group (Ref. R34-35)*
Set-up Time for Procedures	Small Manufacturers (2 to 6 hours) Non-Small Manufacturers (4 to 12 hours)	*Eastern Research Group (Ref. R34-35)*
Annual Time Required for Procedures	Small Manufacturers (1 to 2 hours) Non-Small Manufacturers (2 hours)	*Eastern Research Group (Ref. R34-354)*

In estimating the costs to both domestic and foreign manufacturers, we use FDA inspection reports and exhibits. Depending on the requirement, we estimate that 43-47 percent of small manufacturers and 21-27 percent of non-small manufacturers lack procedures that are aligned with proposed requirements set forth in subpart G. We estimate one-time labor hours for this subpart to range from two to six hours for small manufacturers and four to twelve hours for non-small manufacturers. We estimate annual labor hours to comply with the requirements for this subpart to range from one to two hours for small manufacturers and two hours for non-small manufacturers.

Costs of this subpart would be incurred by an estimated 587 domestic and 992 foreign establishments. Tables 24c and 24d summarize costs to domestic and foreign establishments respectively. Both tables break down the costs of this subpart by written procedure requirements, training requirements, and equipment requirements. Costs are also broken down by costs incurred to small and non-small manufacturers. Detailed estimated costs incurred by domestic and foreign manufacturers are laid out in Appendix A, Table 7, and Appendix B, Table 7 respectively. We request comment on the methods and estimates in this section. The one-time cost to domestic manufacturers for the written procedure requirements for this subpart is estimated to be between $356,000 and $1.1 million; the annual cost is estimated to be between $180,000 and $340,000 (Table 24c).

We assume that for all proposed written procedure requirements, training would also be needed. We estimate that, for each proposed requirement where training is necessary, one manager would conduct training for every ten workers who are trained. For the proposed requirements where training is necessary, there would be costs associated with training records. We estimate the cost of preparing a training record at 0.05 hours. We estimate one-time labor hours to comply with the training requirements for this subpart range from two to four hours. The one-time cost to domestic establishments for the training requirements for this subpart is estimated to be between $1.1 million and $2.2million (Table 24c, sum of training related activities including records).

For some manufacturers, proposed section §1120.102 may result in the purchase of additional capital equipment to protect against contamination. We lack the information that would allow us to precisely estimate the number of manufacturers that may need to purchase equipment. However, our food GMP survey indicates that 95% of food processing establishments include proper storage plans in their food safety plan (Ref. R33). We use this information to assume that five percent of

tobacco product manufacturers would need to purchase equipment to align with the proposed requirements for this subpart (e.g., to separate or contain incoming raw materials or in-process and final products). We estimate that the cost of the equipment that would need to be purchased is $3,200 ($6,400) per small and non-small manufacturer, respectively (PCHF RIA) (80 FR 55907). The one-time capital cost to domestic manufacturers for this subpart is estimated to be about $337,000 (in Table 24c).

Table 24c.—Subpart G Costs- Domestic Manufacturers: Handling, Storage and Distribution (n= 587 establishments) (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Written Procedure	$356,586	$713,171	$1,069,757	$178,293	$259,733	$341,173
Employee Training	$620,160	$930,241	$1,240,321	$0	$0	$0
Training by Manager	$438,554	$657,831	$877,107	$0	$0	$0
Record of Training	$50,964	$50,964	$50,964	$0	$0	$0
Equipment	$336,918	$336,918	$336,918	$0	$0	$0
Subtotal Non-small (n=28)	$288,558	$415,482	$542,407	$15,412	$15,412	$15,412
Cost/ non-small est.	$10,347	$14,899	$19,450	$553	$553	$553
Subtotal Small (n= 559)	$1,514,623	$2,273,641	$3,032,660	$162,880	$244,321	$325,761
Cost/small est.	$2,711	$4,070	$5,428	$292	$437	$583
Total	**$1,803,181**	**$2,689,124**	**$3,575,066**	**$178,293**	**$259,733**	**$341,173**

Table 24d provides the same breakdown of the components used to estimate costs of the proposed subpart G for foreign establishments as for domestic establishments in Table 24c. We estimate that one-time costs to foreign establishments range from $0.9 million to $1.2 million and annual costs range from $41,000 to $79,000. We request comment on the methods and estimates in this section.

Table 24d.—Subpart G Costs- Foreign Manufacturers: Handling, Storage and Distribution (n= 992 establishments) (2020 U.S. Dollars)

Requirement	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Written Procedure	$82,168	$164,335	$246,503	$41,084	$59,850	$78,616
Employee Training	$138,514	$207,771	$277,028	$0	$0	$0
Training by Manager	$64,045	$96,067	$128,090	$0	$0	$0
Record of Training	$7,443	$7,443	$7,443	$0	$0	$0
Equipment	$577,724	$577,724	$577,724	$0	$0	$0
Subtotal Non-small (n=47)	$142,377	$169,478	$196,579	$3,551	$3,551	$3,551
Cost/ non-small est.	$3,019	$3,593	$4,168	$75	$75	$75
Subtotal Small (n= 945)	$727,516	$883,862	$1,040,208	$37,532	$56,299	$75,065
Cost/small est.	$770	$935	$1,101	$40	$60	$79
Total	**$869,893**	**$1,053,340**	**$1,236,787**	**$41,084**	**$59,850**	**$78,616**

9. Subpart H Costs

Proposed subpart H of the proposed rule involves proposed general recordkeeping and document control requirements (§ 1120.122). The proposed requirements outlined in subpart H include the following:

- Proposed § 1120.122(a) would establish general requirements that apply to all documents and records required under proposed part 1120. Proposed § 1120.122(a) would require that documents and records required under proposed part 1120 be written in English, or an accurate English translation must be made available upon request. All documents and records required by proposed part 1120, that are associated with a batch of finished or bulk tobacco product, must be retained for a period of not less than 4 years from the date of

distribution of the batch or until the product reaches its expiration date if one exists, whichever is later. Documents and records not associated with a batch must be retained for not less than 4 years from the date they were last in effect. Furthermore, all documents and records required under proposed part 1120 must be maintained at the manufacturing establishment or another location that is readily accessible to responsible officials of the tobacco product manufacturer and to FDA. FDA interprets "readily accessible" to FDA as the documents and records being made available to FDA upon request within the course of an inspection.

- Proposed § 1120.122 (b) would require that records required under the proposed rule are attributable, legible, contemporaneously recorded, original, and accurate.
- Proposed § 1120.122(c) would require tobacco product manufacturers to establish and maintain procedures to control all documents established to meet requirements under proposed part 1120.

We assume that manufacturers are already conducting activities under § 1120.122(a) and § 1120.122 (b). To the extent that manufacturers must make records available to FDA for inspection or reproduction purposes, manufacturers may incur additional retrieval costs per record. However, the costs of retrieving one or more additional records from any number of records are part of the private costs for records retention which are determined by a firm's business plan. Thus, any potential costs to manufacturers from this requirement would be negligible. We request comment on this assumption.

We provide cost estimates of one-time and annual costs for proposed § 1120.122(c) in Table 25a. One-time costs to domestic manufacturers range from $246,000 to $737,000 and annual costs range from $123,000 and $251,000.

Table 25a provides a summarized breakdown of the requirements of this subpart of the costs to foreign establishments. As stated under § 1120.122(a)(1), all documents and records would be required to be written in English, or an accurate English translation must be made available upon request. Accounting for the lack of English proficiency and internet access, we estimate that for any activity that requires learning or translating something to English, that for every hour used by a domestic establishment, a foreign establishment would require 2.13 hours on average (see Tables 16 and 17 for how we derived this estimate). We estimate one-time costs to foreign establishments for this subpart to range from $121,000 to $362,000 and annual costs to range from $60,000 and $123,000. We request comments on the methods and estimates in this section.

A more detailed cost table showing how we derived these costs estimates can be found in Appendix A, Table 8 for domestic manufacturers and Appendix B, Table 8 for foreign manufacturers. We request comment on the methods and estimates in this section.

Table 25a.— Subpart H Costs- Records and Document Controls (2020 U.S. Dollars)

Requirement § 1120.122 (c)	**One-Time Cost**			**Recurring Annual Cost**		
	L	M	H	L	M	H
Subtotal Domestic Non-small (n=24)	$10,508	$21,017	$31,525	$5,254	$10,508	$15,763
Cost/ non-small est.	$62	$123	$185	$31	$62	$92
Subtotal Domestic Small (n= 1,153)	$235,272	$470,544	$705,815	$117,636	$176,454	$235,272
Cost/small est.	$133	$267	$400	$67	$100	$133
Subpart H Domestic	**$245,780**	**$491,560**	**$737,341**	**$122,890**	**$186,962**	**$251,034**
Subtotal Foreign Non-small (n=41)	$5,156	$10,311	$15,467	$2,578	$5,156	$7,734
Cost/ non-small est.	$119	$238	$357	$60	$119	$179
Subtotal Foreign Small (n= 1,950)	$115,431	$230,861	$346,292	$57,715	$86,573	$115,431
Cost/small est.	$59.52	$119	$179	$30	$45	$60

Requirement § 1120.122 (c)	One-Time Cost			Recurring Annual Cost		
	L	M	H	L	M	H
Subpart H Foreign	**$120,586**	**$241,173**	**$361,759**	**$60,293**	**$91,729**	**$123,164**
Total	**$366,366**	**$732,733**	**$1,099,099**	**$183,183**	**$278,691**	**$374,199**

Table 25b provides a detailed breakdown of the values or distribution used to estimate the compliance costs of section 1120.122(c), along with sources for this information.

Table 25b.— Values Used in Cost Calculations—Subpart H

Cost Calculation Item	***Value or Distribution Used***	***Source***
Hourly Wage Rate	Domestic: General and Operations Manager ($103) Foreign: General and Operations Manager ($14)	*See Table 15*
Set-up Time for Procedures	Domestic: Small Manufacturers (2 to 6 hours) Non-Small Manufacturers (4 to 12 hours) Foreign: Small Manufacturers (4 to 13) Non-Small Manufacturers (9 to 26 hours)	*Eastern Research Group (Refs. R33-R35)* *See Tables 16 & 17**
Annual Time Required for Procedures	Domestic: Small Manufacturers (1 to 2 hours) Non-Small Manufacturers (2 to 6 hours) Foreign: Small Manufacturers (2 to 4 hours) Non-Small Manufacturers (4 to 13 hours)	*Eastern Research Group (Refs. R33-R35)* *See Tables 16 & 17**

* From Tables 16 and 17, the average of both weighted sums of 1.8 hours to account for differences in English proficiency and of 2.4 hours to account for differences in internet usage give us a single estimate of 2.13 ((1.8 hours + 2.4 hours)/2) for foreign manufacturers as equivalent to one hour for domestic manufacturers.

We use FDA inspection reports and exhibits to estimate costs to both domestic and foreign manufacturers. We estimate that 65 percent of small manufacturers and 15 percent of non-small manufacturers do not currently have written procedures that align with the proposed requirements set forth in section 1120.122(c). We estimate one-time labor hours to comply with the requirements for this section to range from two to six hours for small manufacturers and four to 12 hours for non-small manufacturers. We estimate annual labor hours to comply with the

requirements for this section to range from one to two hours for small manufacturers and two to six hours for non-small manufacturers.

10. Subpart J Exemptions and Variances

Subpart J consists of five sections, and it sets forth the proposed procedures and requirements for petitioning for an exemption or variance from a TPMP requirement. Pursuant to section 906(e)(2)(B) of the FD&C Act, this subpart would also establish that a petition for an exemption or variance may be referred to the Tobacco Product Scientific Advisory Committee (TPSAC). In addition, this subpart would describe how FDA would make a determination on a petition for an exemption or variance. This subpart would also provide that the petitioner has an opportunity for a hearing after FDA issues an order respecting a petition for an exemption or a variance. Manufacturers of finished and bulk tobacco products may request an exemption or variance from a TPMP requirement, either on a temporary or permanent basis, by submitting a written request to FDA with certain information, including why the manufacturer is not able to comply with the requirements of this part. For a petition for a variance, manufacturers of finished and bulk tobacco products would need to provide a detailed explanation setting forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the requirements of this part as well as the basis for the petitioner's determination that the proposed methods will be sufficient to assure that the public health is protected and the tobacco product(s) will be in compliance with chapter IX of the FD&C Act. For a petition for an exemption, manufacturers of finished and bulk tobacco products would need to provide a detailed explanation setting forth the basis for its determination that compliance with the requirement(s) is not required to assure that the public health is protected and the tobacco product will be in compliance with chapter IX of the FD&C Act.

We do not know how many manufacturers would pursue petitioning for an exemption or variance from TPMP requirements, nor do we know how many TPMP requirements may be included in each petition. However, we assume that the cost of petitioning for an exemption or variance from a specific TPMP requirement would cost less than the cost of compliance with a specific TPMP requirement. We assume that a manufacturer would petition for an exemption or variance from a TPMP requirement only if compliance with a TPMP requirement is not a financially viable choice compared to the cost of a filing a petition. To the extent that any number of manufacturers are granted a variance or exemption for compliance with a TPMP requirement or requirements, our estimated compliance costs of this proposed rule would be overestimated. We request comment on the number of manufacturers that might petition for a variance or exemption from TPMP requirements.

As a hypothetical example, we estimate the costs of this subpart in terms of the costs of submitting a single petition for variance or exemption. We assume that both a general operations manager and a legal professional would prepare the petition (See Table 15 for wage rates). We also estimate that the amount of time for a manager to prepare this petition would be equivalent to the amount of time estimated to prepare five written procedures (between ten and sixty hours, depending on the size of the establishment) as each petition may address more than one requirement. We estimate that a legal professional would require between two and four hours to review and submit the petition on behalf of the manufacturer. For a domestic manufacturer of finished or bulk tobacco products, one-time costs of submitting a petition for an exemption or variance from a TPMP requirement range from $1,300 to $6,700 (Table 26).

For a foreign manufacturer of finished or bulk tobacco products, we estimate costs by multiplying the estimated number of hours for a general operations manager and legal

professional by 2.13 to adjust for English proficiency (as explained in Section E.1 Measurement of Costs of this analysis). We multiply these adjusted hours for both the manager (approximately 21 to 128 hours) and the legal professional (approximately four to nine hours) by their respective adjusted wage rates of $14/ hour and $12/hour from Table 15. For a foreign manufacturer of finished or bulk tobacco products, one-time costs of submitting a petition for an exemption or variance from a TPMP requirement range from $352 to $1,900 (Table 26). We request comment on the costs to foreign manufacturers that might petition for a variance or exemption from TPMP requirements.

Table 26.— Estimated costs for submitting a petition for an exemption or variance from TPMP (2020 U.S. Dollars)

Petition for exemption or variance	One-Time Cost		
	L	M	H
Domestic	$1,321	$4,033	$6,746
Foreign	$352	$1,123	$1,894

11. Summary of Costs

From Table 27a (domestic) and Table 27b (Foreign), as non-small and small manufacturers represent a respective eight and 92 percent of all manufacturers affected by this rule, we assume that 92 percent of estimated costs correspond to small manufacturers and 8 percent of costs correspond to non-small manufacturers. Because non-small and small manufacturers are assumed to begin working towards compliance with the requirements of this rule in year one and year five respectively, estimated costs begin to accrue for non-small and small manufacturers on year one and year five respectively.

We estimate that one-time costs to domestic manufacturers range from $39 million to $73 million and annual costs range from $15 million to $56 million. The present value of total costs

annualized over ten years using a discount rate of seven percent is estimated to range from $12 million per year and $41 million per year, and from $14 million per year and $43 million per year using a discount rate of three percent. Table 27c shows our summary of the estimated costs to domestic manufacturers of the proposed rule, by requirement.

We also estimate that one-time costs to foreign manufacturers range from $18 million to $25 million and annual costs range from $3 million to $14 million. The present value of total costs annualized over ten years using a discount rate of seven percent is estimated to range from $4 million per year and $11 million per year, and from $4 million per year and $11 million per year using a discount rate of three percent. Table 27d shows our summary of the estimated costs to foreign manufacturers of the proposed rule, by requirement.

Table 27a.— Annual Accrual of Domestically Incurred Costs, Present Value and Annualized Costs over a Ten-year Period (2020 U.S. Dollars)

Year	One time Cost (undiscounted)	Recurring Annual Costs (undiscounted)	Undiscounted Sum	Discount Rate (3 percent)	Discount Rate (7 percent)
1	$10,217,576	$5,389,739	$15,607,315	$15,152,733	$14,586,275
2	$1,864,814	$5,389,739	$7,254,552	$6,838,111	$6,336,407
3	$1,864,814	$5,389,739	$7,254,552	$6,638,943	$5,921,876
4	$1,864,814	$5,389,739	$7,254,552	$6,445,576	$5,534,463
5	$38,423,979	$35,720,125	$74,144,104	$63,957,355	$52,863,721
6	$0	$35,720,125	$35,720,125	$29,915,042	$23,801,827
7	$0	$35,720,125	$35,720,125	$29,043,730	$22,244,699
8	$0	$35,720,125	$35,720,125	$28,197,796	$20,789,438
9	$0	$35,720,125	$35,720,125	$27,376,501	$19,429,381
10	$0	$35,720,125	$35,720,125	$26,579,128	$18,158,300
Present Value				***$240,144,917***	***$189,666,388***
Annualized				***$28,152,310***	***$27,004,227***

Table 27b.— Annual Accrual of Internationally Incurred Costs, Present Value and Annualized Costs over a Ten-year Period (2020 U.S. Dollars)

Year	One-time Cost (undiscounted)	Recurring Annual Costs (undiscounted)	Undiscounted Sum	Discount Rate (3 percent)	Discount Rate (7 percent)
1	$3,988,130	$1,262,771	$5,250,901	$5,097,962	$4,907,384
2	$839,929	$1,262,771	$2,102,700	$1,981,996	$1,836,579
3	$839,929	$1,262,771	$2,102,700	$1,924,268	$1,716,429
4	$839,929	$1,262,771	$2,102,700	$1,868,221	$1,604,139
5	$14,321,046	$5,664,259	$19,985,305	$17,239,500	$14,249,246
6	$0	$8,467,718	$8,467,718	$7,091,580	$5,642,398
7	$0	$8,467,718	$8,467,718	$6,885,029	$5,273,269
8	$0	$8,467,718	$8,467,718	$6,684,495	$4,928,289
9	$0	$8,467,718	$8,467,718	$6,489,800	$4,605,877
10	$0	$8,467,718	$8,467,718	$6,300,777	$4,304,558
Present Value				***$61,794,325***	***$49,549,196***
Annualized				***$7,244,180***	***$7,054,691***

Table 27c.— Summary of Total Quantified Costs, by Subpart: Domestic Manufacturers (2020 U.S. Dollars)

Requirement	One-Time Costs			Recurring Costs (Annual costs)			Annualized Costs Over a 10-Year Period					
							3% Discount Rate			7% Discount Rate		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
Learn About Rule	$10,226,398	$10,226,398	$10,226,398	$0	$0	$0	$1,163,928	$1,163,928	$1,163,928	$1,360,756	$1,360,756	$1,360,756
Subpart B	$1,488,550	$2,603,136	$3,717,722	$3,108,353	$6,231,330	$9,354,307	$2,110,434	$4,188,934	$6,267,435	$1,990,405	$3,947,165	$5,903,925
Subpart C	$5,694,953	$10,427,621	$16,538,338	$1,281,715	$8,242,464	$15,203,213	$1,409,082	$6,272,109	$11,282,549	$1,385,212	$5,994,246	$10,763,201
Subpart D	$2,736,840	$4,186,359	$5,635,878	$780,649	$1,233,077	$1,685,506	$758,094	$1,180,388	$1,602,681	$734,688	$1,142,426	$1,550,165
Subpart E	$14,143,431	$20,098,172	$26,166,372	$9,588,172	$19,176,343	$28,764,515	$7,527,930	$14,208,621	$20,901,072	$7,202,345	$13,525,788	$19,861,461
Subpart F	$2,225,780	$3,513,627	$6,596,737	$195,108	$390,215	$585,323	$352,476	$607,852	$1,049,037	$353,146	$605,478	$1,050,657
Subpart G	$1,803,181	$2,689,124	$3,575,066	$178,293	$259,733	$341,173	$293,324	$430,477	$567,630	$291,892	$427,996	$564,100
Subpart H	$245,780	$491,560	$737,341	$122,890	$186,962	$251,034	$96,617	$160,047	$223,476	$91,440	$152,428	$213,416
Total Costs	**$38,564,913**	**$54,235,996**	**$73,193,851**	**$15,255,179**	**$35,720,125**	**$56,185,071**	**$13,651,840**	**$28,152,310**	**$42,997,763**	**$13,257,827**	**$27,004,227**	**$41,115,624**
Cost share Small(<350 employees)	$34,124,374	$47,718,563	$63,697,662	$13,447,559	$31,543,602	$49,639,644	$11,099,110	$22,684,369	$34,510,800	$10,574,179	$21,323,165	$32,314,251

Table 27d.— Summary of Total Quantified Costs, by Subpart: Foreign Manufacturers (2020 U.S. Dollars)

Requirement	One-Time Costs			Recurring Costs (Annual costs)			Annualized Costs Over a 10-Year Period					
							3% Discount Rate			7% Discount Rate		
	Low	Primary	High	Low	Primary	High	Low	Primary	High	Low	Primary	High
Learn About Rule	$4,606,062	$4,606,062	$4,606,062	$0	$0	$0	$470,942	$470,942	$470,942	$480,399	$480,399	$480,399
Subpart B	$299,721	$536,025	$772,328	$483,091	$969,551	$1,456,011	$333,868	$662,692	$991,516	$315,244	$625,078	$934,913
Subpart C	$1,175,728	$2,153,430	$3,408,962	$421,445	$3,957,036	$7,492,627	$399,554	$2,720,375	$5,070,964	$389,454	$2,574,494	$4,791,896
Subpart D	$580,958	$892,524	$1,204,091	$177,642	$279,835	$382,027	$152,044	$236,400	$320,756	$146,525	$227,515	$308,505
Subpart E	$9,445,703	$10,662,546	$11,900,414	$1,509,900	$3,019,801	$4,529,701	$1,929,301	$2,750,769	$3,703,416	$1,903,464	$2,668,586	$3,565,479
Subpart F	$427,898	$683,863	$1,271,923	$44,958	$89,917	$134,875	$72,519	$127,190	$216,330	$72,479	$126,361	$216,156
Subpart G	$869,893	$1,053,340	$1,236,787	$41,084	$59,850	$78,616	$114,503	$143,987	$173,470	$115,781	$144,974	$174,168
Subpart H	$120,586	$241,173	$361,759	$60,293	$91,729	$123,164	$47,403	$78,523	$109,643	$44,863	$74,785	$104,708
Total Costs	**$17,526,549**	**$20,828,963**	**$24,762,327**	**$2,738,413**	**$8,467,718**	**$14,197,022**	**$3,546,390**	**$7,217,135**	**$11,083,295**	**$3,532,219**	**$6,986,203**	**$10,640,233**
Cost share Small (<350 employees)	$15,534,745	$18,387,992	$21,682,988	$2,404,295	$7,493,145	$12,581,995	$2,954,850	$6,114,728	$9,319,278	$2,888,346	$5,812,676	$8,781,849

12. Government Impacts

The TPMP proposed regulation would benefit FDA's inspection and enforcement efforts by establishing requirements for the manufacture, preproduction design validation, packing, and storage of tobacco products and providing more clarity and transparency for when a finished or bulk tobacco product is adulterated or misbranded, as follows:

- The proposed rule requirements are expected to help minimize or prevent instances of adulteration or misbranding of a tobacco product under sections 902 and 903 of the FD&C Act, respectively.
- The proposed documents (such as MMR) and records (such as acceptance, production, distribution) would help FDA assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. For example, the proposed TPMP requirements would help assure that tobacco products are manufactured in accordance with the specifications provided in their substantial equivalence (SE) reports, exemptions from SE, premarket tobacco applications (PMTAs), and modified risk tobacco product applications (MRTPAs) as applicable, and are in compliance with any applicable tobacco product standards under section 907 of the FD&C Act. In addition, the proposed documents and records would help FDA determine whether grandfathered tobacco products are manufactured to their original specifications and have not undergone any modification that would render them "new" and in violation of the requirements of chapter IX of the FD&C Act because they lack proper marketing authorization. FDA could also determine if a manufacturer has included unauthorized modified risk claims on tobacco product labels or labeling or if product label or labeling is false or misleading or a tobacco product is otherwise misbranded under section 903 of the FD&C Act. Finally, it would

enable FDA to verify that the ingredients of tobacco products are consistent with the listing of ingredients reported to the Agency under section 904(a)(1) of the FD&C Act.

- The proposed documents and records requirements established by TPMP would assist FDA's enforcement efforts. For example, TPMP documents and records can provide evidence of adulteration and misbranding as well as interstate shipment to support a seizure, injunction, or criminal prosecution. In addition, TPMP records can assist with FDA's trace-back investigations to determine the scope and extent of nonconforming tobacco products as well as public health impact of a problem and determine whether a recall is necessary.

FDA anticipated that because of the Deeming Rule, additional tobacco products would be subject to FDA inspection and the requirements established under TPMP. At the same time, government resources and costs needed to perform these additional inspections had already been accounted for under the Deeming Rule. In addition, FDA anticipates that any costs due to an increase of government resources in performing inspections would be negligible. Although additional TPMP records would need to be reviewed, inspections would likely be more efficient with the clearer and more predictable criteria.

F. Analysis of Regulatory Alternatives

We considered four different regulatory options in addition to the proposed option. We estimate costs of regulatory alternatives keeping in mind that FDA is also proposing that any final rule become effective two years after the date the final rule publishes in the *Federal Register* and that manufacturers meeting the definition of small tobacco product manufacturer would be required to comply with the rule four years after the effective date of the final rule (total of six years from the publication date). We estimate cost of all regulatory alternatives as if

they have the same effective and compliance dates as the proposed rule. We assess costs of regulatory alternatives keeping in mind that large manufacturers and small manufacturers would incur costs beginning in a respective time period of one and five years as we did in estimating the costs of the proposed rule.

The four options we consider are: 1) To require manufacturers to implement a complete HACCP system in addition to the requirements of the proposed rule; 2) To expand coverage of this proposed rule to include manufacturers of all tobacco products, including tobacco products for further manufacturing (FFMs) beyond bulk products; 3) To require manufacturers to implement a complete HACCP system instead of the requirements of the proposed rule; and 4) Implement the Tobacco Industry Stakeholder's Proposal for a "Tobacco Product Good Manufacturing Practices Regulation" instead of the proposed rule. Tables 29a, 29b, and 29c show a detailed summary of the costs associated with each regulatory option and the change in the estimated costs relative to those associated with the proposed rule.

1. Require a Complete HACCP System in Addition to the Proposed Rule.

The first regulatory option we considered is requiring tobacco product manufacturers a complete HACCP system in addition to the requirements in the proposed rule. The Agency, however, determined that requiring tobacco product manufacturers to implement TPMP's proposed design and development activities that include a risk management process in addition to a complete HACCP system would be redundant and require additional costs with marginal public health benefits. For this option we estimate one-time and annual costs of implementing a complete HACCP system.[59]

[59] This estimate takes into account that some of the HACCP system elements (e.g., recordkeeping) already included in the proposed rule are not counted twice.

FDA's proposed design and development activities that include a risk management process is flexible to accommodate different types of tobacco products and risk management tools. This approach is also a preventive means to identify and control for potential risks throughout the tobacco product's lifecycle (e.g., during design, manufacturing, storage, distribution, and use of products). An established risk management framework can reduce or eliminate risks associated with each finished and bulk tobacco product and its package, as well as its production process, packing, and storage.

HACCP is a management system, primarily used for food safety, that helps prevent problems from occurring through the analysis and control of physical, chemical, and biological hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.[60] HACCP plans use seven basic principles to identify, evaluate, and control food safety hazards: hazard analysis, critical control point (CCP) identification, establishing critical limits, monitoring procedures, corrective actions, verification procedures, and record-keeping and documentation.

TPMP's proposed design and development controls, that include a risk management process, overlap with HACCP with respect to risks associated with the tobacco product and its production process – physical, chemical, and microbiological hazards. The HACCP requirements to apply the seven principles would require additional costs to establish and maintain HACCP procedures and associated recordkeeping to address physical, chemical, and microbiological hazards, in addition to the costs of TPMP's proposed design and development controls.

To estimate the additional costs of implementing a complete HACCP system we use information from the Regulatory Impact Analysis (RIA) for the Food Safety Modernization Act

[60] HACCP Principles and Application Guidelines, https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines.

(FSMA) Final Rulemaking for Current Good Manufacturing Practice and Hazard Analysis Risk Based Preventive Controls for Human Foods (80 FR 55907), otherwise known as the PC rule for human foods.[61] From Table 1 of the PC rule (80 FR 55907), one-time costs per domestic and foreign facilities are reported as $18,868 and $21,677 per facility, respectively. Annual recurring costs per facility are reported as a respective $3,500 for facilities with 500 or more employees and $6,500 for facilities with less than 500 employees. Annual recurring costs are also estimated as $4,000 for foreign facilities. We adjust per facility costs for foreign facilities to 17 percent of the cost which is roughly the difference in average hourly wages between domestic wages and foreign wages (as discussed in Section E.1 and Table 15)[62]. If this requirement is added, we estimate that the marginal difference in one-time costs would range from $12 million and $14 million and recurring marginal costs would range from $7.2 million to $7.7 million per year.

FDA believes that requiring tobacco product manufacturers to implement a complete HACCP system in addition to the proposed design and development controls that include a risk management process would be redundant and would require additional costs associated with the tobacco product and its production process with marginal public health benefits.

Total one-time and recurring annual costs incurred by both domestic and foreign establishments of regulatory option 1, would range from a respective $76 million to $122 million and $28 million to $81 million. The present value of total costs annualized over ten years using a discount rate of seven percent are estimated to range from $25 million per year and $61 million

[61] Regulatory Impact Analysis-FSMA Final Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (PDF - 1.74MB);)
Federal Register: 80 FR 55907, September 17, 2015;
Docket: FDA-2011-N-0920 available at
https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm469324.htm.

[62] The estimates provided in the PC rule are primary estimates. For our low estimates in this analysis of alternatives, we estimate low estimates as being 10% less than the primary estimate and 10% more for the higher estimate.

per year, and from $26 million per year and $64 million per year using a discount rate of three percent (Tables 29a, 29b, and 29c).

2. Expanding Coverage to Include Other Manufacturers of Tobacco Products for Further Manufacture

The second regulatory alternative we considered is to expand coverage of the proposed rule to all tobacco product manufacturers, including manufacturers of tobacco products for further manufacture (FFMs) beyond bulk products. This includes, but is not limited to, manufacturers of components, parts, additives or ingredients of finished or bulk tobacco products. This approach would apply all of the proposed TPMP requirements to all FFM manufacturers to protect the public health by minimizing the likelihood of the manufacture and distribution of nonconforming FFMs as well as to ensure compliance with Chapter IX of the FD&C Act by assuring that FFMs conform to the specifications in authorized marketing applications, are in compliance with applicable tobacco product standards under section 907 of the FD&C Act, and do not undergo any modification that would render them a "new tobacco product." Using FDA Registration and Product Listing data[63], we estimate that there is a total of 80 domestic FFMs. We estimate 135 foreign FFMs by applying the ratio of domestic FFMs and domestic manufacturers to foreign manufacturers. In our computations, we assume that the size distribution of other FFMs is the same as that of manufacturers of finished and bulk tobacco products. That is, we assume that 91.2% of FFMs are small and 8.8% are non-small manufacturers. We request comment on the estimated number of FFMs, both small and non-small.

[63] Under current guidance, FDA is enforcing the registration and listing requirements for manufacturers of finished tobacco products. However, some manufacturers of tobacco products for further manufacturing (FFMs) have registered with FDA. We use this count of registered establishments to estimate a count of FFMs.

This regulatory alternative would increase one-time costs by between $2.3 million to $4 million and increase annual costs by between $700,000 and $3 million (Table 29c). FDA acknowledges that expanding the scope of TPMP to cover FFM manufacturers would better equip the Agency to know the full details of an FFM's specifications (beyond those established by the finished or bulk tobacco product manufacturer) and production processes. This could help, for example, FDA investigations of nonconforming products produced by suppliers to determine the specific production process or control that caused the nonconformity or better pinpoint the source of FFM contamination. We request comment on whether expanding coverage to all FFMs would cause an increase in benefits above and beyond the rise in costs imposed on tobacco manufacturers.

If coverage is expanded to include all FFMs, we estimate that one-time costs would range from $58 million to $102 million and recurring costs would range from $19 million per year to $73 million per year. The present value of total costs annualized over ten years using a discount rate of seven percent are estimated to range from $17 million per year and $54 million per year, and from $18 million per year and $56 million per year using a discount rate of three percent (Table 29c). Costs by domestic and foreign establishments of this regulatory option are illustrated in Tables 29a and 29b respectively.

3. Require Only a Complete HACCP System Instead of the Proposed Rule

The third regulatory alternative we consider is to reduce the burden on tobacco product manufacturers by requiring only that they implement a complete HACCP system instead of the proposed rule. HACCP is a recognized system used for food safety to identify, evaluate, and control for risks associated with the product and its production process – physical, chemical, and microbiological hazards. If only a complete HACCP system is required, we estimate that one-

time costs would fall by $32 million and $69 million and recurring costs would fall by a range from $7 million and $57 million per year.

FDA decided not to require only a complete HACCP system for all regulated finished and bulk tobacco products because HACCP alone does not address several issues that would provide significant public health benefits.

An established risk management framework can reduce or eliminate not only risks associated with the tobacco product and its production process that are addressed in a complete HACCP system – which includes physical hazards such as NTRMs (e.g., glass, metal, rocks, and stones), chemical hazards such as pesticide residues, and biological hazards such as bacteria, mold, yeast, and microbes – but also risks associated with the design of a tobacco product such as defective batteries in ENDS tobacco products that can cause fires and explosions and risks associated with the package such as an e-liquid package that can be opened by a child and lead to a toxic exposure to nicotine; risks that would not be addressed with a HACCP system. TPMP's proposed design and development controls, that include a risk management process, are important because they can affect the toxicity and addictiveness of tobacco products. In the absence of proper controls to address all potential risks associated with the tobacco product and its production process, including risks associated with the design of a tobacco product, users may be exposed to preventable harms not normally associated with the use of a tobacco product. We believe that the proposed TPMP requirements provide important benefits necessary to assure that the public health is protected that a complete HACCP system alone would not address.

Moreover, requiring only a complete HACCP system would not help ensure that finished and bulk tobacco products conform to its established specifications or that its packaging, labeling, or labels are appropriate and not misbranded. A tobacco product that does not conform to

established specifications or has incorrect packaging, labeling, or labels could increase the tobacco product's risks compared to what would normally be expected from use of the product. For example, packaging or label solvents can transfer from the packaging materials to tobacco products and may render the product adulterated.

This regulatory alternative would also impair FDA's ability to help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. HACCP does not establish the manufacturing controls (e.g., MMR, acceptance activities, production processes and controls, production record, nonconforming tobacco product, distribution record) that would enable FDA to determine if finished and bulk tobacco products are manufactured in accordance with the specifications provided in their applications authorized by FDA, or are in compliance with tobacco product standards under section 907 of the FD&C Act. Lack of manufacturing control records would impair the tobacco manufacturer's and FDA's ability to investigate the scope and cause of nonconforming tobacco products and take appropriate corrective action such as a recall.

We request comment on whether requiring only a complete HACCP system would be sufficient for manufacturers to maintain a state of control in the manufacture, preproduction design validation, packing, and storage operations comparable to the state of control that would be generated by the complete set of the proposed rule's requirements.

If a complete HACCP system is the only requirement, we estimate that one-time costs would range from $24 million and $29 million and recurring costs would range from $11 million $13 million per year. The present value of total costs annualized over ten years using a discount rate of seven percent are estimated to range from $9.2 million and $11.9 million per year, and from

$9.4 million to $12.1 million per year using a discount rate of three percent (Tables 29a, 29b, and 29c).

4. Implement the Tobacco Industry Stakeholders' Proposal for a Tobacco Product Good Manufacturing Practice

The fourth regulatory alternative we considered to reduce the burden on tobacco product manufacturers is to implement the tobacco industry stakeholders' (companies') proposal for a tobacco product good manufacturing practice (proposed cGMP), submitted to CTP on January 10, 2012, and supplemented on June 7, 2017. Twelve companies and organizations, representing large and small cigarette, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco companies submitted the 2012 cGMP proposal. Thirteen companies and organizations representing large and small cigarette, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and ENDS product companies submitted the 2017 supplement to the 2012 cGMP proposal. FDA is proposing many requirements similar to those included in the industry proposal (IP), particularly in the areas of personnel; contamination prevention; requirements for buildings, facilities, and equipment; development of an MMR; purchasing controls; process controls; production records; procedures for nonconforming tobacco product; complaints; packaging and labeling; distribution; and document control procedures. However, FDA's proposal deviates from the IP in several ways, as discussed in NPRM Section III.C ("Development of the Proposed Regulation"). This regulatory option would forgo many of the benefits that would be generated by the other requirements of the proposed rule.

We estimate costs of the industry's 2017 proposal by comparing the differences between their suggested requirements to estimated costs for requirements under this proposed rule.[64] In some cases, the 2017 industry proposal (IP) includes less stringent requirements than the proposed requirements under this proposed rule. In other cases, the IP includes more stringent requirements than those under this proposed rule. Some more stringent IP recommendations include:

1) Increasing the scope to also include all ENDS FFM manufacturers.
2) Stricter procedures for testing and laboratory controls to require test method validation.
    - Requirement for a hazard and critical control point (HACCP) analysis for ENDS and e-liquids.
    - Requirements for stability testing and retention of reserve samples for ENDS products.

Other recommendations in the 2012 IP and the 2017 supplement include less stringent requirements than this proposed rule such as:

3) A smaller number of written procedure and record requirements than required in this proposed rule.
4) No requirement that English translation of records be made available upon request.
5) No proposed requirements for returned tobacco product, warning plans, environmental controls, process validation, laboratory controls, and sampling.

[64] For example, the IP does not propose requirements for design and development activities generally, returned tobacco product, and warning plans, which are critical to ensure that the public health is protected and for efficient enforcement of the FD&C Act.

We lack information on the percentage of FFMs that have registered with FDA who manufacture ENDS FFMs, so we assume that all FFMs are covered under this regulatory alternative, as with regulatory option 2. This rise in costs to both domestic and foreign establishments might be partially offset by a rise in benefits because the FFM records required by this regulatory alternative could help FDA better pinpoint, for example, the source of contaminated ingredient that is supplied to finished and bulk tobacco product manufacturing establishments.

To estimate other costs associated with the 2017 IP, the approach we followed was to identify requirements that were generally consistent between both the IP and the proposed rule and not to estimate these overlapping costs. For example, we made adjustments to some estimated costs for written procedures in the proposed rule that were not identified as recommendations in the IP. Further, if the IP recommended less stringent requirements for a section, we estimated the cost for each IP recommendation as a percentage of the estimated section cost for the proposed rule. For example, in the IP section regarding complaints, complaints are defined as allegations of deficiencies related to the quality of a finished tobacco product. Also, complaints are reviewed to only identify complaints that involve a "a reasonable probability that a finished tobacco product contains a manufacturing or other defect not ordinarily contained in the same category of tobacco products on the market that would cause an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products." The IP would only require investigation, "where appropriate," of complaints that involve "an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products." In contrast, the proposed rule would define complaints more broadly to include any situation where a tobacco product does not meet expectations, is unsatisfactory or unacceptable, or appears to be a nonconforming product. In addition, the proposed rule would require an investigation of all

complaints that could be related to a nonconforming tobacco product, a product design issue, or an adverse experience that is required to be reported under a regulation promulgated under section 909(a) of the FD&C Act. In this case we estimate the cost of handling a complaint as recommended by the IP to be 20 percent of the estimated cost of FDA's proposed requirements for handling complaints. In estimating a more stringent recommendation from the 2017 IP such as stability testing and retention of reserve samples, we doubled the estimated cost for each requirement in the proposed rule. We acknowledge that there is uncertainty in this approach and request comments on our estimates.

Table 28 shows the difference in domestic primary estimated costs between the IP recommendations and the proposed TPMP requirements by requirement categories. Under this alternative, estimated one time and recurring net costs for requirements that involve written procedures would decrease by a respective $5.2 and $2.2 million.[65] Estimated recurring costs under Complaint and CAPA processing (in subpart B) would be reduced by $4.4 million. Under this alternative we also estimate an increase in one-time capital costs of $4 million (in equipment costs) along with an increase in $3 million to account for more IP recommended laboratory control activities such as batch testing of ENDS. The difference in one-time costs for other activities under the IP recommendations from TPMP is about $0.8 million more than TPMP. Recurring costs for other activities under the IP recommendations are about $2 million less than estimated costs for TPMP. Total estimated net one-time costs for the IP recommendations are $ 0.23 million less than estimated one- time costs for TPMP requirements. Total estimated net recurring costs are $6 million less than recurring costs for TPMP requirements.

[65] The net estimated reduction in costs for written procedures is offset by an increase of $1.8 million in one-time costs and $1million in recurring costs under IP recommendation for a HACCP plan for manufacturers of finished ENDS and e-liquids.

Table 28.— Difference between TPMP and IP Estimated One-time and Recurring Costs. (2020 U.S. Dollars)

Activity Description	Associated Subpart	TPMP Costs		IP Costs		Percent Difference IP/TPMP	
		One-time	Recurring	One-time	Recurring	One-time	Recurring
1) Written Procedure	B,C,D,E,F,G	$15,274,351	$6,900,623	$10,097,064	$4,655,927	-34%	-33%
2) Complaint & CAPA Processing	B	$0	$5,525,719	$0	$1,150,834	-	-79%
3) Equipment	E,G	$4,799,938	$0	$8,954,304	$0	87%	-
4) Conducting Laboratory Activities	E	$0	$2,762,859	$0	$5,754,172	-	108%
5) Other Activities	B,C,D,E,F,G, H	$34,161,707	$20,530,923	$34,954,104	$18,502,661	2%	-10%
Total	B,C,D,E,F,G	$54,235,996	$35,720,125	$54,005,473	$30,063,595	**0%**	**-16%**
Difference (IP-TPMP)				-$230,523	-$5,656,530		

Regulatory alternative 4 would change one-time costs to domestic and foreign manufacturers by between $4 million to $9 million. Annual costs would decrease between $3 and $6 million. We estimate total one-time costs would range from $66 million to $102 million and recurring costs would range from $15 million and $61 million per year. The present value of total costs annualized over ten years using a discount rate of seven percent are estimated to range from $15 million and $46 million per year, and from $15 million and $48 million per year using a discount rate of three percent (Table 29c).

FDA decided not to implement the IP recommendations because they did not clearly address several important issues that would provide public health benefits. The scope of the IP recommendations differ from the proposed TPMP rule in that the requirements are intended to

"protect against *manufacturing defects* not ordinarily contained in tobacco products that present a risk of injury beyond the risks generally posed by the same category of tobacco products." (emphasis added). Except for ENDS, the IP recommendations do not fully address risks associated with the *design* of a tobacco product, which may expose users to preventable harms not normally associated with the use of a tobacco product.

The IP recommendations propose a HACCP analysis for ENDS e-liquids and ENDS finished product manufacturing operations "to address, among other things, the potential for microbial contamination" and a provision "to ensure that specified design requirements for ENDS products are met," and "prior to implementation, such changes should be properly qualified, where appropriate." However, the IP recommendations does not propose a HACCP analysis for tobacco products other than ENDS e-liquids and ENDS finished products. These proposed approaches do not take into account TPMP's proposed design and development activities including a risk management process that addresses not only risks associated with the tobacco product and its production process but also risks associated with the tobacco product and package design. FDA believes that evaluating risks associated with the tobacco product as well as its packaging is the most comprehensive, proactive approach to assure that the public health, including consumers and non-users, are protected. Accordingly, the IP recommendations do not adequately address risks associated with the tobacco product and its production process for tobacco products other than ENDS (e.g., the design and shape or the packaging of a dissolvable tobacco product that could be misused by a child and cause choking or inadvertent exposure) or design defects (e.g., defective batteries that can cause fires and explosions and risks associated with the package such as an e-liquid package that can be opened by a child and lead to a toxic exposure to nicotine).

We also believe that this regulatory alternative would not be as effective to help assure that tobacco products are in compliance with the requirements of chapter IX of the FD&C Act. The IP recommendations generally contain less robust provisions for procedures and records than the proposed TPMP rule. The IP recommendations do not propose to require specific procedures for nonconforming tobacco product, corrective and preventive action, final acceptance activities for products other than ENDS products (IP recommendations only propose that samples be tested for each batch of e-liquid or finished ENDS products but does not require a procedure), sampling for products other than ENDS products (IP recommendations only propose procedures for sampling plans for ENDS products), packaging and labeling, and repackaging and relabeling. TPMP's proposed requirements to establish and maintain procedures are necessary to ensure that all responsible personnel can be trained to consistently implement the activities. Lack of procedures for these activities can increase the likelihood of nonconforming, contaminated, adulterated, or misbranded tobacco product.

TPMP's proposed requirements to maintain records are also necessary to demonstrate that the proposed requirements are met and to assure that tobacco products are in compliance with chapter IX of the FD&C Act. The IP recommendations do not propose to require specific records for buildings, facilities, and grounds (such as cleaning and sanitation, pest control); incoming acceptance activities (described by the IP recommendations as receiving acceptance), routine in-process acceptance (IP recommendations only propose to require records of in-process evaluation activities that fail), and final acceptance activities for products other than ENDS products (IP recommendations propose that samples be tested for each batch of e-liquid or finished ENDS products but does not require that records be maintained); packaging and labeling; repackaging and relabeling; and sampling. Lack of records for these activities can

increase the likelihood that nonconforming, contaminated, adulterated, or misbranded finished and bulk tobacco products are released for commercial distribution. In addition, lack of records makes it difficult for tobacco product manufacturers to conduct adequate nonconforming tobacco product investigations and to implement appropriate corrective action such as a recall. FDA relies on records to ensure that tobacco products are in compliance with Chapter IX, and, during an inspection, to investigate the scope and cause of any issues and the risk of illness or injury that they pose.

Lack of specific procedures and records for these activities can increase the likelihood of nonconforming, contaminated, adulterated, or misbranded finished and bulk tobacco products are released for commercial distribution. In addition, lack of specific procedures and records for these activities make it difficult for tobacco product manufacturers to conduct adequate nonconforming tobacco product investigations and to implement appropriate corrective action such as a recall and for FDA, during an inspection, to investigate the scope and cause of any issues and the risk of illness or injury that they pose.

The IP recommendations also do not address TPMP's proposed requirements for environmental controls, process validation (IP recommendations proposed procedures for process qualification of ENDS products only), laboratory controls, returned tobacco product, and warning plans. FDA believes these controls will decrease the incidence of tobacco product manufacturers distributing nonconforming products, which increase the probability of product recalls, into interstate commerce.

FDA believes that the proposed TPMP requirements provide important benefits that implementing the IP recommendations would not address. These controls institute checks and balances within the manufacturing facility prior to the tobacco products leaving the manufacturer's

control and would help assure that the public health is protected and that tobacco products are in compliance with chapter IX of the FD&C Act. Under regulatory alternative 4, we estimate that one-time costs to domestic manufacturers would range from $40 million and $71 million and recurring costs would range from $12 million and $48 million per year. The present value of total costs annualized over ten years using a discount rate of seven percent are estimated to range from $12 million and $36 million per year, and from $12 million and $38 million per year using a discount rate of three percent (Table 29a).

Regulatory alternative 4 would change one-time costs to domestic manufacturers by between $2 million to –($3 million). Annual costs would decrease between $3 and $9 million.

Regulatory alternative 4 would increase one-time costs to foreign manufacturers by between $6 to $8 million. Annual costs would decrease from $0.3 to $0.6 million (Table 29b).

The sum of one-time costs, recurring annual costs and present value of total costs annualized over ten years (using a seven and three percent discount rate) estimated for both domestic and foreign manufacturers is illustrated in Table 29c.

Table 29a.— Summary of Total Costs to Domestic Manufacturers by Regulatory Option (2020 U.S. Dollars)

Regulatory Option - Domestic Facilities	One-Time Costs			Recurring Costs ($/year)			3% Discount Rate			7% Discount Rate		
	Low	Medium	High	Low	Medium	High	Low	Med.	High	Low	Med.	High
Proposed Rule	$38,564,913	$54,235,996	$73,193,851	$15,255,179	$35,720,125	$56,185,071	$13,651,840	$28,152,310	$42,997,763	$13,257,827	$27,004,227	$41,115,624
Regulatory Alternative 1: PR Plus HACCP	$50,565,118	$67,211,317	$87,144,289	$22,479,285	$42,808,973	$63,843,442	$19,209,682	$33,726,132	$49,008,661	$18,560,311	$32,332,836	$46,861,181
Change from PR	$12,000,205	$12,975,321	$13,950,438	$7,224,107	$7,088,848	$7,658,371	$5,557,842	$5,573,821	$6,010,898	$5,302,483	$5,328,609	$5,745,557
Regulatory Alternative 2: Expand Coverage from PR to FFMS	$40,159,328	$56,478,311	$76,219,954	$15,885,884	$37,196,926	$58,507,968	$14,216,257	$29,316,230	$44,775,448	$13,805,955	$28,120,681	$42,815,495
Change from PR	$1,594,415	$2,242,315	$3,026,102	$630,705	$1,476,801	$2,322,897	$564,417	$1,163,920	$1,777,685	$548,127	$1,116,454	$1,699,871
Regulatory Alternative 3: Require only a HACCP System	$14,410,048	$16,011,164	$17,127,539	$7,682,111	$8,535,679	$9,389,247	$6,087,267	$6,763,631	$7,439,994	$5,822,466	$6,469,406	$7,116,347
Change from PR	($24,154,865)	($38,224,832)	($56,066,313)	($7,573,068)	($27,184,446)	($46,795,824)	($7,564,572)	($21,388,680)	($35,557,769)	($7,435,362)	($20,534,820)	($33,999,277)
Regulatory Alternative 4: Require 2017 Industry proposal (IP)	$40,435,000	$54,005,473	$70,639,623	$12,204,437	$30,063,595	$47,922,752	$11,297,384	$23,819,979	$36,966,165	$10,972,869	$22,818,950	$35,359,209
Change from PR	$1,870,087	($230,523)	($2,554,228)	($3,050,741)	($5,656,530)	($8,262,320)	($2,354,456)	($4,332,331)	($6,031,598)	($2,284,958)	($4,185,277)	($5,756,416)

Table 29b.— Summary of Total Costs to Foreign Manufacturers by Regulatory Option (2020 U.S. Dollars)

Regulatory Option-Foreign Facilities	One-Time Costs			Recurring Costs ($/year)			3% Discount Rate			7% Discount Rate		
	Low	Medium	High	Low	Medium	High	Low	Med.	High	Low	Med.	High
Proposed Rule	$17,526,549	$20,828,963	$24,762,327	$2,738,413	$8,467,718	$14,197,022	$3,546,390	$7,217,135	$11,083,295	$3,532,219	$6,986,203	$10,640,233
Regulatory Alternative 1: PR Plus HACCP	$25,851,844	$29,998,605	$34,776,316	$5,535,709	$11,540,143	$17,544,577	$6,488,488	$10,455,528	$14,617,983	$6,501,013	$10,255,397	$14,209,825
Change from PR	*$8,325,294*	*$9,169,642*	*$10,013,990*	*$2,797,296*	*$3,072,425*	*$3,347,555*	*$2,942,098*	*$3,238,393*	*$3,534,687*	*$2,968,794*	*$3,269,193*	*$3,569,592*
Regulatory Alternative 2: Expand Coverage from PR to FFMS	$18,251,161	$21,690,109	$25,786,092	$2,851,629	$8,817,804	$14,783,979	$3,693,011	$7,515,518	$11,541,519	$3,678,254	$7,275,039	$11,080,139
Change from PR	*$724,612*	*$861,146*	*$1,023,765*	*$113,216*	*$350,087*	*$586,957*	*$146,621*	*$298,383*	*$458,224*	*$146,035*	*$288,835*	*$439,906*
Regulatory Alternative 3: Require only a HACCP System	$9,374,829	$10,416,477	$11,458,125	$3,181,790	$3,535,322	$3,888,854	$3,318,730	$3,687,478	$4,677,197	$3,343,296	$3,714,773	$4,743,169
Change from PR	*($8,151,720)*	*($10,412,486)*	*($13,304,202)*	*$443,377*	*($4,932,395)*	*($10,308,168)*	*($227,660)*	*($3,529,657)*	*($6,406,098)*	*($188,923)*	*($3,271,430)*	*($5,897,064)*
Regulatory Alternative 4: Require 2017 Industry proposal (IP)	$25,134,575	$27,778,201	$30,993,946	$2,428,384	$7,995,562	$13,562,740	$3,860,269	$7,624,343	$11,448,845	$3,845,484	$7,398,774	$11,016,541
Change from PR	*$7,608,026*	*$6,949,238*	*$6,231,619*	*($310,028)*	*($472,155)*	*($634,282)*	*$313,879*	*$407,207*	*$365,550*	*$313,265*	*$412,571*	*$376,309*

Table 29c.— Summary of Total Costs to Domestic and Foreign Manufacturers by Regulatory Option (2020 U.S. Dollars)

Regulatory Option- Domestic and Foreign Facilities	One-Time Costs			Recurring Costs ($/year)			3% Discount Rate			7% Discount Rate		
	Low	Medium	High	Low	Medium	High	Low	Med.	High	Low	Med.	High
Proposed Rule	***$56,091,462***	***$75,064,959***	***$97,956,178***	***$17,993,592***	***$44,187,843***	***$70,382,094***	***$17,198,230***	***$35,369,446***	***$54,081,058***	***$16,790,046***	***$33,990,430***	***$51,755,857***
Regulatory Alternative 1: PR Plus HACCP	$76,416,961	$97,209,922	$121,920,606	$28,014,994	$54,349,116	$81,388,019	$25,698,170	$44,181,660	$63,626,643	$25,061,323	$42,588,233	$61,071,007
Change from PR	*$20,325,500*	*$22,144,964*	*$23,964,428*	*$10,021,402*	*$10,161,273*	*$11,005,925*	*$8,499,940*	*$8,812,214*	*$9,545,585*	*$8,271,277*	*$8,597,803*	*$9,315,149*
Regulatory Alternative 2: Expand Coverage from PR to FFMS	$58,410,489	$78,168,420	$102,006,046	$18,737,513	$46,014,730	$73,291,948	$17,909,268	$36,831,748	$56,316,968	$17,484,208	$35,395,719	$53,895,634
Change from PR	*$2,319,027*	*$3,103,461*	*$4,049,868*	*$743,921*	*$1,826,888*	*$2,909,854*	*$711,038*	*$1,462,303*	*$2,235,909*	*$694,162*	*$1,405,289*	*$2,139,777*
Regulatory Alternative 3: Require only a HACCP System	$23,784,877	$26,427,641	$28,585,664	$10,863,901	$12,071,001	$13,278,101	$9,405,998	$10,451,109	$12,117,190	$9,165,761	$10,184,179	$11,859,516
Change from PR	*($32,306,585)*	*($48,637,318)*	*($69,370,514)*	*($7,129,691)*	*($32,116,842)*	*($57,103,992)*	*($7,792,232)*	*($24,918,337)*	*($41,963,868)*	*($7,624,285)*	*($23,806,251)*	*($39,896,341)*
Regulatory Alternative 4: Require 2017 Industry proposal (IP)	$65,569,575	$81,783,674	$101,633,569	$14,632,822	$38,059,157	$61,485,492	$15,157,653	$31,444,321	$48,415,010	$14,818,353	$30,217,724	$46,375,750
Change from PR	*$9,478,113*	*$6,718,715*	*$3,677,391*	*($3,360,770)*	*($6,128,686)*	*($8,896,602)*	*($2,040,577)*	*($3,925,124)*	*($5,666,048)*	*($1,971,693)*	*($3,772,706)*	*($5,380,107)*

III. Initial Small Entity Analysis

A. Introduction

We examined the economic implications of the proposed rule for small entities as required by the Regulatory Flexibility Act. If a proposed rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. Because small entities are likely to incur a large portion of the costs to comply with the proposed rule, we find that the proposed rule would have a significant economic impact on a substantial number of small entities. This analysis, together with other relevant sections of this document and the preamble of the proposed rule, serves as the initial regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

B. Description and Number of Affected Small Entities

This proposed rule would primarily affect domestic and foreign manufacturers of tobacco products and domestic importers. We use U.S. Census data for domestic entities to estimate the number of affected domestic and foreign small entities. Although U.S. Census data are not ideal for estimating the total number of such entities that would be affected, they offer the best available insight into the proportion that may be small.[66] Manufacturers of tobacco products that could be affected by this proposed rule would be designated under the NAICS as "tobacco product manufacturers." Importers that repackage and/or relabel tobacco products are subject to the requirements of the proposed rule. Most tobacco product-importing wholesalers would be

[66] The Census establishment count for tobacco product manufacturing should be viewed as an approximation since many of these establishments have fewer than 20 employees, and such establishments are not counted as accurately as larger establishments (U.S. Census, 2017).

classified in NAICS as "tobacco and tobacco product merchant wholesalers." Table 30 shows the Small Business Administration (SBA) size thresholds for small businesses in each of these categories, as well as the most comparable size categories reported in the Statistics of U.S. Businesses data from 20172 (SUSB) (Ref. R38; Ref. R39).[67,68] For tobacco and tobacco product merchant wholesalers, the proportion found to be small would be underestimated because the Census size category is lower than the SBA size threshold.

Table 30.— SBA Size Standards and Census Statistics of U.S. Businesses 2017 Size Categories for Tobacco Product Manufacturers and Importers

NAICS Code	Description of NAICS Category	SBA Size Standard (Employees)	Census Size Category (Employees)
312230	Tobacco Manufacturing	1,500	1,500
424940	Tobacco and Tobacco Product Merchant Wholesalers[69]	250	200

Table 31 shows the number of businesses with employees in each of the categories described above, the number qualifying as small according to the Census size standard, and the percent qualifying as small. Statistics of U.S. Businesses data from 2017 indicate that 96 percent of "tobacco manufacturing" businesses with employees are small (Ref. R38; Ref. R39). These data also show that 96 percent of "tobacco and tobacco product merchant wholesalers" qualify as small. For several reasons, these numbers are only an approximation: (1) large firms are more likely to have multiple establishments, so the percentage of establishments belonging to small firms is

[67] Tobacco product manufacturers (and importers) are considered small under chapter IX of the FD&C Act if they employ fewer than 350 people. However, the Small Business Administration's threshold for small tobacco manufacturing (fewer than 1,500 employees) is applicable to the small entity analysis required under the Regulatory Flexibility Act.
[68] Business receipts are only included in the Statistics of U.S. Businesses (SUSB) data for Economic Census years (years ending in 2 and 7). The 2017 SUSB Annual Data Tables by Establishment Industry contain the most recent data for firm size and associated receipts.
[69] Category for Tobacco and Tobacco Product Merchant Wholesalers is used as a proxy for domestically-located tobacco importers.

smaller than the percentage of firms that are small; and (2) because the Census manufacturing category excludes manufacturers without payroll, which would (by definition) be small, the Census understates the percentage of manufacturing firms that are small.

Table 31.—Estimated Percentage of Small Firms with Employees

NAICS	Description of NAICS Category	Number of Firms	Number of Firms Below Census Size Standard	Percentage of Small Firms* (%)
312230	Tobacco Manufacturing	136	130	96%
424940	Tobacco and Tobacco Product Merchant Wholesalers	1,285	1,240	96%

*Calculations may not appear exact due to rounding.

Without other information, we assume that the percentage of domestic tobacco product manufacturing establishments in the FDA registration data that are small is the same as the percentage of tobacco manufacturers or tobacco merchant wholesalers that are small; thus 1,866 (1,935 x 0.96) small domestic manufacturing establishments would be affected by this proposed rule. In a similar manner we assume that the percentage of foreign manufacturing establishments from FDA import data that are small is the same as the percentage tobacco manufacturing firms or tobacco merchant wholesalers that are small; thus 3,155 (3,273 x 0.96) small foreign manufacturing establishments would be affected by this proposed rule.

Table 32 shows the estimated number of domestic and foreign establishments that are small broken down by major tobacco group.

Table 32.— Estimated Number of Small Establishments by Major Tobacco Group

Major Tobacco Group	Domestic Entities	Foreign Entities	Total
Cigarettes, Cigarette Tobacco, Smokeless and roll your own	99	380	479
Cigars, pipes and pipe tobacco, waterpipes and water pipe tobacco	215	417	632
ENDS	1,248	2,424	3,672
Other	304	31	335
Total	1,866	3,155	5,021

C. Description of the Potential Impacts of the Proposed Rule on Small Entities

Given the estimated number of small entities that would be affected by the proposed rule, we provide a summary of the total costs to small business in Table 33.

Throughout this analysis we have estimated costs for disaggregated size categories for manufacturers with fewer than 350 and at least 350 employees. From Table 2 we have estimated 1,764 domestic and 2,984 foreign establishments with 350 or fewer employees which represent about 92% of all tobacco manufacturers. From Tables 27b and 27c we estimated the cost share to establishments with less than 350 employees to be about 80% of the total costs of this rule. To estimate costs to manufacturers with <1,500 employees, we first estimate the additional percentage of affected manufacturers with >= than 350 employees but less than 1,500 employees by subtracting 92% (which represents tobacco manufacturers' with <350 employees) from 96% (which represents tobacco manufacturers with less than 1,500 employees). The resulting difference is 4% which also represents an additional 83 domestic and 141 foreign establishments. We then multiply the average cost for small domestic and foreign establishments, shown in Tables 27b and 27c, by additional 83 domestic and 141 foreign establishments and add it to the cost estimates for small establishments in the primary analysis to now represent estimated costs that

SBA-assessed small entities would incur. We estimate that one-time costs to domestic small businesses range from $34 million to $64 million and annual costs range from $13 million to $50 million. If total costs are annualized over a ten-year period at a seven percent discount rate, we estimate that the annualized costs to domestic establishments would be between $11 million and $32 million per year; the corresponding range if annualized at a three percent discount rate is from $11 million and $35 million per year (Table 33).

Table 33— Total Domestic Costs to Small Businesses and Summary Costs to Foreign Small Businesses (1) (2020 U.S. Dollars)

	One-Time Costs*			Recurring Costs *			Annualized Costs Over a 10- Year Period					
							3% Discount Rate			7% Discount Rate		
	Low	Medium	High	Low	Medium	High	Low	Medium	High	Low	Medium	High
Learn About Rule	$9,697,031	$9,697,031	$9,697,031	$0	$0	$0	$1,041,231	$1,041,231	$1,041,231	$1,132,179	$1,132,179	$1,132,179
Subpart B	$1,431,742	$2,512,242	$3,592,742	$2,744,330	$5,508,424	$8,272,517	$1,693,252	$3,362,136	$5,031,020	$1,566,183	$3,106,942	$4,647,702
Subpart C	$4,628,495	$8,414,646	$12,973,657	$1,108,181	$7,290,008	$13,471,835	$1,093,335	$4,964,257	$8,913,333	$1,043,600	$4,628,507	$8,291,869
Subpart D	$2,402,343	$3,687,579	$4,972,814	$727,291	$1,155,524	$1,583,758	$653,303	$1,024,899	$1,396,495	$620,415	$972,596	$1,324,777
Subpart E	$12,247,743	$17,549,679	$22,946,128	$8,402,251	$16,804,503	$25,206,754	$5,979,450	$11,256,513	$16,543,132	$5,593,467	$10,481,842	$15,379,812
Subpart F	$1,897,130	$3,003,434	$5,627,275	$173,769	$347,537	$521,306	$289,893	$499,815	$863,196	$282,550	$484,821	$841,142
Subpart G	$1,575,208	$2,364,587	$3,153,966	$169,396	$254,093	$338,791	$254,872	$382,487	$510,102	$247,607	$371,590	$495,574
Subpart H	$244,683	$489,365	$734,048	$122,341	$183,512	$244,683	$93,773	$153,032	$212,290	$88,179	$144,688	$201,197
Total Domestic Costs	**$34,124,374**	**$47,718,563**	**$63,697,662**	**$13,447,559**	**$31,543,602**	**$49,639,644**	$11,099,110	$22,684,369	$34,510,800	$10,574,179	$21,323,165	$32,314,251
Cost per Small Domestic Establishment N=1,858	**$18,370**	**$25,688**	**$34,290**	**$7,239**	**$16,981**	**$26,722**	$5,975	$12,212	$18,578	$5,692	$11,479	$17,396
Total Foreign Costs	**$15,534,745**	**$18,387,992**	**$21,682,988**	**$2,404,295**	**$7,493,145**	**$12,581,995**	$2,954,850	$6,114,728	$9,319,278	$2,888,346	$5,812,676	$8,781,849
Cost per Small Foreign Establishment N=3,142	**$4,945**	**$5,853**	**$6,902**	**$765**	**$2,385**	**$4,005**	$941	$1,946	$2,966	$919	$1,850	$2,795
Total Domestic & Foreign	**$49,659,119**	**$66,106,555**	**$85,380,650**	**$15,851,854**	**$39,036,747**	**$62,221,639**	$14,053,960	$28,799,097	$43,830,078	$13,462,525	$27,135,841	$41,096,100
Cost per Small Domestic & Foreign Establishment	**$9,933**	**$13,223**	**$17,079**	**$3,171**	**$7,809**	**$12,446**	$2,811	$5,761	$8,767	$2,693	$5,428	$8,221

(1) Small businesses as defined by the U.S. Small Business Administration (SBA).

To obtain the costs per small entity, we divide the one-time and recurring estimated costs by the estimated number of affected small entities. We estimate that one-time costs per small domestic entity range from $18,000 to $34,000 and annual costs range from $7,000 to $27,000. If total costs are annualized over a ten-year period at a seven percent discount rate, the annualized costs per small entity range from $6,000 to $17,000; the corresponding range if annualized at a three percent discount rate is $6,000 to $19,000.

An alternative way to get a sense of the impact of the proposed rule on small entities, Table 34 shows the average value of shipments and receipts for services in 2017 by size of operation from the Census Statistics of U.S. Businesses 2017 (Ref. R38). Information is withheld by the U.S. Census in many cases to avoid disclosing data for individual companies. Using the average of all available information from tobacco product manufacturers considered to be small ($32,543,737), we estimate that the one-time costs per small entity are between 0.06% and 0.11% of their average value of shipments and receipts for services.

It is important to emphasize, however, that there are many missing values, and these average small-entity impacts are likely to hide a significant amount of heterogeneity in small-entity impacts across manufacturers of different sizes. For example, among manufacturers with 20-49 employees, we estimate that the one-time costs per small entity are between 0.004% and 0.008% of the average value of shipments and receipts for services—which is much higher than our estimated average costs to small-entities. The impacts are likely to be even larger for manufacturers that employ fewer than 20 employees (as much as 0.6% to 1.2% of the average value of shipments for recurring costs, if we assume an order-of-magnitude increase). Thus, among the segment of small-entity manufacturers, there may be substantial effects of the proposed rule on some small entities.

Table 34.— Average Value of Shipments and Receipts for Services, by Size of Operation

NAICS code	Description of NAICS Category	Meaning of Employment Size of Establishments Code	Number of Establishments	Average Value of Shipments and Receipts for Services ($1,000)
312230	Tobacco manufacturing	All establishments	159	$301,282
312230	Tobacco manufacturing	Establishments with 0 to 4 employees	46	$1,367
312230	Tobacco manufacturing	Establishments with 5 to 9 employees	23	$3,724
312230	Tobacco manufacturing	Establishments with 10 to 19 employees	13	$7,358
312230	Tobacco manufacturing	Establishments with 20 to 49 employees	22	$19,760
312230	Tobacco manufacturing	Establishments with 50 to 99 employees	9	$39,428
312230	Tobacco manufacturing	Establishments with 100 to 149 employees	9	$104,326
312230	Tobacco manufacturing	Establishments with 150 to 499 employees	6	$99,549
312230	Tobacco manufacturing	Establishments with 500 to 1,499 employees	5	$351,670
312230	Tobacco manufacturing	Establishments with 1,500 + employees	26	$1,675,982

D. Alternatives to Minimize the Burden on Small Entities

Section 906(e)(2) of the FD&C Act allows any person subject to any requirement of the final regulation to petition the Secretary for a permanent or temporary exemption or variance from the regulation. The person who petitions is required to comply with the final rule until the Secretary grants the petition. Subpart I of the proposed rule provides regulatory relief to small tobacco product manufacturers by requiring compliance four years after the effective date of the final rule. The primary analysis for this proposed rule considers the impacts to small businesses, and, thus, the regulatory alternatives discussed and analyzed earlier may also minimize the burden to small businesses.

In addition to these allowances, we considered regulatory alternatives that would further alleviate the burden to small entities: 1) extend the compliance period and, 2) exempt a subset of small manufacturers.

One alternative to further reduce the burden on small entities is to lengthen the compliance period for these manufacturers. This alternative would provide more time for small entities to comply with the rule and spread the costs over a longer time period. This would provide regulatory relief since it would provide small tobacco manufacturers with the opportunity to finance compliance costs with additional years of revenue from continued operation without the need to be in compliance with the rule.

A second alternative is to exempt a subset of small manufacturers, particularly those that are likely to incur costs that make up a very large share of their annual revenue. This would provide regulatory relief to the small manufacturers that are likely to suffer the greatest regulation-induced financial burden. An important caveat, however, is that small entities make up a substantial share of the tobacco manufacturing industry and exempting a subset of small manufacturers would also necessarily forgo a subset of the benefits associated with the proposed rule. Depending on the size cutoff, exempting small entities could forgo a substantial share of the benefits of the proposed rule.

We request comment on additional alternatives that may further minimize the burden on small entities.

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Appendix A – Costs to Domestic Facilities

Costs attributable to written procedures may include costs to define, document in writing, and update each procedure. Additionally, they may include the costs of creating and maintaining records to document the performance of activities in writing. Where applicable, the marginal costs to implement the procedures and conduct the specific activities required in each Subpart are estimated separately.

For each quantified provision in the proposed regulation, the total estimated costs of the provisions are equal to the sum of the two products:

1.Estimated nonalignment rate among small manufacturers (see section C.2.2) × total number of small manufacturing establishments (see section C.1) × cost of performing the task required by the provision.

2.Estimated nonalignment rate among non-small manufacturers (see section C.2.2) × total number of non-small manufacturing establishments (see section C.1) × cost of performing the task required by the provision.

Table 1 lists the tasks under each provision. Subsequent tables refer to tasks and line items in Table 1.

Table 1: List of Tasks by Rule Provision

Line Item	Sub-part	Provision	Task
12.1	B	§1120.12 Organization and personnel	Written Procedure for Organizational Structure
12.2			Written Procedure for Designation of Responsibility
12.3			Written Procedure for Training Needs
14.1		§1120.14 Tobacco product complaints	Written Procedure for Handling Complaints
14.2			Employee Training for Handling Complaints
14.3			Training by Manager for Handling Complaints
14.4			Record of Training for Handling Complaints
14.5			Complaint Processing
14.6			Written Procedure for Handling Complaints
14.7			Employee Training for Handling Complaints
14.8			Training by Manager for Handling Complaints
14.9			Record of Training for Handling Complaints
14.10			Complaint Processing
16.1		§1120.16 Corrective and preventive actions (CAPA)	Written Procedure for Implementing CAPA
16.2			Employee Training for Implementing CAPA
16.3			Training by Manager for Implementing CAPA
16.4			Record of Training for Implementing CAPA
16.5			CAPA Implementation
16.6			Written Procedure for Implementing CAPA
16.7			Employee Training for Implementing CAPA
16.8			Training by Manager for Implementing CAPA
16.9			Record of Training for Implementing CAPA

Line Item	Sub-part	Provision	Task
16.10			CAPA Implementation
32.1	C	§1120.32 Personnel	Written Procedure for Personnel Cleaning Practices
32.2			Employee Training for Personnel Cleaning Practices
32.3			Training by Manager for Personnel Cleaning Practices
32.4			Record of Training for Personnel Cleaning Practices
32.5			Written Procedure for Personnel Cleaning Practices
32.6			Employee Training for Personnel Cleaning Practices
32.7			Training by Manager for Personnel Cleaning Practices
32.8			Record of Training for Personnel Cleaning Practices
34.1		§1120.34 Buildings, facilities and grounds	Written Procedure for Facility Cleaning Practices
34.2			Employee Training for Facility Cleaning Practices
34.3			Training by Manager for Facility Cleaning Practices
34.4			Record of Training for Facility Cleaning Practices
34.5			Written Procedure for Facility Cleaning Practices
34.6			Employee Training for Facility Cleaning Practices
34.7			Training by Manager for Facility Cleaning Practices
34.8			Record of Training for Facility Cleaning Practices
34.9			Written Procedure for Animal and Pest Control
34.10			Employee Training for Animal and Pest Control
34.11			Training by Manager for Animal and Pest Control
34.12			Record of Training for Animal and Pest Control
34.13			3rd Party Pest Control
34.14			Written Procedure for Animal and Pest Control
34.15			Employee Training for Animal and Pest Control
34.16			Training by Manager for Animal and Pest Control
34.17			Record of Training for Animal and Pest Control
34.18			3rd Party Pest Control
36.1		§1120.36 Equipment	Written Procedure for Maintenance of Equipment
36.2			Employee Training for Maintenance of Equipment
36.3			Training by Manager for Maintenance of Equipment
36.4			Record of Training for Maintenance of Equipment
36.5			Written Procedure for Maintenance of Equipment
36.6			Employee Training for Maintenance of Equipment
36.7			Training by Manager for Maintenance of Equipment
36.8			Record of Training for Maintenance of Equipment
36.9			Written Procedure for Monitoring Equipment
36.10			Employee Training for Monitoring Equipment
36.11			Training by Manager for Monitoring Equipment
36.12			Record of Training for Monitoring Equipment
36.13			Written Procedure for Monitoring Equipment
36.14			Employee Training for Monitoring Equipment
36.15			Training by Manager for Monitoring Equipment
36.16			Record of Training for Monitoring Equipment

Line Item	Sub-part	Provision	Task
36.17			Written Procedure for Calibrating Equipment
36.18			Employee Training for Calibrating Equipment
36.19			Training by Manager for Calibrating Equipment
36.20			Record of Training for Calibrating Equipment
36.21			Written Procedure for Calibrating Equipment
36.22			Employee Training for Calibrating Equipment
36.23			Training by Manager for Calibrating Equipment
36.24			Record of Training for Calibrating Equipment
38.1		§1120.38 Environment controls	Written Procedure for Controlling Environmental Conditions
38.2			Employee Training for Controlling Environmental Conditions
38.3			Training by Manager for Controlling Environmental Conditions
38.4			Record of Training for Controlling Environmental Conditions
38.5			Written Procedure for Controlling Environmental Conditions
38.6			Employee Training for Controlling Environmental Conditions
38.7			Training by Manager for Controlling Environmental Conditions
38.8			Record of Training for Controlling Environmental Conditions
42.1		§1120.42 Design and development activities	Written Procedure for Product Design and Risk Management Procedures
42.2			Employee Training for Product Design and Risk Management Procedures
42.3			Training by Manager for Product Design and Risk Management Procedures
42.4			Record of Training for Product Design and Risk Management Procedures
42.5			Written Procedure for Product Design and Risk Management Procedures
42.6			Employee Training for Product Design and Risk Management Procedures
42.7			Training by Manager for Product Design and Risk Management Procedures
42.8			Record of Training for Product Design and Risk Management Procedures
44.1	D	§1120.44 Master manufacturing record	Written Procedure for Master Manufacturing Record
44.2			Written Procedure for Review and Approval of Master Manufacturing Record
44.3			Employee Training for Review and Approval of Master Manufacturing Record
44.4			Training by Manager for Review and Approval of Master Manufacturing Record
44.5			Record of Training for Review and Approval of Master Manufacturing Record
44.6			Review and Approval of Master Manufacturing Record
44.7			Written Procedure for Review and Approval of Master Manufacturing Record
44.8			Employee Training for Review and Approval of Master Manufacturing Record
44.9			Training by Manager for Review and Approval of Master Manufacturing Record

Line Item	Sub-part	Provision	Task
44.10			Record of Training for Review and Approval of Master Manufacturing Record
44.11			Review and Approval of Master Manufacturing Record
62.1		§1120.62 Purchasing controls	Written Procedure for Purchasing Products or Services
62.2			Employee Training for Purchasing Products or Services
62.3			Training by Manager for Purchasing Products or Services
62.4			Record of Training for Purchasing Products or Services
62.5			Written Procedure for Purchasing Products or Services
62.6			Employee Training for Purchasing Products or Services
62.7			Training by Manager for Purchasing Products or Services
62.8			Record of Training for Purchasing Products or Services
62.9			Written Procedure for Qualifying Suppliers
62.10			Employee Training for Qualifying Suppliers
62.11			Training by Manager for Qualifying Suppliers
62.12			Record of Training for Qualifying Suppliers
62.13			Written Procedure for Qualifying Suppliers
62.14			Employee Training for Qualifying Suppliers
62.15			Training by Manager for Qualifying Suppliers
62.16			Record of Training for Qualifying Suppliers
64.1	E	§1120.64 Acceptance Activities	Written Procedure for General Acceptance Activities
64.2			Employee Training for General Acceptance Activities
64.3			Training by Manager for General Acceptance Activities
64.4			Record of Training for General Acceptance Activities
64.5			Conducting Acceptance Activities
64.6			Written Procedure for General Acceptance Activities
64.7			Employee Training for General Acceptance Activities
64.8			Training by Manager for General Acceptance Activities
64.9			Record of Training for General Acceptance Activities
64.10			Conducting Acceptance Activities
64.11			Written Procedure for Incoming Acceptance Activities
64.12			Employee Training for Incoming Acceptance Activities
64.13			Training by Manager for Incoming Acceptance Activities
64.14			Record of Training for Incoming Acceptance Activities
64.15			Written Procedure for Incoming Acceptance Activities
64.16			Employee Training for Incoming Acceptance Activities
64.17			Training by Manager for Incoming Acceptance Activities
64.18			Record of Training for Incoming Acceptance Activities
64.19			Written Procedure for Pesticide Testing
64.20			Employee Training for Pesticide Testing
64.21			Training by Manager for Pesticide Testing
64.22			Record of Training for Pesticide Testing
64.23			Written Procedure for Pesticide Testing
64.24			Employee Training for Pesticide Testing
64.25			Training by Manager for Pesticide Testing

Line Item	Sub-part	Provision	Task
64.26			Record of Training for Pesticide Testing
64.27			Written Procedure for Tobacco Product Acceptance Activities
64.28			Employee Training for Tobacco Product Acceptance Activities
64.29			Training by Manager for Tobacco Product Acceptance Activities
64.30			Record of Training for Tobacco Product Acceptance Activities
64.31			Written Procedure for Tobacco Product Acceptance Activities
64.32			Employee Training for Tobacco Product Acceptance Activities
64.33			Training by Manager for Tobacco Product Acceptance Activities
64.34			Record of Training for Tobacco Product Acceptance Activities
66.1		§1120.66 Production and Process controls	Written Procedure for Monitoring and Controlling Production Operations
66.2			Employee Training for Monitoring and Controlling Production Operations
66.3			Training by Manager for Monitoring and Controlling Production Operations
66.4			Record of Training for Monitoring and Controlling Production Operations
66.5			Equipment Production Materials
66.6			Written Procedure for Monitoring and Controlling Production Operations
66.7			Employee Training for Monitoring and Controlling Production Operations
66.8			Training by Manager for Monitoring and Controlling Production Operations
66.9			Record of Training for Monitoring and Controlling Production Operations
66.10			Equipment Production Materials
66.11			Written Procedure for Removing Manufacturing Material
66.12			Employee Training for Removing Manufacturing Material
66.13			Training by Manager for Removing Manufacturing Material
66.14			Record of Training for Removing Manufacturing Material
66.15			Written Procedure for Removing Manufacturing Material
66.16			Employee Training for Removing Manufacturing Material
66.17			Training by Manager for Removing Manufacturing Material
66.18			Record of Training for Removing Manufacturing Material
66.19			Written Procedure for Changes to Process Controls
66.20			Employee Training for Changes to Process Controls
66.21			Training by Manager for Changes to Process Controls
66.22			Record of Training for Changes to Process Controls
66.23			Written Procedure for Changes to Process Controls
66.24			Employee Training for Changes to Process Controls
66.25			Training by Manager for Changes to Process Controls
66.26			Record of Training for Changes to Process Controls
66.27			Written Procedure for Process Validation

Line Item	Sub-part	Provision	Task
66.28			Employee Training for Process Validation
66.29			Training by Manager for Process Validation
66.30			Record of Training for Process Validation
66.31			Production Processes Control Activities
66.32			Written Procedure for Process Validation
66.33			Employee Training for Process Validation
66.34			Training by Manager for Process Validation
66.35			Record of Training for Process Validation
66.36			Production Processes Control Activities
68.1		§1120.68 Laboratory controls	Written Procedure for Laboratory Functions
68.2			Employee Training for Laboratory Functions
68.3			Training by Manager for Laboratory Functions
68.4			Record of Training for Laboratory Functions
68.5			Conducting Laboratory Control Activities
68.6			Equipment Laboratory Materials
68.7			Written Procedure for Laboratory Functions
68.8			Employee Training for Laboratory Functions
68.9			Training by Manager for Laboratory Functions
68.10			Record of Training for Laboratory Functions
68.11			Conducting Laboratory Control Activities
68.12			Equipment Laboratory Materials
70.1			Written Procedure for Production Record Practices
70.2			Employee Training for Production Record Practices
70.3			Training by Manager for Production Record Practices
70.4			Record of Training for Production Record Practices
70.5			Review of Production Record
70.6			Written Procedure for Production Record Practices
70.7			Employee Training for Production Record Practices
70.8			Training by Manager for Production Record Practices
70.9			Record of Training for Production Record Practices
70.10			Review of Production Record
72.1		§1120.72 Sampling	Written Procedure for Sampling Plans
72.2			Employee Training for Sampling Plans
72.3			Training by Manager for Sampling Plans
72.4			Record of Training for Sampling Plans
72.5			Written Procedure for Sampling Plans
72.6			Employee Training for Sampling Plans
72.7			Training by Manager for Sampling Plans
72.8			Record of Training for Sampling Plans
74.1		§1120.74 Nonconforming tobacco product	Written Procedure for Controlling Nonconforming Products
74.2			Employee Training for Controlling Nonconforming Products
74.3			Training by Manager for Controlling Nonconforming Products

Line Item	Sub-part	Provision	Task
74.4			Record of Training for Controlling Nonconforming Products
74.5			Control and Disposition of Nonconforming Products
74.6			Written Procedure for Controlling Nonconforming Products
74.7			Employee Training for Controlling Nonconforming Products
74.8			Training by Manager for Controlling Nonconforming Products
74.9			Record of Training for Controlling Nonconforming Products
74.10			Control and Disposition of Nonconforming Products
76.1		§1120.76 Returned tobacco product	Written Procedure for Controlling Returned Tobacco Products
76.2			Employee Training for Controlling Returned Tobacco Products
76.3			Training by Manager for Controlling Returned Tobacco Products
76.4			Record of Training for Controlling Returned Tobacco Products
76.5			Inspection and Evaluation of Returned Tobacco Products
76.6			Written Procedure for Controlling Returned Tobacco Products
76.7			Employee Training for Controlling Returned Tobacco Products
76.8			Training by Manager for Controlling Returned Tobacco Products
76.9			Record of Training for Controlling Returned Tobacco Products
76.10			Inspection and Evaluation of Returned Tobacco Products
78.1		§1120.78 Reprocessing and rework	Written Procedure for Reprocessing and Reworking Tobacco Products
78.2			Employee Training for Reprocessing and Reworking Tobacco Products
78.3			Training by Manager for Reprocessing and Reworking Tobacco Products
78.4			Record of Training for Reprocessing and Reworking Tobacco Products
78.5			Written Procedure for Reprocessing and Reworking Tobacco Products
78.6			Employee Training for Reprocessing and Reworking Tobacco Products
78.7			Training by Manager for Reprocessing and Reworking Tobacco Products
78.8			Record of Training for Reprocessing and Reworking Tobacco Products
92.1	F	§1120.92 Packaging and labeling controls	Written Procedure for Controlling Packaging and Labeling
92.2			Employee Training for Controlling Packaging and Labeling
92.3			Training by Manager for Controlling Packaging and Labeling
92.4			Record of Training for Controlling Packaging and Labeling
92.5			Written Procedure for Controlling Packaging and Labeling
92.6			Employee Training for Controlling Packaging and Labeling
92.7			Training by Manager for Controlling Packaging and Labeling
92.8			Record of Training for Controlling Packaging and Labeling
94.1		§1120.94 Repackaging and relabeling	Written Procedure for Repacking and Relabeling Operations

Line Item	Sub-part	Provision	Task
94.2			Employee Training for Repacking and Relabeling Operations
94.3			Training by Manager for Repacking and Relabeling Operations
94.4			Record of Training for Repacking and Relabeling Operations
94.5			Written Procedure for Repacking and Relabeling Operations
94.6			Employee Training for Repacking and Relabeling Operations
94.7			Training by Manager for Repacking and Relabeling Operations
94.8			Record of Training for Repacking and Relabeling Operations
98.1		§1120.98 Warning plans	Written Procedure for Implementing FDA-approved Warning Plan
98.2			Employee Training for Implementing FDA-approved Warning Plan
98.3			Training by Manager for Implementing FDA-approved Warning Plan
98.4			Record of Training for Implementing FDA-approved Warning Plan
98.5			Written Procedure for Implementing FDA-approved Warning Plan
98.6			Employee Training for Implementing FDA-approved Warning Plan
98.7			Training by Manager for Implementing FDA-approved Warning Plan
98.8			Record of Training for Implementing FDA-approved Warning Plan
102.1	G	§1120.102 Handling and storage	Written Procedure for Preventing Adulteration During Handling and Storage
102.2			Employee Training for Preventing Adulteration During Handling and Storage
102.3			Training by Manager for Preventing Adulteration During Handling and Storage
102.4			Record of Training for Preventing Adulteration During Handling and Storage
102.5			Equipment Extra Storage Materials or Space
102.6			Written Procedure for Preventing Adulteration During Handling and Storage
102.7			Employee Training for Preventing Adulteration During Handling and Storage
102.8			Training by Manager for Preventing Adulteration During Handling and Storage
102.9			Record of Training for Preventing Adulteration During Handling and Storage
102.10			Equipment Extra Storage Materials or Space
104.1		§1120.104 Distribution	Written Procedure for Preventing Adulteration During Distribution
104.2			Employee Training for Preventing Adulteration During Distribution
104.3			Training by Manager for Preventing Adulteration During Distribution
104.4			Record of Training for Preventing Adulteration During Distribution
104.5			Written Procedure for Preventing Adulteration During Distribution

Line Item	Sub-part	Provision	Task
104.6			Employee Training for Preventing Adulteration During Distribution
104.7			Training by Manager for Preventing Adulteration During Distribution
104.8			Record of Training for Preventing Adulteration During Distribution
124.1	H	§1120.124 Document controls	Written Procedure for controlling documents

Subpart B Costs

Table 2 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart B to domestic facilities only. Total estimated one-time costs range from $1.5 million to $3.7 million; total annual costs range from $3.1 million to $9.3 million. These costs include:

- One-time costs for the written procedure requirements for this subpart to domestic facilities estimated to be between $0.8 and $2.3 million; and the annual cost estimated to be between $0.3 million and $1.1 million (in Table 2, sum of line items 12.1-12.3, 14.1, 14.6, 16.1, and 16.6).
- The one-time cost for the training requirements for this subpart is estimated to be between $0.7 million and $1.4 million (in Table 2, sum of line items 14.2-14.4, 14.7-14.9, 16.2-16.4, 16.7-16.9).
- The annual cost for CAPA requirement estimated to be between $2.7 million and $8.3 million (in Table 2, sum of line items 14.5, 14.10, 16.5, and 16.10).

Table 2: Detailed Calculation of Subpart B Costs - Management System Requirements

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
12.1	Written Procedure for Organizational Structure	Small	21	370	1	103	2	4	6	0	1	2	$76,011	$152,022	$228,033	$0	$38,005	$76,011
12.1	Written Procedure for Organizational Structure	Non-Small	7	12	1	103	4	8	12	2	2	2	$4,904	$9,808	$14,712	$2,452	$2,452	$2,452
12.2	Written Procedure for Designation of Responsibility	Small	21	370	1	103	2	4	6	1	1.5	2	$76,011	$152,022	$228,033	$38,005	$57,008	$76,011
12.2	Written Procedure for Designation of Responsibility	Non-Small	6	9	1	103	4	8	12	2	2	2	$3,853	$7,706	$11,559	$1,927	$1,927	$1,927
12.3	Written Procedure for Training Needs	Small	56	988	1	103	2	4	6	1	2	3	$202,696	$405,391	$608,087	$101,348	$202,696	$304,043
12.3	Written Procedure for Training Needs	Non-Small	18	31	1	103	4	8	12	2	4	6	$12,610	$25,220	$37,830	$6,305	$12,610	$18,915
14.1	Written Procedure for Handling Complaints	Small	52	917	1	103	2	4	6	1	2	3	$188,217	$376,435	$564,652	$94,109	$188,217	$282,326
14.2	Employee Training for Handling Complaints	Small	52	917	1	49	2	3	4	0	0	0	$89,723	$134,585	$179,447	$0	$0	$0
14.3	Training by Manager for Handling Complaints	Small	52	917	1	126	2	3	4	0	0	0	$231,483	$347,224	$462,966	$0	$0	$0
14.4	Record of Training for Handling Complaints	Small	52	917	2	126	0.05	0.05	0.05	0	0	0	$11,574	$11,574	$11,574	$0	$0	$0
14.5	Complaint Processing	Small	10	176	1	126	0	0	0	52	104	156	$0	$0	$0	$1,157,414	$2,314,828	$3,472,242
14.6	Written Procedure for	Non-Small	18	31	1	103	4	8	12	2	4	6	$12,610	$25,220	$37,830	$6,305	$12,610	$18,915

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Handling Complaints																	
14.7	Employee Training for Handling Complaints	Non-Small	18	31	10	49	2	3	4	0	0	0	$30,056	$45,084	$60,112	$0	$0	$0
14.8	Training by Manager for Handling Complaints	Non-Small	18	31	1	126	2	3	4	0	0	0	$7,754	$11,632	$15,509	$0	$0	$0
14.9	Record of Training for Handling Complaints	Non-Small	18	31	11	126	0.05	0.05	0.05	0	0	0	$2,132	$2,132	$2,132	$0	$0	$0
14.1	Complaint Processing	Non-Small	10	17	1	126	0	0	0	104	208	312	$0	$0	$0	$224,016	$448,031	$672,047
16.1	Written Procedure for Implementing CAPA	Small	50	882	1	103	2	4	6	1	2	3	$180,978	$361,957	$542,935	$90,489	$180,978	$271,467
16.2	Employee Training for Implementing CAPA	Small	50	882	1	49	2	3	4	0	0	0	$86,273	$129,409	$172,545	$0	$0	$0
16.3	Training by Manager for Implementing CAPA	Small	50	882	1	126	2	3	4	0	0	0	$222,580	$333,869	$445,159	$0	$0	$0
16.4	Record of Training for Implementing CAPA	Small	50	882	2	126	0.05	0.05	0.05	0	0	0	$11,129	$11,129	$11,129	$0	$0	$0
16.5	CAPA Implementation	Small	10	176	1	126	0	0	0	52	104	156	$0	$0	$0	$1,157,414	$2,314,828	$3,472,242
16.6	Written Procedure for Implementing CAPA	Non-Small	13	22	1	103	4	8	12	2	4	6	$9,107	$18,215	$27,322	$4,554	$9,107	$13,661
16.7	Employee Training for Implementing CAPA	Non-Small	13	22	10	49	2	3	4	0	0	0	$21,707	$32,561	$43,415	$0	$0	$0
16.8	Training by Manager for	Non-Small	13	22	1	126	2	3	4	0	0	0	$5,600	$8,401	$11,201	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Implementing CAPA																	
16.9	Record of Training for Implementing CAPA	Non-Small	13	22	11	126	0.05	0.05	0.05	0	0	0	$1,540	$1,540	$1,540	$0	$0	$0
16.1	CAPA Implementation	Non-Small	10	17	1	126	0	0	0	104	208	312	$0	$0	$0	$224,016	$448,031	$672,047
Total													**$1,488,550**	**$2,603,136**	**$3,717,722**	**$3,108,353**	**$6,231,330**	**$9,354,307**

(2020 USD)

Subpart C Costs

Table 3 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart C to domestic facilities only. Total estimated one-time costs range from $5.7 million to $16.5 million; total annual costs range from $1.3 million to $15.2 million. These costs include:

- One-time costs for the written procedure requirements for this subpart to domestic facilities estimated to be between $2.4 million and $5.9 million; and the annual cost estimated to be between $0.9 million and $ 2.3 million (in Table 3, sum of line numbers 32.1, 32.5, 34.1, 34.5, 34.9, 34.14, 36.1, 36.5, 36.9, 36.13, 36.17, 36.21, 38.1, and 38.5).
- The one-time cost for the training requirements for this subpart estimated to be between $3.3 million and $10.6 million (in Table 3, sum of line numbers 32.2-32.4, 32.6-32.8, 34.2-34.4, 34.6-34.8, 34.10-34.12, 34.15-34.17, 36.2-36.4, 36.6-36.8, 36.10-36.12, 36.14-36.16, 36.18-36.20, 36.22-36.24, 38.2-38.4, 38.6-38.8).
- The annual cost for the pest-control-related requirements for this subpart is estimated to be between $0.4 million and $12.9 million (in Table 3, sum of line numbers 34.13 and 34.18).

Table 3: Detailed Calculation of Subpart C Costs - Buildings, Facilities, and Equipment

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
32.1	Written Procedure for Personnel Cleaning Practices	Small	28	485	1	103	2	4	6	1	2	3	$99,538	$199,076	$298,614	$49,769	$99,538	$149,307
32.2	Employee Training for Personnel Cleaning Practices	Small	28	485	13	49	0.5	1	2	0	0	0	$154,212	$308,424	$616,849	$0	$0	$0
32.3	Training by Manager for Personnel Cleaning Practices	Small	28	485	1	126	0.5	1	2	0	0	0	$30,605	$61,209	$122,419	$0	$0	$0
32.4	Record of Training for Personnel Cleaning Practices	Small	28	485	14	126	0.05	0.05	0.05	0	0	0	$42,847	$42,847	$42,847	$0	$0	$0
32.5	Written Procedure for Personnel Cleaning Practices	Non-Small	27	46	1	103	4	8	12	2	3	4	$18,915	$37,830	$56,745	$9,458	$14,186	$18,915
32.6	Employee Training for Personnel Cleaning Practices	Non-Small	27	46	210	49	0.5	1	2	0	0	0	$236,693	$473,386	$946,772	$0	$0	$0
32.7	Training by Manager for Personnel Cleaning Practices	Non-Small	27	46	21	126	0.5	1	2	0	0	0	$61,066	$122,132	$244,263	$0	$0	$0
32.8	Record of Training for Personnel Cleaning Practices	Non-Small	27	46	231	126	0.05	0.05	0.05	0	0	0	$67,172	$67,172	$67,172	$0	$0	$0
34.1	Written Procedure for Facility	Small	44	776	1	103	2	4	6	1	2	3	$159,261	$318,522	$477,783	$79,630	$159,261	$238,891

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Cleaning Practices																	
34.2	Employee Training for Facility Cleaning Practices	Small	44	776	2	49	1	2	4	0	0	0	$75,920	$151,840	$303,679	$0	$0	$0
34.3	Training by Manager for Facility Cleaning Practices	Small	44	776	1	126	1	2	4	0	0	0	$97,935	$195,870	$391,740	$0	$0	$0
34.4	Record of Training for Facility Cleaning Practices	Small	44	776	3	126	0.05	0.05	0.05	0	0	0	$14,690	$14,690	$14,690	$0	$0	$0
34.5	Written Procedure for Facility Cleaning Practices	Non-Small	19	32	1	103	4	8	12	2	4	6	$13,311	$26,621	$39,932	$6,655	$13,311	$19,966
34.6	Employee Training for Facility Cleaning Practices	Non-Small	19	32	21	49	1	2	4	0	0	0	$33,312	$66,625	$133,249	$0	$0	$0
34.7	Training by Manager for Facility Cleaning Practices	Non-Small	19	32	2	126	1	2	4	0	0	0	$8,185	$16,370	$32,741	$0	$0	$0
34.8	Record of Training for Facility Cleaning Practices	Non-Small	19	32	23	126	0.05	0.05	0.05	0	0	0	$4,706	$4,706	$4,706	$0	$0	$0
34.9	Written Procedure for Animal and Pest Control	Small	36	635	1	103	20	30	40	5	7.5	10	$1,303,044	$1,954,565	$2,606,087	$325,761	$488,641	$651,522
34.1	Employee Training for Animal and Pest Control	Small	36	635	2	49	0.5	1	2	0	0	0	$31,058	$62,116	$124,232	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
34.11	Training by Manager for Animal and Pest Control	Small	36	635	1	126	0.5	1	2	0	0	0	$40,064	$80,129	$160,257	$0	$0	$0
34.12	Record of Training for Animal and Pest Control	Small	36	635	3	126	0.05	0.05	0.05	0	0	0	$12,019	$12,019	$12,019	$0	$0	$0
34.13	3rd Party Pest Control	Small	5	88	1								$0	$0	$0	$273,461	$5,588,308	$10,903,156
34.14	Written Procedure for Animal and Pest Control	Non-Small	17	29	1	103	20	30	40	5	7.5	10	$59,548	$89,322	$119,095	$14,887	$22,330	$29,774
34.15	Employee Training for Animal and Pest Control	Non-Small	17	29	10	49	0.5	1	2	0	0	0	$7,097	$14,193	$28,386	$0	$0	$0
34.16	Training by Manager for Animal and Pest Control	Non-Small	17	29	1	126	0.5	1	2	0	0	0	$1,831	$3,662	$7,324	$0	$0	$0
34.17	Record of Training for Animal and Pest Control	Non-Small	17	29	11	126	0.05	0.05	0.05	0	0	0	$2,014	$2,014	$2,014	$0	$0	$0
34.18	3rd Party Pest Control	Non-Small	5	9	1								$0	$0	$0	$132,320	$1,077,340	$2,022,360
36.1	Written Procedure for Maintenance of Equipment	Small	20	353	1	103	2	4	6	1	2	3	$72,391	$144,783	$217,174	$36,196	$72,391	$108,587
36.2	Employee Training for Maintenance of Equipment	Small	20	353	13	49	1	2	4	0	0	0	$224,309	$448,617	$897,234	$0	$0	$0
36.3	Training by Manager for Maintenance of Equipment	Small	20	353	2	126	1	2	4	0	0	0	$89,032	$178,064	$356,127	$0	$0	$0
36.4	Record of Training for Maintenance of Equipment	Small	20	353	15	126	0.05	0.05	0.05	0	0	0	$33,387	$33,387	$33,387	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
36.5	Written Procedure for Maintenance of Equipment	Non-Small	13	22	1	103	4	8	12	2	4	6	$9,107	$18,215	$27,322	$4,554	$9,107	$13,661
36.6	Employee Training for Maintenance of Equipment	Non-Small	13	22	210	49	1	2	4	0	0	0	$227,926	$455,853	$911,706	$0	$0	$0
36.7	Training by Manager for Maintenance of Equipment	Non-Small	13	22	21	126	1	2	4	0	0	0	$58,804	$117,608	$235,216	$0	$0	$0
36.8	Record of Training for Maintenance of Equipment	Non-Small	13	22	231	126	0.05	0.05	0.05	0	0	0	$32,342	$32,342	$32,342	$0	$0	$0
36.9	Written Procedure for Monitoring Equipment	Small	34	600	1	103	2	4	6	1	2	3	$123,065	$246,130	$369,196	$61,533	$123,065	$184,598
36.1	Employee Training for Monitoring Equipment	Small	34	600	2	49	2	4	6	0	0	0	$117,331	$234,661	$351,992	$0	$0	$0
36.11	Training by Manager for Monitoring Equipment	Small	34	600	1	126	2	4	6	0	0	0	$151,354	$302,708	$454,062	$0	$0	$0
36.12	Record of Training for Monitoring Equipment	Small	34	600	3	126	0.05	0.05	0.05	0	0	0	$11,352	$11,352	$11,352	$0	$0	$0
36.13	Written Procedure for Monitoring Equipment	Non-Small	27	46	1	103	4	8	12	2	4	6	$18,682	$37,363	$56,045	$9,341	$18,682	$28,022
36.14	Employee Training for Monitoring Equipment	Non-Small	27	46	10	49	2	4	6	0	0	0	$44,528	$89,056	$133,583	$0	$0	$0
36.15	Training by Manager for Monitoring Equipment	Non-Small	27	46	1	126	2	4	6	0	0	0	$11,488	$22,976	$34,464	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
36.16	Record of Training for Monitoring Equipment	Non-Small	27	46	11	126	0.05	0.05	0.05	0	0	0	$3,159	$3,159	$3,159	$0	$0	$0
36.17	Written Procedure for Calibrating Equipment	Small	70	1238	1	103	2	4	6	1	2	3	$254,005	$508,009	$762,014	$127,002	$254,005	$381,007
36.18	Employee Training for Calibrating Equipment	Small	70	1238	2	49	2	4	6	0	0	0	$242,169	$484,337	$726,506	$0	$0	$0
36.19	Training by Manager for Calibrating Equipment	Small	70	1238	1	126	2	4	6	0	0	0	$312,392	$624,785	$937,177	$0	$0	$0
36.2	Record of Training for Calibrating Equipment	Small	70	1238	3	126	0.05	0.05	0.05	0	0	0	$23,429	$23,429	$23,429	$0	$0	$0
36.21	Written Procedure for Calibrating Equipment	Non-Small	70	120	1	103	4	8	12	2	4	6	$49,162	$98,324	$147,487	$24,581	$49,162	$73,743
36.22	Employee Training for Calibrating Equipment	Non-Small	70	120	10	49	2	4	6	0	0	0	$117,178	$234,357	$351,535	$0	$0	$0
36.23	Training by Manager for Calibrating Equipment	Non-Small	70	120	1	126	2	4	6	0	0	0	$30,232	$60,463	$90,695	$0	$0	$0
36.24	Record of Training for Calibrating Equipment	Non-Small	70	120	11	126	0.05	0.05	0.05	0	0	0	$8,314	$8,314	$8,314	$0	$0	$0
38.1	Written Procedure for Controlling Environmental Conditions	Small	62	1094	1	103	2	4	6	1	2	3	$224,413	$448,826	$673,239	$112,207	$224,413	$336,620
38.2	Employee Training for Controlling	Small	62	1094	2	49	2	4	6	0	0	0	$213,956	$427,912	$641,868	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Environmental Conditions																	
38.3	Training by Manager for Controlling Environmental Conditions	Small	62	1094	1	126	2	4	6	0	0	0	$275,999	$551,997	$827,996	$0	$0	$0
38.4	Record of Training for Controlling Environmental Conditions	Small	62	1094	3	126	0.05	0.05	0.05	0	0	0	$20,700	$20,700	$20,700	$0	$0	$0
38.5	Written Procedure for Controlling Environmental Conditions	Non-Small	41	70	1	103	4	8	12	2	4	6	$28,723	$57,446	$86,169	$14,362	$28,723	$43,085
38.6	Employee Training for Controlling Environmental Conditions	Non-Small	41	70	10	49	2	4	6	0	0	0	$68,461	$136,923	$205,384	$0	$0	$0
38.7	Training by Manager for Controlling Environmental Conditions	Non-Small	41	70	1	126	2	4	6	0	0	0	$17,663	$35,326	$52,988	$0	$0	$0
38.8	Record of Training for Controlling Environmental Conditions	Non-Small	41	70	11	126	0.05	0.05	0.05	0	0	0	$4,857	$4,857	$4,857	$0	$0	$0
Total													**$5,694,953**	**$10,427,621**	**$16,538,338**	**$1,281,715**	**$8,242,464**	**$15,203,213**

(2020 USD)

Subpart D Costs

Table 4 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart D to domestic facilities only. Total estimated one-time costs range from $2.7 million to $5.6 million; total annual costs range from $0.8 million to $1.7 million. These costs include:

- The one-time cost for the written procedure requirements for this subpart estimated to be between $1.5 and $3.2 million; and the annual cost estimated to be between $0.7 and $1.6 million (in Table 4, sum of line items 42.1, 42.5, 44.1, 44.2, 44.7).
- The one-time cost for the training requirements for this subpart estimated to be between $1.2 million and $2.4 million (in Table 4, sum of line items 42.2-42.4, 42.6-42.8, 44.3-44.5, and 44.8-44.10).
- The annual cost for activities related to review and approval of the master manufacturing record estimated to be between $25,000 and $75,000 (in Table 4, sum of line items 44.6 and 44.11)

Table 4: Detailed Calculation of Subpart D Costs - Performance Controls

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
42.1	Written Procedure for Product Design and Risk Management Procedures	Small	64	1121	1	103	10	15	20	5	7.5	10	$1,150,217	$1,725,326	$2,300,435	$575,109	$862,663	$1,150,217
42.2	Employee Training for Product Design and Risk Management Procedures	Small	64	1121	3	49	2	3	4	0	0	0	$328,986	$493,479	$657,972	$0	$0	$0
42.3	Training by Manager for Product Design and Risk Management Procedures	Small	64	1121	1	126	2	3	4	0	0	0	$282,923	$424,385	$565,847	$0	$0	$0
42.4	Record of Training for Product Design and Risk Management Procedures	Small	64	1121	4	126	0.05	0.05	0.05	0	0	0	$28,292	$28,292	$28,292	$0	$0	$0
42.5	Written Procedure for Product Design and Risk Management Procedures	Non-Small	37	64	1	103	20	30	40	10	15	20	$131,161	$196,741	$262,321	$65,580	$98,370	$131,161
42.6	Employee Training for Product Design and Risk Management Procedures	Non-Small	37	64	21	49	2	3	4	0	0	0	$131,301	$196,952	$262,602	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
42.7	Training by Manager for Product Design and Risk Management Procedures	Non-Small	37	64	2	126	2	3	4	0	0	0	$32,262	$48,393	$64,524	$0	$0	$0
42.8	Record of Training for Product Design and Risk Management Procedures	Non-Small	37	64	23	126	0.05	0.05	0.05	0	0	0	$9,275	$9,275	$9,275	$0	$0	$0
44.1	Written Procedure for Master Manufacturing Record	Small	25	441	1	103	2	4	6	1	2	3	$90,489	$180,978	$271,467	$45,245	$90,489	$135,734
44.1	Written Procedure for Master Manufacturing Record	Non-Small	11	19	1	103	4	6	8	2	3	4	$7,706	$11,559	$15,412	$3,853	$5,780	$7,706
44.2	Written Procedure for Review and Approval of Master Manufacturing Record	Small	31	553	1	103	2	4	6	1	2	3	$113,413	$226,826	$340,239	$56,707	$113,413	$170,120
44.3	Employee Training for Review and Approval of Master Manufacturing Record	Small	31	553	3	49	2	3	4	0	0	0	$162,192	$243,289	$324,385	$0	$0	$0
44.4	Training by Manager for Review and Approval of Master Manufacturing Record	Small	31	553	1	126	2	3	4	0	0	0	$139,483	$209,225	$278,966	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
44.5	Record of Training for Review and Approval of Master Manufacturing Record	Small	31	553	4	126	0.05	0.05	0.05	0	0	0	$13,948	$13,948	$13,948	$0	$0	$0
44.6	Review and Approval of Master Manufacturing Record	Small	10	176	1	126	0	0	0	1	2	3	$0	$0	$0	$22,258	$44,516	$66,774
44.7	Written Procedure for Review and Approval of Master Manufacturing Record	Non-Small	22	37	1	103	4	8	12	2	3	4	$15,179	$30,358	$45,536	$7,589	$11,384	$15,179
44.8	Employee Training for Review and Approval of Master Manufacturing Record	Non-Small	22	37	21	49	2	3	4	0	0	0	$75,975	$113,963	$151,951	$0	$0	$0
44.9	Training by Manager for Review and Approval of Master Manufacturing Record	Non-Small	22	37	2	126	2	3	4	0	0	0	$18,668	$28,002	$37,336	$0	$0	$0
44.1	Record of Training for Review and Approval of Master Manufacturing Record	Non-Small	22	37	23	126	0.05	0.05	0.05	0	0	0	$5,367	$5,367	$5,367	$0	$0	$0
44.11	Review and Approval of Master Manufacturing Record	Non-Small	10	17	1	126	0	0	0	2	3	4	$0	$0	$0	$4,308	$6,462	$8,616

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
Total													**$2,736,840**	**$4,186,359**	**$5,635,878**	**$780,649**	**$1,233,077**	**$1,685,506**

(2020 USD)

Subpart E Costs

Table 5 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart E to domestic facilities only. Total estimated one-time costs range from $14.1 million to $26.2 million; total annual costs range from $9.5 million to $28.7 million. These costs include:

- One-time cost for the written procedure requirements for this subpart estimated to be between $2.6 million and $7.8million; and the annual cost estimated to be between $1.3 million and $3.9 million (in Table 5, sum of line items 62.1, 62.5, 62.9, 62.13, 64.11, 64.15, 64.19, 64.23, 64.27, 64.31, 66.1, 66.6, 66.11, 66.15, 66.19, 66.23, 66.27, 66.32, 68.1, 68.7, 70.1, 70.6, 72.1, 72.5, 74.1, 74.6, 76.1, 76.6, 78.1, and 78.5).
- The one-time cost for the training requirements for this subpart estimated to be between $7.1 million and $13.9 million (in Table 5, sum of line items 62.2-62.4, 62.6-62.8, 62.10-62.12, 62.14-62.16, 64.12-64.14, 64.16-64.18, 64.20-64.22, 64.24-64.26, 64.28-64.30, 64.32-64.34, 66.2-66.4, 66.7-66.9, 66.12-66.14, 66.16-66.18, 66.20-66.22, 66.24-66.26, 66.28-66.30, 66.33-66.35, 68.2-68.4, 68.8-68.10, 70.2-70.4, 70.7-70.9, 72.2-72.4, 72.6-72.8, 74.2-74.4, 74.7-74.9, 76.2-76.4, 76.7-76.9, 78.2-78.4, and 78.6-78.8).
- The annual cost for the activity-related requirements (other than written procedure and training requirements) for this subpart estimated to be between $8.2 million and $24.9 million (in Table 5, sum of line items 64.5, 64.10, 66.31, 66.36, 68.5, 68.11, 70.5, 70.10, 74.5, 74.10 76.5, 76.10).
- The one-time capital cost for this subpart estimated to be $4.5 million (in Table 5, sum of line items 66.5, 66.10, 68.6, and 68.12).

Table 5: Detailed Calculation of Subpart E Costs - Process Controls

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
62.1	Written Procedure for Purchasing Products or Services	Small	54	953	1	103	2	4	6	1	2	3	$195,457	$390,913	$586,370	$97,728	$195,457	$293,185
62.2	Employee Training for Purchasing Products or Services	Small	54	953	2	49	4	6	8	0	0	0	$372,697	$559,046	$745,395	$0	$0	$0
62.3	Training by Manager for Purchasing Products or Services	Small	54	953	1	126	4	6	8	0	0	0	$480,772	$721,158	$961,544	$0	$0	$0
62.4	Record of Training for Purchasing Products or Services	Small	54	953	3	126	0.05	0.05	0.05	0	0	0	$18,029	$18,029	$18,029	$0	$0	$0
62.5	Written Procedure for Purchasing Products or Services	Non-Small	25	43	1	103	4	8	12	2	4	6	$17,514	$35,028	$52,542	$8,757	$17,514	$26,271
62.6	Employee Training for Purchasing Products or Services	Non-Small	25	43	10	49	8	10	12	0	0	0	$166,979	$208,724	$250,469	$0	$0	$0
62.7	Training by Manager for Purchasing Products or Services	Non-Small	25	43	1	126	8	10	12	0	0	0	$43,080	$53,850	$64,620	$0	$0	$0
62.8	Record of Training for Purchasing Products or Services	Non-Small	25	43	11	126	0.05	0.05	0.05	0	0	0	$2,962	$2,962	$2,962	$0	$0	$0
62.9	Written Procedure for	Small	58	1023	1	103	2	4	6	1	2	3	$209,935	$419,870	$629,804	$104,967	$209,935	$314,902

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Qualifying Suppliers																	
62.1	Employee Training for Qualifying Suppliers	Small	58	1023	2	49	4	6	8	0	0	0	$400,305	$600,457	$800,609	$0	$0	$0
62.11	Training by Manager for Qualifying Suppliers	Small	58	1023	1	126	4	6	8	0	0	0	$516,385	$774,577	$1,032,770	$0	$0	$0
62.12	Record of Training for Qualifying Suppliers	Small	58	1023	3	126	0.05	0.05	0.05	0	0	0	$19,364	$19,364	$19,364	$0	$0	$0
62.13	Written Procedure for Qualifying Suppliers	Non-Small	27	46	1	103	4	8	12	2	4	6	$18,915	$37,830	$56,745	$9,458	$18,915	$28,373
62.14	Employee Training for Qualifying Suppliers	Non-Small	27	46	10	49	8	10	12	0	0	0	$180,337	$225,422	$270,506	$0	$0	$0
62.15	Training by Manager for Qualifying Suppliers	Non-Small	27	46	1	126	8	10	12	0	0	0	$46,526	$58,158	$69,789	$0	$0	$0
62.16	Record of Training for Qualifying Suppliers	Non-Small	27	46	11	126	0.05	0.05	0.05	0	0	0	$3,199	$3,199	$3,199	$0	$0	$0
64.1	Written Procedure for General Acceptance Activities	Small	0	0		103	2	4	6	1	2	3						
64.2	Employee Training for General Acceptance Activities	Small	0	0		49	2	3	4	0	0	0						
64.3	Training by Manager for General Acceptance Activities	Small	0	0		126	2	3	4	0	0	0						

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
64.4	Record of Training for General Acceptance Activities	Small	0	0		126	0.05	0.05	0.05	0	0	0						
64.5	Conducting Acceptance Activities	Small	10	176	1	126	0	0	0	52	104	156	$0	$0	$0	$1,157,414	$2,314,828	$3,472,242
64.6	Written Procedure for General Acceptance Activities	Non-Small	0	0		103	4	8	12	2	4	6						
64.7	Employee Training for General Acceptance Activities	Non-Small	0	0		49	2	3	4	0	0	0						
64.8	Training by Manager for General Acceptance Activities	Non-Small	0	0		126	2	3	4	0	0	0						
64.9	Record of Training for General Acceptance Activities	Non-Small	0	0		126	0.05	0.05	0.05	0	0	0						
64.1	Conducting Acceptance Activities	Non-Small	10	17	1	126	0	0	0	104	208	312	$0	$0	$0	$224,016	$448,031	$672,047
64.11	Written Procedure for Incoming Acceptance Activities	Small	33	582	1	103	2	4	6	1	2	3	$119,446	$238,891	$358,337	$59,723	$119,446	$179,168
64.12	Employee Training for Incoming Acceptance Activities	Small	33	582	2	49	2	3	4	0	0	0	$113,880	$170,820	$227,760	$0	$0	$0
64.13	Training by Manager for Incoming	Small	33	582	1	126	2	3	4	0	0	0	$146,903	$220,354	$293,805	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Acceptance Activities																	
64.14	Record of Training for Incoming Acceptance Activities	Small	33	582	3	126	0.05	0.05	0.05	0	0	0	$11,018	$11,018	$11,018	$0	$0	$0
64.15	Written Procedure for Incoming Acceptance Activities	Non-Small	17	29	1	103	4	8	12	2	4	6	$11,910	$23,819	$35,729	$5,955	$11,910	$17,864
64.16	Employee Training for Incoming Acceptance Activities	Non-Small	17	29	10	49	2	3	4	0	0	0	$28,386	$42,580	$56,773	$0	$0	$0
64.17	Training by Manager for Incoming Acceptance Activities	Non-Small	17	29	1	126	2	3	4	0	0	0	$7,324	$10,985	$14,647	$0	$0	$0
64.18	Record of Training for Incoming Acceptance Activities	Non-Small	17	29	11	126	0.05	0.05	0.05	0	0	0	$2,014	$2,014	$2,014	$0	$0	$0
64.19	Written Procedure for Pesticide Testing	Small	60	1059	1	103	2	4	6	1	2	3	$217,174	$434,348	$651,522	$108,587	$217,174	$325,761
64.2	Employee Training for Pesticide Testing	Small	60	1059	2	49	2	3	4	0	0	0	$207,054	$310,581	$414,108	$0	$0	$0
64.21	Training by Manager for Pesticide Testing	Small	60	1059	1	126	2	3	4	0	0	0	$267,096	$400,643	$534,191	$0	$0	$0
64.22	Record of Training for Pesticide Testing	Small	60	1059	3	126	0.05	0.05	0.05	0	0	0	$20,032	$20,032	$20,032	$0	$0	$0
64.23	Written Procedure for	Non-Small	32	55	1	103	4	8	12	2	4	6	$22,418	$44,836	$67,254	$11,209	$22,418	$33,627

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Pesticide Testing																	
64.24	Employee Training for Pesticide Testing	Non-Small	32	55	10	49	2	3	4	0	0	0	$53,433	$80,150	$106,867	$0	$0	$0
64.25	Training by Manager for Pesticide Testing	Non-Small	32	55	1	126	2	3	4	0	0	0	$13,786	$20,678	$27,571	$0	$0	$0
64.26	Record of Training for Pesticide Testing	Non-Small	32	55	11	126	0.05	0.05	0.05	0	0	0	$3,791	$3,791	$3,791	$0	$0	$0
64.27	Written Procedure for Tobacco Product Acceptance Activities	Small	43	759	1	103	2	4	6	1	2	3	$155,641	$311,283	$466,924	$77,821	$155,641	$233,462
64.28	Employee Training for Tobacco Product Acceptance Activities	Small	43	759	2	49	2	3	4	0	0	0	$148,389	$222,583	$296,778	$0	$0	$0
64.29	Training by Manager for Tobacco Product Acceptance Activities	Small	43	759	1	126	2	3	4	0	0	0	$191,418	$287,128	$382,837	$0	$0	$0
64.3	Record of Training for Tobacco Product Acceptance Activities	Small	43	759	3	126	0.05	0.05	0.05	0	0	0	$14,356	$14,356	$14,356	$0	$0	$0
64.31	Written Procedure for Tobacco Product Acceptance Activities	Non-Small	22	38	1	103	4	8	12	2	4	6	$15,412	$30,825	$46,237	$7,706	$15,412	$23,119

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
64.32	Employee Training for Tobacco Product Acceptance Activities	Non-Small	22	38	10	49	2	3	4	0	0	0	$36,735	$55,103	$73,471	$0	$0	$0
64.33	Training by Manager for Tobacco Product Acceptance Activities	Non-Small	22	38	1	126	2	3	4	0	0	0	$9,478	$14,216	$18,955	$0	$0	$0
64.34	Record of Training for Tobacco Product Acceptance Activities	Non-Small	22	38	11	126	0.05	0.05	0.05	0	0	0	$2,606	$2,606	$2,606	$0	$0	$0
66.1	Written Procedure for Monitoring and Controlling Production Operations	Small	31	547	1	103	2	4	6	1	2	3	$112,207	$224,413	$336,620	$56,103	$112,207	$168,310
66.2	Employee Training for Monitoring and Controlling Production Operations	Small	31	547	2	49	2	3	4	0	0	0	$106,978	$160,467	$213,956	$0	$0	$0
66.3	Training by Manager for Monitoring and Controlling Production Operations	Small	31	547	1	126	2	3	4	0	0	0	$137,999	$206,999	$275,999	$0	$0	$0
66.4	Record of Training for Monitoring and Controlling Production Operations	Small	31	547	3	126	0.05	0.05	0.05	0	0	0	$10,350	$10,350	$10,350	$0	$0	$0
66.5	Equipment Production Materials	Small	5	88									$308,746	$308,746	$308,746	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
66.6	Written Procedure for Monitoring and Controlling Production Operations	Non-Small	19	32	1	103	4	8	12	2	4	6	$13,311	$26,621	$39,932	$6,655	$13,311	$19,966
66.7	Employee Training for Monitoring and Controlling Production Operations	Non-Small	19	32	10	49	2	3	4	0	0	0	$31,726	$47,589	$63,452	$0	$0	$0
66.8	Training by Manager for Monitoring and Controlling Production Operations	Non-Small	19	32	1	126	2	3	4	0	0	0	$8,185	$12,278	$16,370	$0	$0	$0
66.9	Record of Training for Monitoring and Controlling Production Operations	Non-Small	19	32	11	126	0.05	0.05	0.05	0	0	0	$2,251	$2,251	$2,251	$0	$0	$0
66.1	Equipment Production Materials	Non-Small	5	9									$68,294	$68,294	$68,294	$0	$0	$0
66.11	Written Procedure for Removing Manufacturing Material	Small	32	559	1	103	2	4	6	1	2	3	$114,620	$229,239	$343,859	$57,310	$114,620	$171,929
66.12	Employee Training for Removing Manufacturing Material	Small	32	559	2	49	2	3	4	0	0	0	$109,279	$163,918	$218,557	$0	$0	$0
66.13	Training by Manager for Removing Manufacturing Material	Small	32	559	1	126	2	3	4	0	0	0	$140,967	$211,451	$281,934	$0	$0	$0
66.14	Record of Training for Removing	Small	32	559	3	126	0.05	0.05	0.05	0	0	0	$10,573	$10,573	$10,573	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Manufacturing Material																	
66.15	Written Procedure for Removing Manufacturing Material	Non-Small	37	63	1	103	4	8	12	2	4	6	$25,687	$51,374	$77,062	$12,844	$25,687	$38,531
66.16	Employee Training for Removing Manufacturing Material	Non-Small	37	63	10	49	2	3	4	0	0	0	$61,226	$91,839	$122,451	$0	$0	$0
66.17	Training by Manager for Removing Manufacturing Material	Non-Small	37	63	1	126	2	3	4	0	0	0	$15,796	$23,694	$31,592	$0	$0	$0
66.18	Record of Training for Removing Manufacturing Material	Non-Small	37	63	11	126	0.05	0.05	0.05	0	0	0	$4,344	$4,344	$4,344	$0	$0	$0
66.19	Written Procedure for Changes to Process Controls	Small	32	565	1	103	2	4	6	1	2	3	$115,826	$231,652	$347,478	$57,913	$115,826	$173,739
66.2	Employee Training for Changes to Process Controls	Small	32	565	2	49	2	3	4	0	0	0	$110,429	$165,643	$220,858	$0	$0	$0
66.21	Training by Manager for Changes to Process Controls	Small	32	565	1	126	2	3	4	0	0	0	$142,451	$213,676	$284,902	$0	$0	$0
66.22	Record of Training for Changes to Process Controls	Small	32	565	3	126	0.05	0.05	0.05	0	0	0	$10,684	$10,684	$10,684	$0	$0	$0
66.23	Written Procedure for Changes to	Non-Small	21	36	1	103	4	8	12	2	4	6	$14,712	$29,424	$44,135	$7,356	$14,712	$22,068

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Process Controls																	
66.24	Employee Training for Changes to Process Controls	Non-Small	21	36	10	49	2	3	4	0	0	0	$35,066	$52,598	$70,131	$0	$0	$0
66.25	Training by Manager for Changes to Process Controls	Non-Small	21	36	1	126	2	3	4	0	0	0	$9,047	$13,570	$18,094	$0	$0	$0
66.26	Record of Training for Changes to Process Controls	Non-Small	21	36	11	126	0.05	0.05	0.05	0	0	0	$2,488	$2,488	$2,488	$0	$0	$0
66.27	Written Procedure for Process Validation	Small	32	565	1	103	2	4	6	1	2	3	$115,826	$231,652	$347,478	$57,913	$115,826	$173,739
66.28	Employee Training for Process Validation	Small	32	565	2	49	2	3	4	0	0	0	$110,429	$165,643	$220,858	$0	$0	$0
66.29	Training by Manager for Process Validation	Small	32	565	1	126	2	3	4	0	0	0	$142,451	$213,676	$284,902	$0	$0	$0
66.3	Record of Training for Process Validation	Small	32	565	3	126	0.05	0.05	0.05	0	0	0	$10,684	$10,684	$10,684	$0	$0	$0
66.31	Production Processes Control Activities	Small	10	176	1	126	0	0	0	52	104	156	$0	$0	$0	$1,157,414	$2,314,828	$3,472,242
66.32	Written Procedure for Process Validation	Non-Small	70	120	1	103	4	8	12	2	4	6	$49,039	$98,079	$147,118	$24,520	$49,039	$73,559
66.33	Employee Training for Process Validation	Non-Small	70	120	10	49	2	3	4	0	0	0	$116,885	$175,328	$233,771	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
66.34	Training by Manager for Process Validation	Non-Small	70	120	1	126	2	3	4	0	0	0	$30,156	$45,234	$60,312	$0	$0	$0
66.35	Record of Training for Process Validation	Non-Small	70	120	11	126	0.05	0.05	0.05	0	0	0	$8,293	$8,293	$8,293	$0	$0	$0
66.36	Production Processes Control Activities	Non-Small	10	17	1	126	0	0	0	104	208	312	$0	$0	$0	$224,016	$448,031	$672,047
68.1	Written Procedure for Laboratory Functions	Small	29	512	1	103	2	4	6	1	2	3	$104,967	$209,935	$314,902	$52,484	$104,967	$157,451
68.2	Employee Training for Laboratory Functions	Small	29	512	2	49	2	3	4	0	0	0	$100,076	$150,114	$200,152	$0	$0	$0
68.3	Training by Manager for Laboratory Functions	Small	29	512	1	126	2	3	4	0	0	0	$129,096	$193,644	$258,192	$0	$0	$0
68.4	Record of Training for Laboratory Functions	Small	29	512	3	126	0.05	0.05	0.05	0	0	0	$9,682	$9,682	$9,682	$0	$0	$0
68.5	Conducting Laboratory Control Activities	Small	10	176	1	126	0	0	0	52	104	156	$0	$0	$0	$1,157,414	$2,314,828	$3,472,242
68.6	Equipment Laboratory Materials	Small	5	88									$3,422,674	$3,422,674	$3,422,674	$0	$0	$0
68.7	Written Procedure for Laboratory Functions	Non-Small	19	32	1	103	4	8	12	2	4	6	$13,311	$26,621	$39,932	$6,655	$13,311	$19,966
68.8	Employee Training for Laboratory Functions	Non-Small	19	32	10	49	2	3	4	0	0	0	$31,726	$47,589	$63,452	$0	$0	$0
68.9	Training by Manager for	Non-Small	19	32	1	126	2	3	4	0	0	0	$8,185	$12,278	$16,370	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Laboratory Functions																	
68.1	Record of Training for Laboratory Functions	Non-Small	19	32	11	126	0.05	0.05	0.05	0	0	0	$2,251	$2,251	$2,251	$0	$0	$0
68.11	Conducting Laboratory Control Activities	Non-Small	10	17	1	126	0	0	0	104	208	312	$0	$0	$0	$224,016	$448,031	$672,047
68.12	Equipment Laboratory Materials	Non-Small	5	9									$663,307	$663,307	$663,307	$0	$0	$0
70.1	Written Procedure for Production Record Practices	Small	46	812	1	103	2	4	6	1	2	3	$166,500	$333,000	$499,500	$83,250	$166,500	$249,750
70.2	Employee Training for Production Record Practices	Small	46	812	2	49	0.5	1	2	0	0	0	$39,685	$79,371	$158,741	$0	$0	$0
70.3	Training by Manager for Production Record Practices	Small	46	812	1	126	0.5	1	2	0	0	0	$51,193	$102,387	$204,773	$0	$0	$0
70.4	Record of Training for Production Record Practices	Small	46	812	3	126	0.05	0.05	0.05	0	0	0	$15,358	$15,358	$15,358	$0	$0	$0
70.5	Review of Production Record	Small	10	176	1	126	0	0	0	52	104	156	$0	$0	$0	$1,157,414	$2,314,828	$3,472,242
70.6	Written Procedure for Production Record Practices	Non-Small	43	73	1	103	4	8	12	2	4	6	$30,124	$60,248	$90,372	$15,062	$30,124	$45,186
70.7	Employee Training for Production	Non-Small	43	73	10	49	0.5	1	2	0	0	0	$17,950	$35,901	$71,801	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Record Practices																	
70.8	Training by Manager for Production Record Practices	Non-Small	43	73	1	126	0.5	1	2	0	0	0	$4,631	$9,262	$18,524	$0	$0	$0
70.9	Record of Training for Production Record Practices	Non-Small	43	73	11	126	0.05	0.05	0.05	0	0	0	$5,094	$5,094	$5,094	$0	$0	$0
70.1	Review of Production Record	Non-Small	10	17	1	126	0	0	0	104	208	312	$0	$0	$0	$224,016	$448,031	$672,047
72.1	Written Procedure for Sampling Plans	Small	69	1217	1	103	2	4	6	1	2	3	$249,750	$499,500	$749,250	$124,875	$249,750	$374,625
72.2	Employee Training for Sampling Plans	Small	69	1217	2	49	2	3	4	0	0	0	$238,112	$357,168	$476,224	$0	$0	$0
72.3	Training by Manager for Sampling Plans	Small	69	1217	1	126	2	3	4	0	0	0	$307,160	$460,740	$614,320	$0	$0	$0
72.4	Record of Training for Sampling Plans	Small	69	1217	3	126	0.05	0.05	0.05	0	0	0	$23,037	$23,037	$23,037	$0	$0	$0
72.5	Written Procedure for Sampling Plans	Non-Small	72	123	1	103	4	8	12	2	4	6	$50,440	$100,881	$151,321	$25,220	$50,440	$75,661
72.6	Employee Training for Sampling Plans	Non-Small	72	123	10	49	2	3	4	0	0	0	$120,225	$180,337	$240,450	$0	$0	$0
72.7	Training by Manager for Sampling Plans	Non-Small	72	123	1	126	2	3	4	0	0	0	$31,018	$46,526	$62,035	$0	$0	$0
72.8	Record of Training for Sampling Plans	Non-Small	72	123	11	126	0.05	0.05	0.05	0	0	0	$8,530	$8,530	$8,530	$0	$0	$0
74.1	Written Procedure for Controlling Nonconforming Products	Small	36	640	1	103	2	4	6	1	2	3	$131,250	$262,500	$393,750	$65,625	$131,250	$196,875

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
74.2	Employee Training for Controlling Nonconforming Products	Small	36	640	2	49	2	3	4	0	0	0	$125,134	$187,701	$250,268	$0	$0	$0
74.3	Training by Manager for Controlling Nonconforming Products	Small	36	640	1	126	2	3	4	0	0	0	$161,420	$242,131	$322,841	$0	$0	$0
74.4	Record of Training for Controlling Nonconforming Products	Small	36	640	3	126	0.05	0.05	0.05	0	0	0	$12,107	$12,107	$12,107	$0	$0	$0
74.5	Control and Disposition of Nonconforming Products	Small	10	176	1	126	0	0	0	52	104	156	$0	$0	$0	$1,157,414	$2,314,828	$3,472,242
74.6	Written Procedure for Controlling Nonconforming Products	Non-Small	11	19	1	103	4	8	12	2	4	6	$7,605	$15,210	$22,814	$3,802	$7,605	$11,407
74.7	Employee Training for Controlling Nonconforming Products	Non-Small	11	19	10	49	2	3	4	0	0	0	$18,126	$27,189	$36,252	$0	$0	$0
74.8	Training by Manager for Controlling Nonconforming Products	Non-Small	11	19	1	126	2	3	4	0	0	0	$4,676	$7,015	$9,353	$0	$0	$0
74.9	Record of Training for Controlling Nonconforming Products	Non-Small	11	19	11	126	0.05	0.05	0.05	0	0	0	$1,286	$1,286	$1,286	$0	$0	$0
74.1	Control and Disposition of Nonconforming Products	Non-Small	10	17	1	126	0	0	0	104	208	312	$0	$0	$0	$224,016	$448,031	$672,047
76.1	Written Procedure for	Small	35	617	1	103	2	4	6	1	2	3	$126,685	$253,370	$380,054	$63,342	$126,685	$190,027

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Controlling Returned Tobacco Products																	
76.2	Employee Training for Controlling Returned Tobacco Products	Small	35	617	2	49	2	3	4	0	0	0	$120,782	$181,172	$241,563	$0	$0	$0
76.3	Training by Manager for Controlling Returned Tobacco Products	Small	35	617	1	126	2	3	4	0	0	0	$155,806	$233,709	$311,611	$0	$0	$0
76.4	Record of Training for Controlling Returned Tobacco Products	Small	35	617	3	126	0.05	0.05	0.05	0	0	0	$11,685	$11,685	$11,685	$0	$0	$0
76.5	Inspection and Evaluation of Returned Tobacco Products	Small	10	176	1	126	0	0	0	52	104	156	$0	$0	$0	$1,157,414	$2,314,828	$3,472,242
76.6	Written Procedure for Controlling Returned Tobacco Products	Non-Small	27	46	1	103	4	8	12	2	4	6	$18,915	$37,830	$56,745	$9,458	$18,915	$28,373
76.7	Employee Training for Controlling Returned Tobacco Products	Non-Small	27	46	10	49	2	3	4	0	0	0	$45,084	$67,627	$90,169	$0	$0	$0
76.8	Training by Manager for Controlling Returned Tobacco Products	Non-Small	27	46	1	126	2	3	4	0	0	0	$11,632	$17,447	$23,263	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
76.9	Record of Training for Controlling Returned Tobacco Products	Non-Small	27	46	11	126	0.05	0.05	0.05	0	0	0	$3,199	$3,199	$3,199	$0	$0	$0
76.1	Inspection and Evaluation of Returned Tobacco Products	Non-Small	10	17	1	126	0	0	0	104	208	312	$0	$0	$0	$224,016	$448,031	$672,047
78.1	Written Procedure for Reprocessing and Reworking Tobacco Products	Small	37	653	1	103	2	4	6	1	2	3	$133,924	$267,848	$401,772	$66,962	$133,924	$200,886
78.2	Employee Training for Reprocessing and Reworking Tobacco Products	Small	37	653	2	49	2	3	4	0	0	0	$127,683	$191,525	$255,367	$0	$0	$0
78.3	Training by Manager for Reprocessing and Reworking Tobacco Products	Small	37	653	1	126	2	3	4	0	0	0	$164,709	$247,063	$329,418	$0	$0	$0
78.4	Record of Training for Reprocessing and Reworking Tobacco Products	Small	37	653	3	126	0.05	0.05	0.05	0	0	0	$12,353	$12,353	$12,353	$0	$0	$0
78.5	Written Procedure for Reprocessing and Reworking Tobacco Products	Non-Small	30	50	1	103	4	8	12	2	4	6	$20,667	$41,333	$62,000	$10,333	$20,667	$31,000
78.6	Employee Training for Reprocessing and Reworking	Non-Small	30	50	10	49	2	3	4	0	0	0	$49,259	$73,888	$98,518	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Tobacco Products																	
78.7	Training by Manager for Reprocessing and Reworking Tobacco Products	Non-Small	30	50	1	126	2	3	4	0	0	0	$12,709	$19,063	$25,417	$0	$0	$0
78.8	Record of Training for Reprocessing and Reworking Tobacco Products	Non-Small	30	50	11	126	0.05	0.05	0.05	0	0	0	$3,495	$3,495	$3,495	$0	$0	$0
Total													**$14,143,431**	**$20,098,172**	**$26,166,372**	**$9,588,172**	**$19,176,343**	**$28,764,515**

(2020 USD)

Subpart F Costs

Table 6 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart F to domestic facilities only. Total estimated one-time costs range from $2.2 million to $6.6 million; total annual costs range from $195,000 to $585,000. These costs include:

- The one-time cost for the written procedure requirements for this subpart estimated to be between $0.4 million and $1.2 million; and the annual cost estimated to be between $195,000 and $585,000 (in Table 6, sum of line items 92.1, 92.5, 94.1, 94.5, 98.1, and 98.5).
- The one-time cost for the training requirements for this subpart estimated to be between $1.8 million and $5.4 million (in Table 6, sum of line items 92.2-92.4, 92.6-92.8, 94.2-94.4, 94.6-94.8, 98.2-98.4, and 98.6-98.8).

Table 6: Detailed Calculation of Subpart F Costs - Packaging and Labeling Controls

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
92.1	Written Procedure for Controlling Packaging and Labeling	Small	34	600	1	103	2	4	6	1	2	3	$123,065	$246,130	$369,196	$61,533	$123,065	$184,598
92.2	Employee Training for Controlling Packaging and Labeling	Small	34	600	2	49	4	6	12	0	0	0	$234,661	$351,992	$703,984	$0	$0	$0
92.3	Training by Manager for Controlling Packaging and Labeling	Small	34	600	1	126	4	6	12	0	0	0	$302,708	$454,062	$908,125	$0	$0	$0
92.4	Record of Training for Controlling Packaging and Labeling	Small	34	600	3	126	0.05	0.05	0.05	0	0	0	$11,352	$11,352	$11,352	$0	$0	$0
92.5	Written Procedure for Controlling Packaging and Labeling	Non-Small	27	46	1	103	4	8	12	2	4	6	$18,915	$37,830	$56,745	$9,458	$18,915	$28,373
92.6	Employee Training for Controlling Packaging and Labeling	Non-Small	27	46	10	49	4	6	12	0	0	0	$90,169	$135,253	$270,506	$0	$0	$0
92.7	Training by Manager for Controlling Packaging and Labeling	Non-Small	27	46	1	126	4	6	12	0	0	0	$23,263	$34,895	$69,789	$0	$0	$0
92.8	Record of Training for Controlling Packaging and Labeling	Non-Small	27	46	11	126	0.05	0.05	0.05	0	0	0	$3,199	$3,199	$3,199	$0	$0	$0
94.1	Written Procedure for Repacking	Small	29	512	1	103	2	4	6	1	2	3	$104,967	$209,935	$314,902	$52,484	$104,967	$157,451

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	and Relabeling Operations																	
94.2	Employee Training for Repacking and Relabeling Operations	Small	29	512	2	49	4	6	12	0	0	0	$200,152	$300,228	$600,457	$0	$0	$0
94.3	Training by Manager for Repacking and Relabeling Operations	Small	29	512	1	126	4	6	12	0	0	0	$258,192	$387,289	$774,577	$0	$0	$0
94.4	Record of Training for Repacking and Relabeling Operations	Small	29	512	3	126	0.05	0.05	0.05	0	0	0	$9,682	$9,682	$9,682	$0	$0	$0
94.5	Written Procedure for Repacking and Relabeling Operations	Non-Small	30	51	1	103	4	8	12	2	4	6	$21,017	$42,034	$63,050	$10,508	$21,017	$31,525
94.6	Employee Training for Repacking and Relabeling Operations	Non-Small	30	51	10	49	4	6	12	0	0	0	$100,187	$150,281	$300,562	$0	$0	$0
94.7	Training by Manager for Repacking and Relabeling Operations	Non-Small	30	51	1	126	4	6	12	0	0	0	$25,848	$38,772	$77,544	$0	$0	$0
94.8	Record of Training for Repacking and Relabeling Operations	Non-Small	30	51	11	126	0.05	0.05	0.05	0	0	0	$3,554	$3,554	$3,554	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
98.1	Written Procedure for Implementing FDA-approved Warning Plan	Small	29	517	1	103	2	4	6	1	2	3	$106,138	$212,275	$318,413	$53,069	$106,138	$159,206
98.2	Employee Training for Implementing FDA-approved Warning Plan	Small	29	517	2	49	4	6	12	0	0	0	$202,384	$303,576	$607,151	$0	$0	$0
98.3	Training by Manager for Implementing FDA-approved Warning Plan	Small	29	517	1	126	4	6	12	0	0	0	$261,071	$391,606	$783,213	$0	$0	$0
98.4	Record of Training for Implementing FDA-approved Warning Plan	Small	29	517	3	126	0.05	0.05	0.05	0	0	0	$9,790	$9,790	$9,790	$0	$0	$0
98.5	Written Procedure for Implementing FDA-approved Warning Plan	Non-Small	23	39	1	103	4	8	12	2	4	6	$16,113	$32,226	$48,339	$8,056	$16,113	$24,169
98.6	Employee Training for Implementing FDA-approved Warning Plan	Non-Small	23	39	10	49	4	6	12	0	0	0	$76,810	$115,216	$230,431	$0	$0	$0
98.7	Training by Manager for Implementing FDA-approved Warning Plan	Non-Small	23	39	1	126	4	6	12	0	0	0	$19,817	$29,725	$59,450	$0	$0	$0
98.8	Record of Training for Implementing	Non-Small	23	39	11	126	0.05	0.05	0.05	0	0	0	$2,725	$2,725	$2,725	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	FDA-approved Warning Plan																	
Total													**$2,225,780**	**$3,513,627**	**$6,596,737**	**$195,108**	**$390,215**	**$585,323**

(2020 USD)

Subpart G Costs

Table 7 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart G to domestic facilities only. Total estimated one-time costs range from $1.8 million to $3.6 million; total annual costs range from $180,000 to $340,000. These costs include:

- The one-time cost for the written procedure requirements for this subpart estimated to be between $0.4 million and $1.1 million; and the annual cost estimated to be between $180,000 and $340,000 (in Table 7, sum of line items 102.1, 102.6, 104.1, and 104.5).
- The one-time cost for the training requirements for this subpart estimated to be between $1.1 million and $2.2 million (in Table 7, sum of line items 102.2-102.4, 102.7-102.9, 104.2-104.4, and 104.6-104.8).
- The one-time capital cost for this subpart estimated to be about $340,000 (in Table 7, sum of line items 102.5 and 102.10).

Table 7: Detailed Calculation of Subpart G Costs - Handling, Storage, and Distribution

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
102.1	Written Procedure for Preventing Adulteration During Handling and Storage	Small	43	759	1	103	2	4	6	1	1.5	2	$155,641	$311,283	$466,924	$77,821	$116,731	$155,641
102.2	Employee Training for Preventing Adulteration During Handling and Storage	Small	43	759	3	49	2	3	4	0	0	0	$222,583	$333,875	$445,166	$0	$0	$0
102.3	Training by Manager for Preventing Adulteration During Handling and Storage	Small	43	759	1	126	2	3	4	0	0	0	$191,418	$287,128	$382,837	$0	$0	$0
102.4	Record of Training for Preventing Adulteration During Handling and Storage	Small	43	759	4	126	0.05	0.05	0.05	0	0	0	$19,142	$19,142	$19,142	$0	$0	$0
102.5	Equipment Extra Storage Materials or Space	Small	5	88									$282,282	$282,282	$282,282	$0	$0	$0
102.6	Written Procedure for Preventing Adulteration During Handling and Storage	Non-Small	21	36	1	103	4	8	12	2	2	2	$14,712	$29,424	$44,135	$7,356	$7,356	$7,356

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
102.7	Employee Training for Preventing Adulteration During Handling and Storage	Non-Small	21	36	21	49	2	3	4	0	0	0	$73,638	$110,457	$147,276	$0	$0	$0
102.8	Training by Manager for Preventing Adulteration During Handling and Storage	Non-Small	21	36	2	126	2	3	4	0	0	0	$18,094	$27,140	$36,187	$0	$0	$0
102.9	Record of Training for Preventing Adulteration During Handling and Storage	Non-Small	21	36	23	126	0.05	0.05	0.05	0	0	0	$5,202	$5,202	$5,202	$0	$0	$0
102.1	Equipment Extra Storage Materials or Space	Non-Small	5	9									$54,635	$54,635	$54,635	$0	$0	$0
104.1	Written Procedure for Preventing Adulteration During Distribution	Small	47	829	1	103	2	4	6	1	1.5	2	$170,120	$340,239	$510,359	$85,060	$127,590	$170,120
104.2	Employee Training for Preventing Adulteration During Distribution	Small	47	829	3	49	2	3	4	0	0	0	$243,289	$364,933	$486,577	$0	$0	$0
104.3	Training by Manager for Preventing Adulteration During Distribution	Small	47	829	1	126	2	3	4	0	0	0	$209,225	$313,837	$418,450	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
104.4	Record of Training for Preventing Adulteration During Distribution	Small	47	829	4	126	0.05	0.05	0.05	0	0	0	$20,922	$20,922	$20,922	$0	$0	$0
104.5	Written Procedure for Preventing Adulteration During Distribution	Non-Small	23	39	1	103	4	8	12	2	2	2	$16,113	$32,226	$48,339	$8,056	$8,056	$8,056
104.6	Employee Training for Preventing Adulteration During Distribution	Non-Small	23	39	21	49	2	3	4	0	0	0	$80,651	$120,976	$161,302	$0	$0	$0
104.7	Training by Manager for Preventing Adulteration During Distribution	Non-Small	23	39	2	126	2	3	4	0	0	0	$19,817	$29,725	$39,634	$0	$0	$0
104.8	Record of Training for Preventing Adulteration During Distribution	Non-Small	23	39	23	126	0.05	0.05	0.05	0	0	0	$5,697	$5,697	$5,697	$0	$0	$0
Total													**$1,803,181**	**$2,689,124**	**$3,575,066**	**$178,293**	**$259,733**	**$341,173**

(2020 USD)

Subpart H Costs

Table 8 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart H to domestic facilities only. Total estimated one-time costs range from $0.2 million to $0.7 million; total annual costs range from $125,000 to $250,000.

Table 8: Detailed Calculation of Subpart H Costs - Recordkeeping and Document Controls

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
124.1	Written Procedure for controlling documents	Small	65	1147	1	103	2	4	6	1	1.5	2	$235,272	$470,544	$705,815	$117,636	$176,454	$235,272
124.1	Written Procedure for controlling documents	Non-Small	15	26	1	103	4	8	12	2	4	6	$10,508	$21,017	$31,525	$5,254	$10,508	$15,763
Total													**$245,780**	**$491,560**	**$737,341**	**$122,890**	**$186,962**	**$251,034**

(2020 USD)

Appendix B – Costs to Foreign Facilities

Costs attributable to written procedures may include costs to define, document in writing, and update each procedure. Additionally, they may include the costs of creating and maintaining records to document the performance of activities in writing. Where applicable, the marginal costs to implement the procedures and conduct the specific activities required in each Subpart are estimated separately.

For each quantified provision in the proposed regulation, the total estimated costs of the provisions is equal to the sum of the two products:

1.Estimated nonalignment rate among small manufacturers (see section C.2.2) × total number of small manufacturing establishments (see section C.1) × cost of performing the task required by the provision.

2.Estimated nonalignment rate among non-small manufacturers (see section C.2.2) × total number of non-small manufacturing establishments (see section C.1) × cost of performing the task required by the provision.

Table 1 lists the tasks under each provision. Subsequent tables refer to tasks and line items in Table 1.

Table 1: List of Tasks by Rule Provision

Line Item	Sub-part	Provision	Task
12.1	B	§1120.12 Organization and personnel	Written Procedure for Organizational Structure
12.2			Written Procedure for Designation of Responsibility
12.3			Written Procedure for Training Needs
14.1		§1120.14 Tobacco product complaints	Written Procedure for Handling Complaints
14.2			Employee Training for Handling Complaints
14.3			Training by Manager for Handling Complaints
14.4			Record of Training for Handling Complaints
14.5			Complaint Processing
14.6			Written Procedure for Handling Complaints
14.7			Employee Training for Handling Complaints
14.8			Training by Manager for Handling Complaints
14.9			Record of Training for Handling Complaints
14.10			Complaint Processing
16.1		§1120.16 Corrective and preventive actions (CAPA)	Written Procedure for Implementing CAPA
16.2			Employee Training for Implementing CAPA
16.3			Training by Manager for Implementing CAPA
16.4			Record of Training for Implementing CAPA
16.5			CAPA Implementation
16.6			Written Procedure for Implementing CAPA
16.7			Employee Training for Implementing CAPA
16.8			Training by Manager for Implementing CAPA
16.9			Record of Training for Implementing CAPA
16.10			CAPA Implementation
32.1	C	§1120.32 Personnel	Written Procedure for Personnel Cleaning Practices
32.2			Employee Training for Personnel Cleaning Practices
32.3			Training by Manager for Personnel Cleaning Practices
32.4			Record of Training for Personnel Cleaning Practices
32.5			Written Procedure for Personnel Cleaning Practices
32.6			Employee Training for Personnel Cleaning Practices

Line Item	Sub-part	Provision	Task
32.7			Training by Manager for Personnel Cleaning Practices
32.8			Record of Training for Personnel Cleaning Practices
34.1		§1120.34 Buildings, facilities and grounds	Written Procedure for Facility Cleaning Practices
34.2			Employee Training for Facility Cleaning Practices
34.3			Training by Manager for Facility Cleaning Practices
34.4			Record of Training for Facility Cleaning Practices
34.5			Written Procedure for Facility Cleaning Practices
34.6			Employee Training for Facility Cleaning Practices
34.7			Training by Manager for Facility Cleaning Practices
34.8			Record of Training for Facility Cleaning Practices
34.9			Written Procedure for Animal and Pest Control
34.10			Employee Training for Animal and Pest Control
34.11			Training by Manager for Animal and Pest Control
34.12			Record of Training for Animal and Pest Control
34.13			3rd Party Pest Control
34.14			Written Procedure for Animal and Pest Control
34.15			Employee Training for Animal and Pest Control
34.16			Training by Manager for Animal and Pest Control
34.17			Record of Training for Animal and Pest Control
34.18			3rd Party Pest Control
36.1		§1120.36 Equipment	Written Procedure for Maintenance of Equipment
36.2			Employee Training for Maintenance of Equipment
36.3			Training by Manager for Maintenance of Equipment
36.4			Record of Training for Maintenance of Equipment
36.5			Written Procedure for Maintenance of Equipment
36.6			Employee Training for Maintenance of Equipment
36.7			Training by Manager for Maintenance of Equipment
36.8			Record of Training for Maintenance of Equipment
36.9			Written Procedure for Monitoring Equipment
36.10			Employee Training for Monitoring Equipment
36.11			Training by Manager for Monitoring Equipment
36.12			Record of Training for Monitoring Equipment
36.13			Written Procedure for Monitoring Equipment
36.14			Employee Training for Monitoring Equipment
36.15			Training by Manager for Monitoring Equipment
36.16			Record of Training for Monitoring Equipment
36.17			Written Procedure for Calibrating Equipment
36.18			Employee Training for Calibrating Equipment
36.19			Training by Manager for Calibrating Equipment
36.20			Record of Training for Calibrating Equipment
36.21			Written Procedure for Calibrating Equipment
36.22			Employee Training for Calibrating Equipment
36.23			Training by Manager for Calibrating Equipment
36.24			Record of Training for Calibrating Equipment
38.1		§1120.38 Environment controls	Written Procedure for Controlling Environmental Conditions
38.2			Employee Training for Controlling Environmental Conditions

Line Item	Sub-part	Provision	Task
38.3			Training by Manager for Controlling Environmental Conditions
38.4			Record of Training for Controlling Environmental Conditions
38.5			Written Procedure for Controlling Environmental Conditions
38.6			Employee Training for Controlling Environmental Conditions
38.7			Training by Manager for Controlling Environmental Conditions
38.8			Record of Training for Controlling Environmental Conditions
42.1		§1120.42 Design and development activities	Written Procedure for Product Design and Risk Management Procedures
42.2			Employee Training for Product Design and Risk Management Procedures
42.3			Training by Manager for Product Design and Risk Management Procedures
42.4			Record of Training for Product Design and Risk Management Procedures
42.5			Written Procedure for Product Design and Risk Management Procedures
42.6			Employee Training for Product Design and Risk Management Procedures
42.7			Training by Manager for Product Design and Risk Management Procedures
42.8			Record of Training for Product Design and Risk Management Procedures
44.1	D	§1120.44 Master manufacturing record	Written Procedure for Master Manufacturing Record
44.2			Written Procedure for Review and Approval of Master Manufacturing Record
44.3			Employee Training for Review and Approval of Master Manufacturing Record
44.4			Training by Manager for Review and Approval of Master Manufacturing Record
44.5			Record of Training for Review and Approval of Master Manufacturing Record
44.6			Review and Approval of Master Manufacturing Record
44.7			Written Procedure for Review and Approval of Master Manufacturing Record
44.8			Employee Training for Review and Approval of Master Manufacturing Record
44.9			Training by Manager for Review and Approval of Master Manufacturing Record
44.10			Record of Training for Review and Approval of Master Manufacturing Record
44.11			Review and Approval of Master Manufacturing Record
62.1	E	§1120.62 Purchasing controls	Written Procedure for Purchasing Products or Services
62.2			Employee Training for Purchasing Products or Services
62.3			Training by Manager for Purchasing Products or Services
62.4			Record of Training for Purchasing Products or Services
62.5			Written Procedure for Purchasing Products or Services
62.6			Employee Training for Purchasing Products or Services
62.7			Training by Manager for Purchasing Products or Services
62.8			Record of Training for Purchasing Products or Services
62.9			Written Procedure for Qualifying Suppliers
62.10			Employee Training for Qualifying Suppliers
62.11			Training by Manager for Qualifying Suppliers
62.12			Record of Training for Qualifying Suppliers
62.13			Written Procedure for Qualifying Suppliers
62.14			Employee Training for Qualifying Suppliers

Line Item	Sub-part	Provision	Task
62.15			Training by Manager for Qualifying Suppliers
62.16			Record of Training for Qualifying Suppliers
64.1		§1120.64 Acceptance Activities	Written Procedure for General Acceptance Activities
64.2			Employee Training for General Acceptance Activities
64.3			Training by Manager for General Acceptance Activities
64.4			Record of Training for General Acceptance Activities
64.5			Conducting Acceptance Activities
64.6			Written Procedure for General Acceptance Activities
64.7			Employee Training for General Acceptance Activities
64.8			Training by Manager for General Acceptance Activities
64.9			Record of Training for General Acceptance Activities
64.10			Conducting Acceptance Activities
64.11			Written Procedure for Incoming Acceptance Activities
64.12			Employee Training for Incoming Acceptance Activities
64.13			Training by Manager for Incoming Acceptance Activities
64.14			Record of Training for Incoming Acceptance Activities
64.15			Written Procedure for Incoming Acceptance Activities
64.16			Employee Training for Incoming Acceptance Activities
64.17			Training by Manager for Incoming Acceptance Activities
64.18			Record of Training for Incoming Acceptance Activities
64.19			Written Procedure for Pesticide Testing
64.20			Employee Training for Pesticide Testing
64.21			Training by Manager for Pesticide Testing
64.22			Record of Training for Pesticide Testing
64.23			Written Procedure for Pesticide Testing
64.24			Employee Training for Pesticide Testing
64.25			Training by Manager for Pesticide Testing
64.26			Record of Training for Pesticide Testing
64.27			Written Procedure for Tobacco Product Acceptance Activities
64.28			Employee Training for Tobacco Product Acceptance Activities
64.29			Training by Manager for Tobacco Product Acceptance Activities
64.30			Record of Training for Tobacco Product Acceptance Activities
64.31			Written Procedure for Tobacco Product Acceptance Activities
64.32			Employee Training for Tobacco Product Acceptance Activities
64.33			Training by Manager for Tobacco Product Acceptance Activities
64.34			Record of Training for Tobacco Product Acceptance Activities
66.1		§1120.66 Production and Process controls	Written Procedure for Monitoring and Controlling Production Operations
66.2			Employee Training for Monitoring and Controlling Production Operations
66.3			Training by Manager for Monitoring and Controlling Production Operations
66.4			Record of Training for Monitoring and Controlling Production Operations
66.5			Equipment Production Materials
66.6			Written Procedure for Monitoring and Controlling Production Operations
66.7			Employee Training for Monitoring and Controlling Production Operations

Line Item	Sub-part	Provision	Task
66.8			Training by Manager for Monitoring and Controlling Production Operations
66.9			Record of Training for Monitoring and Controlling Production Operations
66.10			Equipment Production Materials
66.11			Written Procedure for Removing Manufacturing Material
66.12			Employee Training for Removing Manufacturing Material
66.13			Training by Manager for Removing Manufacturing Material
66.14			Record of Training for Removing Manufacturing Material
66.15			Written Procedure for Removing Manufacturing Material
66.16			Employee Training for Removing Manufacturing Material
66.17			Training by Manager for Removing Manufacturing Material
66.18			Record of Training for Removing Manufacturing Material
66.19			Written Procedure for Changes to Process Controls
66.20			Employee Training for Changes to Process Controls
66.21			Training by Manager for Changes to Process Controls
66.22			Record of Training for Changes to Process Controls
66.23			Written Procedure for Changes to Process Controls
66.24			Employee Training for Changes to Process Controls
66.25			Training by Manager for Changes to Process Controls
66.26			Record of Training for Changes to Process Controls
66.27			Written Procedure for Process Validation
66.28			Employee Training for Process Validation
66.29			Training by Manager for Process Validation
66.30			Record of Training for Process Validation
66.31			Production Processes Control Activities
66.32			Written Procedure for Process Validation
66.33			Employee Training for Process Validation
66.34			Training by Manager for Process Validation
66.35			Record of Training for Process Validation
66.36			Production Processes Control Activities
68.1		§1120.68 Laboratory controls	Written Procedure for Laboratory Functions
68.2			Employee Training for Laboratory Functions
68.3			Training by Manager for Laboratory Functions
68.4			Record of Training for Laboratory Functions
68.5			Conducting Laboratory Control Activities
68.6			Equipment Laboratory Materials
68.7			Written Procedure for Laboratory Functions
68.8			Employee Training for Laboratory Functions
68.9			Training by Manager for Laboratory Functions
68.10			Record of Training for Laboratory Functions
68.11			Conducting Laboratory Control Activities
68.12			Equipment Laboratory Materials
70.1			Written Procedure for Production Record Practices
70.2			Employee Training for Production Record Practices
70.3			Training by Manager for Production Record Practices
70.4			Record of Training for Production Record Practices

Line Item	Sub-part	Provision	Task
70.5			Review of Production Record
70.6			Written Procedure for Production Record Practices
70.7			Employee Training for Production Record Practices
70.8			Training by Manager for Production Record Practices
70.9			Record of Training for Production Record Practices
70.10			Review of Production Record
72.1		§1120.72 Sampling	Written Procedure for Sampling Plans
72.2			Employee Training for Sampling Plans
72.3			Training by Manager for Sampling Plans
72.4			Record of Training for Sampling Plans
72.5			Written Procedure for Sampling Plans
72.6			Employee Training for Sampling Plans
72.7			Training by Manager for Sampling Plans
72.8			Record of Training for Sampling Plans
74.1		§1120.74 Nonconforming tobacco product	Written Procedure for Controlling Nonconforming Products
74.2			Employee Training for Controlling Nonconforming Products
74.3			Training by Manager for Controlling Nonconforming Products
74.4			Record of Training for Controlling Nonconforming Products
74.5			Control and Disposition of Nonconforming Products
74.6			Written Procedure for Controlling Nonconforming Products
74.7			Employee Training for Controlling Nonconforming Products
74.8			Training by Manager for Controlling Nonconforming Products
74.9			Record of Training for Controlling Nonconforming Products
74.10			Control and Disposition of Nonconforming Products
76.1		§1120.76 Returned tobacco product	Written Procedure for Controlling Returned Tobacco Products
76.2			Employee Training for Controlling Returned Tobacco Products
76.3			Training by Manager for Controlling Returned Tobacco Products
76.4			Record of Training for Controlling Returned Tobacco Products
76.5			Inspection and Evaluation of Returned Tobacco Products
76.6			Written Procedure for Controlling Returned Tobacco Products
76.7			Employee Training for Controlling Returned Tobacco Products
76.8			Training by Manager for Controlling Returned Tobacco Products
76.9			Record of Training for Controlling Returned Tobacco Products
76.10			Inspection and Evaluation of Returned Tobacco Products
78.1		§1120.78 Reprocessing and rework	Written Procedure for Reprocessing and Reworking Tobacco Products
78.2			Employee Training for Reprocessing and Reworking Tobacco Products
78.3			Training by Manager for Reprocessing and Reworking Tobacco Products
78.4			Record of Training for Reprocessing and Reworking Tobacco Products
78.5			Written Procedure for Reprocessing and Reworking Tobacco Products
78.6			Employee Training for Reprocessing and Reworking Tobacco Products
78.7			Training by Manager for Reprocessing and Reworking Tobacco Products
78.8			Record of Training for Reprocessing and Reworking Tobacco Products
92.1	F	§1120.92 Packaging and labeling controls	Written Procedure for Controlling Packaging and Labeling
92.2			Employee Training for Controlling Packaging and Labeling
92.3			Training by Manager for Controlling Packaging and Labeling

Line Item	Sub-part	Provision	Task
92.4			Record of Training for Controlling Packaging and Labeling
92.5			Written Procedure for Controlling Packaging and Labeling
92.6			Employee Training for Controlling Packaging and Labeling
92.7			Training by Manager for Controlling Packaging and Labeling
92.8			Record of Training for Controlling Packaging and Labeling
94.1		§1120.94 Repackaging and relabeling	Written Procedure for Repacking and Relabeling Operations
94.2			Employee Training for Repacking and Relabeling Operations
94.3			Training by Manager for Repacking and Relabeling Operations
94.4			Record of Training for Repacking and Relabeling Operations
94.5			Written Procedure for Repacking and Relabeling Operations
94.6			Employee Training for Repacking and Relabeling Operations
94.7			Training by Manager for Repacking and Relabeling Operations
94.8			Record of Training for Repacking and Relabeling Operations
98.1		§1120.98 Warning plans	Written Procedure for Implementing FDA-approved Warning Plan
98.2			Employee Training for Implementing FDA-approved Warning Plan
98.3			Training by Manager for Implementing FDA-approved Warning Plan
98.4			Record of Training for Implementing FDA-approved Warning Plan
98.5			Written Procedure for Implementing FDA-approved Warning Plan
98.6			Employee Training for Implementing FDA-approved Warning Plan
98.7			Training by Manager for Implementing FDA-approved Warning Plan
98.8			Record of Training for Implementing FDA-approved Warning Plan
102.1	G	§1120.102 Handling and storage	Written Procedure for Preventing Adulteration During Handling and Storage
102.2			Employee Training for Preventing Adulteration During Handling and Storage
102.3			Training by Manager for Preventing Adulteration During Handling and Storage
102.4			Record of Training for Preventing Adulteration During Handling and Storage
102.5			Equipment Extra Storage Materials or Space
102.6			Written Procedure for Preventing Adulteration During Handling and Storage
102.7			Employee Training for Preventing Adulteration During Handling and Storage
102.8			Training by Manager for Preventing Adulteration During Handling and Storage
102.9			Record of Training for Preventing Adulteration During Handling and Storage
102.10			Equipment Extra Storage Materials or Space
104.1		§1120.104 Distribution	Written Procedure for Preventing Adulteration During Distribution
104.2			Employee Training for Preventing Adulteration During Distribution
104.3			Training by Manager for Preventing Adulteration During Distribution
104.4			Record of Training for Preventing Adulteration During Distribution
104.5			Written Procedure for Preventing Adulteration During Distribution
104.6			Employee Training for Preventing Adulteration During Distribution
104.7			Training by Manager for Preventing Adulteration During Distribution
104.8			Record of Training for Preventing Adulteration During Distribution
124.1	H	§1120.124 Document controls	Written Procedure for controlling documents

Subpart B Costs

Table 2 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart B to foreign facilities only. Total estimated one-time costs range from $300,000 to $770,000; total annual costs range from $0.5 million to $1.5 million. These costs include:

- One-time costs for the written procedure requirements for this subpart to foreign facilities estimated to be between $176,000 and $530,000; and the annual cost estimated to be between $80,000 and $245,000 (in Table 2, sum of line items 12.1-12.3, 14.1, 14.6, 16.1, and 16.6).
- The one-time cost for the training requirements for this subpart is estimated to be between $123,000 and $242,000 (in Table 2, sum of line items 14.2-14.4, 14.7-14.9, 16.2-16.4, 16.7-16.9).
- The annual cost for CAPA requirement estimated to be between $0.4 and $1.2 million (in Table 2, sum of line items 14.5, 14.10, 16.5, and 16.10).

Table 2: Detailed Calculation of Subpart B Costs - Management System Requirements

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
12.1	Written Procedure for Organizational Structure	Small	21	627	1	14	2	4	6	0	1	2	$17,515	$35,030	$52,545	$0	$8,758	$17,515
12.1	Written Procedure for Organizational Structure	Non-Small	7	20	1	14	4	8	12	2	2	2	$1,130	$2,260	$3,390	$565	$565	$565
12.2	Written Procedure for Designation of Responsibility	Small	21	627	1	14	2	4	6	1	1.5	2	$17,515	$35,030	$52,545	$8,758	$13,136	$17,515
12.2	Written Procedure for Designation of Responsibility	Non-Small	6	16	1	14	4	8	12	2	2	2	$888	$1,776	$2,664	$444	$444	$444
12.3	Written Procedure for Training Needs	Small	56	1671	1	14	2	4	6	1	2	3	$46,707	$93,414	$140,121	$23,353	$46,707	$70,060
12.3	Written Procedure for Training Needs	Non-Small	18	52	1	14	4	8	12	2	4	6	$2,906	$5,811	$8,717	$1,453	$2,906	$4,359
14.1	Written Procedure for Handling Complaints	Small	52	1552	1	14	2	4	6	1	2	3	$43,371	$86,741	$130,112	$21,685	$43,371	$65,056
14.2	Employee Training for Handling Complaints	Small	52	1552	1	6	2	3	4	0	0	0	$20,040	$30,060	$40,080	$0	$0	$0
14.3	Training by Manager for Handling Complaints	Small	52	1552	1	11	2	3	4	0	0	0	$33,805	$50,707	$67,610	$0	$0	$0
14.4	Record of Training for Handling Complaints	Small	52	1552	2	11	0.05	0.05	0.05	0	0	0	$1,690	$1,690	$1,690	$0	$0	$0
14.5	Complaint Processing	Small	10	298	1	11	0	0	0	52	104	156	$0	$0	$0	$169,025	$338,050	$507,075
14.6	Written Procedure for	Non-Small	18	52	1	14	4	8	12	2	4	6	$2,906	$5,811	$8,717	$1,453	$2,906	$4,359

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Handling Complaints																	
14.7	Employee Training for Handling Complaints	Non-Small	18	52	10	6	2	3	4	0	0	0	$6,713	$10,070	$13,426	$0	$0	$0
14.8	Training by Manager for Handling Complaints	Non-Small	18	52	1	11	2	3	4	0	0	0	$1,132	$1,699	$2,265	$0	$0	$0
14.9	Record of Training for Handling Complaints	Non-Small	18	52	11	11	0.05	0.05	0.05	0	0	0	$311	$311	$311	$0	$0	$0
14.1	Complaint Processing	Non-Small	10	29	1	11	0	0	0	104	208	312	$0	$0	$0	$32,715	$65,429	$98,144
16.1	Written Procedure for Implementing CAPA	Small	50	1492	1	14	2	4	6	1	2	3	$41,703	$83,405	$125,108	$20,851	$41,703	$62,554
16.2	Employee Training for Implementing CAPA	Small	50	1492	1	6	2	3	4	0	0	0	$19,269	$28,904	$38,538	$0	$0	$0
16.3	Training by Manager for Implementing CAPA	Small	50	1492	1	11	2	3	4	0	0	0	$32,505	$48,757	$65,010	$0	$0	$0
16.4	Record of Training for Implementing CAPA	Small	50	1492	2	11	0.05	0.05	0.05	0	0	0	$1,625	$1,625	$1,625	$0	$0	$0
16.5	CAPA Implementation	Small	10	298	1	11	0	0	0	52	104	156	$0	$0	$0	$169,025	$338,050	$507,075
16.6	Written Procedure for Implementing CAPA	Non-Small	13	38	1	14	4	8	12	2	4	6	$2,099	$4,197	$6,296	$1,049	$2,099	$3,148
16.7	Employee Training for Implementing CAPA	Non-Small	13	38	10	6	2	3	4	0	0	0	$4,848	$7,273	$9,697	$0	$0	$0
16.8	Training by Manager for	Non-Small	13	38	1	11	2	3	4	0	0	0	$818	$1,227	$1,636	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Implementing CAPA																	
16.9	Record of Training for Implementing CAPA	Non-Small	13	38	11	11	0.05	0.05	0.05	0	0	0	$225	$225	$225	$0	$0	$0
16.1	CAPA Implementation	Non-Small	10	29	1	11	0	0	0	104	208	312	$0	$0	$0	$32,715	$65,429	$98,144
Total													**$299,721**	**$536,025**	**$772,328**	**$483,091**	**$969,551**	**$1,456,011**

(2020 USD)

Subpart C Costs

Table 3 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart C to foreign facilities only. Total estimated one-time costs range from $1.1 million to $3.4 million; total annual costs range from $0.4 million to $7.5 million. These costs include:

- One-time costs for the written procedure requirements for this subpart to foreign facilities estimated to be between $0.6 million and $1.4 million; and the annual cost estimated to be between $200,000 and $525,000 million (in Table 3, sum of line numbers 32.1, 32.5, 34.1, 34.5, 34.9, 34.14, 36.1, 36.5, 36.9, 36.13, 36.17, 36.21, 38.1, and 38.5).
- The one-time cost for the training requirements for this subpart estimated to be between $0.6 million and $2.0 million (in Table 3, sum of line numbers 32.2-32.4, 32.6-32.8, 34.2-34.4, 34.6-34.8, 34.10-34.12, 34.15-34.17, 36.2-36.4, 36.6-36.8, 36.10-36.12, 36.14-36.16, 36.18-36.20, 36.22-36.24, 38.2-38.4, 38.6-38.8).
- The annual cost for the pest-control-related requirements for this subpart is estimated to be between $0.2 million and $6.9 million (in Table 3, sum of line numbers 34.13 and 34.18).

Table 3: Detailed Calculation of Subpart C Costs - Buildings, Facilities, and Equipment

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
32.1	Written Procedure for Personnel Cleaning Practices	Small	28	821	1	14	2	4	6	1	2	3	$22,936	$45,873	$68,809	$11,468	$22,936	$34,405
32.2	Employee Training for Personnel Cleaning Practices	Small	28	821	13	6	0.5	1	2	0	0	0	$34,444	$68,887	$137,774	$0	$0	$0
32.3	Training by Manager for Personnel Cleaning Practices	Small	28	821	1	11	0.5	1	2	0	0	0	$4,469	$8,939	$17,878	$0	$0	$0
32.4	Record of Training for Personnel Cleaning Practices	Small	28	821	14	11	0.05	0.05	0.05	0	0	0	$6,257	$6,257	$6,257	$0	$0	$0
32.5	Written Procedure for Personnel Cleaning Practices	Non-Small	27	78	1	14	4	8	12	2	3	4	$4,359	$8,717	$13,076	$2,179	$3,269	$4,359
32.6	Employee Training for Personnel Cleaning Practices	Non-Small	27	78	210	6	0.5	1	2	0	0	0	$52,866	$105,732	$211,463	$0	$0	$0
32.7	Training by Manager for Personnel Cleaning Practices	Non-Small	27	78	21	11	0.5	1	2	0	0	0	$8,918	$17,836	$35,671	$0	$0	$0
32.8	Record of Training for Personnel Cleaning Practices	Non-Small	27	78	231	11	0.05	0.05	0.05	0	0	0	$9,810	$9,810	$9,810	$0	$0	$0
34.1	Written Procedure for Facility	Small	44	1313	1	14	2	4	6	1	2	3	$36,698	$73,397	$110,095	$18,349	$36,698	$55,047

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	Task	Entity Type	Percent Affected (%)	Number Affected	Units	Wage ($)	L	M	H	L	M	H	L	M	H	L	M	H
	Cleaning Practices																	
34.2	Employee Training for Facility Cleaning Practices	Small	44	1313	2	6	1	2	4	0	0	0	$16,957	$33,914	$67,827	$0	$0	$0
34.3	Training by Manager for Facility Cleaning Practices	Small	44	1313	1	11	1	2	4	0	0	0	$14,302	$28,604	$57,208	$0	$0	$0
34.4	Record of Training for Facility Cleaning Practices	Small	44	1313	3	11	0.05	0.05	0.05	0	0	0	$2,145	$2,145	$2,145	$0	$0	$0
34.5	Written Procedure for Facility Cleaning Practices	Non-Small	19	55	1	14	4	8	12	2	4	6	$3,067	$6,134	$9,201	$1,534	$3,067	$4,601
34.6	Employee Training for Facility Cleaning Practices	Non-Small	19	55	21	6	1	2	4	0	0	0	$7,440	$14,881	$29,762	$0	$0	$0
34.7	Training by Manager for Facility Cleaning Practices	Non-Small	19	55	2	11	1	2	4	0	0	0	$1,195	$2,391	$4,781	$0	$0	$0
34.8	Record of Training for Facility Cleaning Practices	Non-Small	19	55	23	11	0.05	0.05	0.05	0	0	0	$687	$687	$687	$0	$0	$0
34.9	Written Procedure for Animal and Pest Control	Small	36	1074	1	14	20	30	40	5	7.5	10	$300,259	$450,388	$600,518	$75,065	$112,597	$150,129
34.1	Employee Training for Animal and Pest Control	Small	36	1074	2	6	0.5	1	2	0	0	0	$6,937	$13,874	$27,748	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
34.11	Training by Manager for Animal and Pest Control	Small	36	1074	1	11	0.5	1	2	0	0	0	$5,851	$11,702	$23,403	$0	$0	$0
34.12	Record of Training for Animal and Pest Control	Small	36	1074	3	11	0.05	0.05	0.05	0	0	0	$1,755	$1,755	$1,755	$0	$0	$0
34.13	3rd Party Pest Control	Small	5	149	1								$0	$0	$0	$147,994	$3,024,329	$5,900,664
34.14	Written Procedure for Animal and Pest Control	Non-Small	17	49	1	14	20	30	40	5	7.5	10	$13,722	$20,582	$27,443	$3,430	$5,146	$6,861
34.15	Employee Training for Animal and Pest Control	Non-Small	17	49	10	6	0.5	1	2	0	0	0	$1,585	$3,170	$6,340	$0	$0	$0
34.16	Training by Manager for Animal and Pest Control	Non-Small	17	49	1	11	0.5	1	2	0	0	0	$267	$535	$1,070	$0	$0	$0
34.17	Record of Training for Animal and Pest Control	Non-Small	17	49	11	11	0.05	0.05	0.05	0	0	0	$294	$294	$294	$0	$0	$0
34.18	3rd Party Pest Control	Non-Small	5	14	1								$0	$0	$0	$71,610	$569,363	$1,067,116
36.1	Written Procedure for Maintenance of Equipment	Small	20	597	1	14	2	4	6	1	2	3	$16,681	$33,362	$50,043	$8,341	$16,681	$25,022
36.2	Employee Training for Maintenance of Equipment	Small	20	597	13	6	1	2	4	0	0	0	$50,100	$100,200	$200,399	$0	$0	$0
36.3	Training by Manager for Maintenance of Equipment	Small	20	597	2	11	1	2	4	0	0	0	$13,002	$26,004	$52,008	$0	$0	$0
36.4	Record of Training for Maintenance of Equipment	Small	20	597	15	11	0.05	0.05	0.05	0	0	0	$4,876	$4,876	$4,876	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
36.5	Written Procedure for Maintenance of Equipment	Non-Small	13	38	1	14	4	8	12	2	4	6	$2,099	$4,197	$6,296	$1,049	$2,099	$3,148
36.6	Employee Training for Maintenance of Equipment	Non-Small	13	38	210	6	1	2	4	0	0	0	$50,908	$101,816	$203,631	$0	$0	$0
36.7	Training by Manager for Maintenance of Equipment	Non-Small	13	38	21	11	1	2	4	0	0	0	$8,588	$17,175	$34,350	$0	$0	$0
36.8	Record of Training for Maintenance of Equipment	Non-Small	13	38	231	11	0.05	0.05	0.05	0	0	0	$4,723	$4,723	$4,723	$0	$0	$0
36.9	Written Procedure for Monitoring Equipment	Small	34	1014	1	14	2	4	6	1	2	3	$28,358	$56,716	$85,073	$14,179	$28,358	$42,537
36.1	Employee Training for Monitoring Equipment	Small	34	1014	2	6	2	4	6	0	0	0	$26,206	$52,412	$78,618	$0	$0	$0
36.11	Training by Manager for Monitoring Equipment	Small	34	1014	1	11	2	4	6	0	0	0	$22,103	$44,207	$66,310	$0	$0	$0
36.12	Record of Training for Monitoring Equipment	Small	34	1014	3	11	0.05	0.05	0.05	0	0	0	$1,658	$1,658	$1,658	$0	$0	$0
36.13	Written Procedure for Monitoring Equipment	Non-Small	27	77	1	14	4	8	12	2	4	6	$4,305	$8,610	$12,914	$2,152	$4,305	$6,457
36.14	Employee Training for Monitoring Equipment	Non-Small	27	77	10	6	2	4	6	0	0	0	$9,945	$19,891	$29,836	$0	$0	$0
36.15	Training by Manager for Monitoring Equipment	Non-Small	27	77	1	11	2	4	6	0	0	0	$1,678	$3,355	$5,033	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
36.16	Record of Training for Monitoring Equipment	Non-Small	27	77	11	11	0.05	0.05	0.05	0	0	0	$461	$461	$461	$0	$0	$0
36.17	Written Procedure for Calibrating Equipment	Small	70	2094	1	14	2	4	6	1	2	3	$58,530	$117,060	$175,590	$29,265	$58,530	$87,795
36.18	Employee Training for Calibrating Equipment	Small	70	2094	2	6	2	4	6	0	0	0	$54,089	$108,178	$162,267	$0	$0	$0
36.19	Training by Manager for Calibrating Equipment	Small	70	2094	1	11	2	4	6	0	0	0	$45,621	$91,242	$136,862	$0	$0	$0
36.2	Record of Training for Calibrating Equipment	Small	70	2094	3	11	0.05	0.05	0.05	0	0	0	$3,422	$3,422	$3,422	$0	$0	$0
36.21	Written Procedure for Calibrating Equipment	Non-Small	70	203	1	14	4	8	12	2	4	6	$11,328	$22,657	$33,985	$5,664	$11,328	$16,993
36.22	Employee Training for Calibrating Equipment	Non-Small	70	203	10	6	2	4	6	0	0	0	$26,172	$52,344	$78,516	$0	$0	$0
36.23	Training by Manager for Calibrating Equipment	Non-Small	70	203	1	11	2	4	6	0	0	0	$4,415	$8,830	$13,245	$0	$0	$0
36.24	Record of Training for Calibrating Equipment	Non-Small	70	203	11	11	0.05	0.05	0.05	0	0	0	$1,214	$1,214	$1,214	$0	$0	$0
38.1	Written Procedure for Controlling Environmental Conditions	Small	62	1850	1	14	2	4	6	1	2	3	$51,711	$103,423	$155,134	$25,856	$51,711	$77,567
38.2	Employee Training for Controlling	Small	62	1850	2	6	2	4	6	0	0	0	$47,787	$95,575	$143,362	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Environmental Conditions																	
38.3	Training by Manager for Controlling Environmental Conditions	Small	62	1850	1	11	2	4	6	0	0	0	$40,306	$80,612	$120,918	$0	$0	$0
38.4	Record of Training for Controlling Environmental Conditions	Small	62	1850	3	11	0.05	0.05	0.05	0	0	0	$3,023	$3,023	$3,023	$0	$0	$0
38.5	Written Procedure for Controlling Environmental Conditions	Non-Small	41	118	1	14	4	8	12	2	4	6	$6,619	$13,237	$19,856	$3,309	$6,619	$9,928
38.6	Employee Training for Controlling Environmental Conditions	Non-Small	41	118	10	6	2	4	6	0	0	0	$15,291	$30,582	$45,873	$0	$0	$0
38.7	Training by Manager for Controlling Environmental Conditions	Non-Small	41	118	1	11	2	4	6	0	0	0	$2,579	$5,159	$7,738	$0	$0	$0
38.8	Record of Training for Controlling Environmental Conditions	Non-Small	41	118	11	11	0.05	0.05	0.05	0	0	0	$709	$709	$709	$0	$0	$0
Total													**$1,175,728**	**$2,153,430**	**$3,408,962**	**$421,445**	**$3,957,036**	**$7,492,627**

(2020 USD)

Subpart D Costs

Table 4 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart D to foreign facilities only. Total estimated one-time costs range from $0.6 million to $1.2 million; total annual costs range from $178,000 to $380,000. These costs include:

- The one-time cost for the written procedure requirements for this subpart estimated to be between $350,000 and $745,000; and the annual cost estimated to be between $173,000 and $370,000 (in Table 4, sum of line items 42.1, 42.5, 44.1, 44.2, 44.7).
- The one-time cost for the training requirements for this subpart estimated to be between $233,000 and $460,000 (in Table 4, sum of line items 42.2-42.4, 42.6-42.8, 44.3-44.5, and 44.8-44.10).
- The annual cost for activities related to review and approval of the master manufacturing record estimated to be between $4,000 and $11,000 (in Table 4, sum of line items 44.6 and 44.11)

Table 4: Detailed Calculation of Subpart D Costs - Performance Controls

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
42.1	Written Procedure for Product Design and Risk Management Procedures	Small	64	1896	1	14	10	15	20	5	7.5	10	$265,043	$397,565	$530,087	$132,522	$198,783	$265,043
42.2	Employee Training for Product Design and Risk Management Procedures	Small	64	1896	3	6	2	3	4	0	0	0	$73,480	$110,220	$146,959	$0	$0	$0
42.3	Training by Manager for Product Design and Risk Management Procedures	Small	64	1896	1	11	2	3	4	0	0	0	$41,317	$61,976	$82,634	$0	$0	$0
42.4	Record of Training for Product Design and Risk Management Procedures	Small	64	1896	4	11	0.05	0.05	0.05	0	0	0	$4,132	$4,132	$4,132	$0	$0	$0
42.5	Written Procedure for Product Design and Risk Management Procedures	Non-Small	37	108	1	14	20	30	40	10	15	20	$30,223	$45,335	$60,446	$15,112	$22,667	$30,223
42.6	Employee Training for Product Design and Risk Management Procedures	Non-Small	37	108	21	6	2	3	4	0	0	0	$29,326	$43,990	$58,653	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
42.7	Training by Manager for Product Design and Risk Management Procedures	Non-Small	37	108	2	11	2	3	4	0	0	0	$4,711	$7,067	$9,423	$0	$0	$0
42.8	Record of Training for Product Design and Risk Management Procedures	Non-Small	37	108	23	11	0.05	0.05	0.05	0	0	0	$1,355	$1,355	$1,355	$0	$0	$0
44.1	Written Procedure for Master Manufacturing Record	Small	25	746	1	14	2	4	6	1	2	3	$20,851	$41,703	$62,554	$10,426	$20,851	$31,277
44.1	Written Procedure for Master Manufacturing Record	Non-Small	11	32	1	14	4	6	8	2	3	4	$1,776	$2,664	$3,551	$888	$1,332	$1,776
44.2	Written Procedure for Review and Approval of Master Manufacturing Record	Small	31	935	1	14	2	4	6	1	2	3	$26,134	$52,267	$78,401	$13,067	$26,134	$39,200
44.3	Employee Training for Review and Approval of Master Manufacturing Record	Small	31	935	3	6	2	3	4	0	0	0	$36,226	$54,339	$72,452	$0	$0	$0
44.4	Training by Manager for Review and Approval of Master Manufacturing Record	Small	31	935	1	11	2	3	4	0	0	0	$20,370	$30,555	$40,739	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
44.5	Record of Training for Review and Approval of Master Manufacturing Record	Small	31	935	4	11	0.05	0.05	0.05	0	0	0	$2,037	$2,037	$2,037	$0	$0	$0
44.6	Review and Approval of Master Manufacturing Record	Small	10	298	1	11	0	0	0	1	2	3	$0	$0	$0	$3,250	$6,501	$9,751
44.7	Written Procedure for Review and Approval of Master Manufacturing Record	Non-Small	22	63	1	14	4	8	12	2	3	4	$3,498	$6,995	$10,493	$1,749	$2,623	$3,498
44.8	Employee Training for Review and Approval of Master Manufacturing Record	Non-Small	22	63	21	6	2	3	4	0	0	0	$16,969	$25,454	$33,939	$0	$0	$0
44.9	Training by Manager for Review and Approval of Master Manufacturing Record	Non-Small	22	63	2	11	2	3	4	0	0	0	$2,726	$4,089	$5,452	$0	$0	$0
44.1	Record of Training for Review and Approval of Master Manufacturing Record	Non-Small	22	63	23	11	0.05	0.05	0.05	0	0	0	$784	$784	$784	$0	$0	$0
44.11	Review and Approval of Master Manufacturing Record	Non-Small	10	29	1	11	0	0	0	2	3	4	$0	$0	$0	$629	$944	$1,258

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
Total													$580,958	$892,524	$1,204,091	$177,642	$279,835	$382,027

(2020 USD)

Subpart E Costs

Table 5 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart E to foreign facilities only. Total estimated one-time costs range from $9.5 million to $11.9 million; total annual costs range from $1.5 million to $4.5 million. These costs include:

- One-time cost for the written procedure requirements for this subpart estimated to be between $0.6 million and $1.8million; and the annual cost estimated to be between $0.3 million and $0.9 million (in Table 5, sum of line items 62.1, 62.5, 62.9, 62.13, 64.11, 64.15, 64.19, 64.23, 64.27, 64.31, 66.1, 66.6, 66.11, 66.15, 66.19, 66.23, 66.27, 66.32, 68.1, 68.7, 70.1, 70.6, 72.1, 72.5, 74.1, 74.6, 76.1, 76.6, 78.1, and 78.5).
- The one-time cost for the training requirements for this subpart estimated to be between $1.3 million and $2.6 million (in Table 5, sum of line items 62.2-62.4, 62.6-62.8, 62.10-62.12, 62.14-62.16, 64.12-64.14, 64.16-64.18, 64.20-64.22, 64.24-64.26, 64.28-64.30, 64.32-64.34, 66.2-66.4, 66.7-66.9, 66.12-66.14, 66.16-66.18, 66.20-66.22, 66.24-66.26, 66.28-66.30, 66.33-66.35, 68.2-68.4, 68.8-68.10, 70.2-70.4, 70.7-70.9, 72.2-72.4, 72.6-72.8, 74.2-74.4, 74.7-74.9, 76.2-76.4, 76.7-76.9, 78.2-78.4, and 78.6-78.8).
- The annual cost for the activity-related requirements (other than written procedure and training requirements) for this subpart estimated to be between $1.2 million and $3.6 million (in Table 5, sum of line items 64.5, 64.10, 66.31, 66.36, 68.5, 68.11, 70.5, 70.10, 74.5, 74.10 76.5, 76.10).
- The one-time capital cost for this subpart estimated to be $7.5 million (in Table 5, sum of line items 66.5, 66.10, 68.6, and 68.12).

Table 5: Detailed Calculation of Subpart E Costs - Process Controls

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
62.1	Written Procedure for Purchasing Products or Services	Small	54	1611	1	14	2	4	6	1	2	3	$45,039	$90,078	$135,117	$22,519	$45,039	$67,558
62.2	Employee Training for Purchasing Products or Services	Small	54	1611	2	6	4	6	8	0	0	0	$83,243	$124,864	$166,485	$0	$0	$0
62.3	Training by Manager for Purchasing Products or Services	Small	54	1611	1	11	4	6	8	0	0	0	$70,210	$105,316	$140,421	$0	$0	$0
62.4	Record of Training for Purchasing Products or Services	Small	54	1611	3	11	0.05	0.05	0.05	0	0	0	$2,633	$2,633	$2,633	$0	$0	$0
62.5	Written Procedure for Purchasing Products or Services	Non-Small	25	72	1	14	4	8	12	2	4	6	$4,036	$8,071	$12,107	$2,018	$4,036	$6,054
62.6	Employee Training for Purchasing Products or Services	Non-Small	25	72	10	6	8	10	12	0	0	0	$37,295	$46,619	$55,943	$0	$0	$0
62.7	Training by Manager for Purchasing Products or Services	Non-Small	25	72	1	11	8	10	12	0	0	0	$6,291	$7,864	$9,437	$0	$0	$0
62.8	Record of Training for Purchasing Products or Services	Non-Small	25	72	11	11	0.05	0.05	0.05	0	0	0	$433	$433	$433	$0	$0	$0
62.9	Written Procedure for	Small	58	1731	1	14	2	4	6	1	2	3	$48,375	$96,750	$145,125	$24,188	$48,375	$72,563

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Qualifying Suppliers																	
62.1	Employee Training for Qualifying Suppliers	Small	58	1731	2	6	4	6	8	0	0	0	$89,409	$134,113	$178,818	$0	$0	$0
62.11	Training by Manager for Qualifying Suppliers	Small	58	1731	1	11	4	6	8	0	0	0	$75,411	$113,117	$150,822	$0	$0	$0
62.12	Record of Training for Qualifying Suppliers	Small	58	1731	3	11	0.05	0.05	0.05	0	0	0	$2,828	$2,828	$2,828	$0	$0	$0
62.13	Written Procedure for Qualifying Suppliers	Non-Small	27	78	1	14	4	8	12	2	4	6	$4,359	$8,717	$13,076	$2,179	$4,359	$6,538
62.14	Employee Training for Qualifying Suppliers	Non-Small	27	78	10	6	8	10	12	0	0	0	$40,279	$50,348	$60,418	$0	$0	$0
62.15	Training by Manager for Qualifying Suppliers	Non-Small	27	78	1	11	8	10	12	0	0	0	$6,795	$8,493	$10,192	$0	$0	$0
62.16	Record of Training for Qualifying Suppliers	Non-Small	27	78	11	11	0.05	0.05	0.05	0	0	0	$467	$467	$467	$0	$0	$0
64.1	Written Procedure for General Acceptance Activities	Small	0	0		14	2	4	6	1	2	3						
64.2	Employee Training for General Acceptance Activities	Small	0	0		6	2	3	4	0	0	0						
64.3	Training by Manager for General Acceptance Activities	Small	0	0		11	2	3	4	0	0	0						

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
64.4	Record of Training for General Acceptance Activities	Small	0	0		11	0.05	0.05	0.05	0	0	0						
64.5	Conducting Acceptance Activities	Small	10	298	1	11	0	0	0	52	104	156	$0	$0	$0	$169,025	$338,050	$507,075
64.6	Written Procedure for General Acceptance Activities	Non-Small	0	0		14	4	8	12	2	4	6						
64.7	Employee Training for General Acceptance Activities	Non-Small	0	0		6	2	3	4	0	0	0						
64.8	Training by Manager for General Acceptance Activities	Non-Small	0	0		11	2	3	4	0	0	0						
64.9	Record of Training for General Acceptance Activities	Non-Small	0	0		11	0.05	0.05	0.05	0	0	0						
64.1	Conducting Acceptance Activities	Non-Small	10	29	1	11	0	0	0	104	208	312	$0	$0	$0	$32,715	$65,429	$98,144
64.11	Written Procedure for Incoming Acceptance Activities	Small	33	985	1	14	2	4	6	1	2	3	$27,524	$55,047	$82,571	$13,762	$27,524	$41,286
64.12	Employee Training for Incoming Acceptance Activities	Small	33	985	2	6	2	3	4	0	0	0	$25,435	$38,153	$50,871	$0	$0	$0
64.13	Training by Manager for Incoming	Small	33	985	1	11	2	3	4	0	0	0	$21,453	$32,180	$42,906	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Acceptance Activities																	
64.14	Record of Training for Incoming Acceptance Activities	Small	33	985	3	11	0.05	0.05	0.05	0	0	0	$1,609	$1,609	$1,609	$0	$0	$0
64.15	Written Procedure for Incoming Acceptance Activities	Non-Small	17	49	1	14	4	8	12	2	4	6	$2,744	$5,489	$8,233	$1,372	$2,744	$4,116
64.16	Employee Training for Incoming Acceptance Activities	Non-Small	17	49	10	6	2	3	4	0	0	0	$6,340	$9,510	$12,680	$0	$0	$0
64.17	Training by Manager for Incoming Acceptance Activities	Non-Small	17	49	1	11	2	3	4	0	0	0	$1,070	$1,604	$2,139	$0	$0	$0
64.18	Record of Training for Incoming Acceptance Activities	Non-Small	17	49	11	11	0.05	0.05	0.05	0	0	0	$294	$294	$294	$0	$0	$0
64.19	Written Procedure for Pesticide Testing	Small	60	1790	1	14	2	4	6	1	2	3	$50,043	$100,086	$150,129	$25,022	$50,043	$75,065
64.2	Employee Training for Pesticide Testing	Small	60	1790	2	6	2	3	4	0	0	0	$46,246	$69,369	$92,492	$0	$0	$0
64.21	Training by Manager for Pesticide Testing	Small	60	1790	1	11	2	3	4	0	0	0	$39,006	$58,509	$78,012	$0	$0	$0
64.22	Record of Training for Pesticide Testing	Small	60	1790	3	11	0.05	0.05	0.05	0	0	0	$2,925	$2,925	$2,925	$0	$0	$0
64.23	Written Procedure for	Non-Small	32	92	1	14	4	8	12	2	4	6	$5,166	$10,331	$15,497	$2,583	$5,166	$7,749

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Pesticide Testing																	
64.24	Employee Training for Pesticide Testing	Non-Small	32	92	10	6	2	3	4	0	0	0	$11,934	$17,902	$23,869	$0	$0	$0
64.25	Training by Manager for Pesticide Testing	Non-Small	32	92	1	11	2	3	4	0	0	0	$2,013	$3,020	$4,026	$0	$0	$0
64.26	Record of Training for Pesticide Testing	Non-Small	32	92	11	11	0.05	0.05	0.05	0	0	0	$554	$554	$554	$0	$0	$0
64.27	Written Procedure for Tobacco Product Acceptance Activities	Small	43	1283	1	14	2	4	6	1	2	3	$35,864	$71,729	$107,593	$17,932	$35,864	$53,796
64.28	Employee Training for Tobacco Product Acceptance Activities	Small	43	1283	2	6	2	3	4	0	0	0	$33,143	$49,714	$66,286	$0	$0	$0
64.29	Training by Manager for Tobacco Product Acceptance Activities	Small	43	1283	1	11	2	3	4	0	0	0	$27,954	$41,931	$55,908	$0	$0	$0
64.3	Record of Training for Tobacco Product Acceptance Activities	Small	43	1283	3	11	0.05	0.05	0.05	0	0	0	$2,097	$2,097	$2,097	$0	$0	$0
64.31	Written Procedure for Tobacco Product Acceptance Activities	Non-Small	22	64	1	14	4	8	12	2	4	6	$3,551	$7,103	$10,654	$1,776	$3,551	$5,327

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
64.32	Employee Training for Tobacco Product Acceptance Activities	Non-Small	22	64	10	6	2	3	4	0	0	0	$8,205	$12,307	$16,410	$0	$0	$0
64.33	Training by Manager for Tobacco Product Acceptance Activities	Non-Small	22	64	1	11	2	3	4	0	0	0	$1,384	$2,076	$2,768	$0	$0	$0
64.34	Record of Training for Tobacco Product Acceptance Activities	Non-Small	22	64	11	11	0.05	0.05	0.05	0	0	0	$381	$381	$381	$0	$0	$0
66.1	Written Procedure for Monitoring and Controlling Production Operations	Small	31	925	1	14	2	4	6	1	2	3	$25,856	$51,711	$77,567	$12,928	$25,856	$38,783
66.2	Employee Training for Monitoring and Controlling Production Operations	Small	31	925	2	6	2	3	4	0	0	0	$23,894	$35,841	$47,787	$0	$0	$0
66.3	Training by Manager for Monitoring and Controlling Production Operations	Small	31	925	1	11	2	3	4	0	0	0	$20,153	$30,229	$40,306	$0	$0	$0
66.4	Record of Training for Monitoring and Controlling Production Operations	Small	31	925	3	11	0.05	0.05	0.05	0	0	0	$1,511	$1,511	$1,511	$0	$0	$0
66.5	Equipment Production Materials	Small	5	149									$522,156	$522,156	$522,156	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
66.6	Written Procedure for Monitoring and Controlling Production Operations	Non-Small	19	55	1	14	4	8	12	2	4	6	$3,067	$6,134	$9,201	$1,534	$3,067	$4,601
66.7	Employee Training for Monitoring and Controlling Production Operations	Non-Small	19	55	10	6	2	3	4	0	0	0	$7,086	$10,629	$14,172	$0	$0	$0
66.8	Training by Manager for Monitoring and Controlling Production Operations	Non-Small	19	55	1	11	2	3	4	0	0	0	$1,195	$1,793	$2,391	$0	$0	$0
66.9	Record of Training for Monitoring and Controlling Production Operations	Non-Small	19	55	11	11	0.05	0.05	0.05	0	0	0	$329	$329	$329	$0	$0	$0
66.1	Equipment Production Materials	Non-Small	5	14									$115,500	$115,500	$115,500	$0	$0	$0
66.11	Written Procedure for Removing Manufacturing Material	Small	32	945	1	14	2	4	6	1	2	3	$26,412	$52,823	$79,235	$13,206	$26,412	$39,617
66.12	Employee Training for Removing Manufacturing Material	Small	32	945	2	6	2	3	4	0	0	0	$24,408	$36,611	$48,815	$0	$0	$0
66.13	Training by Manager for Removing Manufacturing Material	Small	32	945	1	11	2	3	4	0	0	0	$20,586	$30,880	$41,173	$0	$0	$0
66.14	Record of Training for Removing	Small	32	945	3	11	0.05	0.05	0.05	0	0	0	$1,544	$1,544	$1,544	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Manufacturing Material																	
66.15	Written Procedure for Removing Manufacturing Material	Non-Small	37	106	1	14	4	8	12	2	4	6	$5,919	$11,838	$17,757	$2,960	$5,919	$8,879
66.16	Employee Training for Removing Manufacturing Material	Non-Small	37	106	10	6	2	3	4	0	0	0	$13,675	$20,512	$27,350	$0	$0	$0
66.17	Training by Manager for Removing Manufacturing Material	Non-Small	37	106	1	11	2	3	4	0	0	0	$2,307	$3,460	$4,614	$0	$0	$0
66.18	Record of Training for Removing Manufacturing Material	Non-Small	37	106	11	11	0.05	0.05	0.05	0	0	0	$634	$634	$634	$0	$0	$0
66.19	Written Procedure for Changes to Process Controls	Small	32	955	1	14	2	4	6	1	2	3	$26,690	$53,379	$80,069	$13,345	$26,690	$40,035
66.2	Employee Training for Changes to Process Controls	Small	32	955	2	6	2	3	4	0	0	0	$24,665	$36,997	$49,329	$0	$0	$0
66.21	Training by Manager for Changes to Process Controls	Small	32	955	1	11	2	3	4	0	0	0	$20,803	$31,205	$41,606	$0	$0	$0
66.22	Record of Training for Changes to Process Controls	Small	32	955	3	11	0.05	0.05	0.05	0	0	0	$1,560	$1,560	$1,560	$0	$0	$0
66.23	Written Procedure for Changes to	Non-Small	21	61	1	14	4	8	12	2	4	6	$3,390	$6,780	$10,170	$1,695	$3,390	$5,085

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Process Controls																	
66.24	Employee Training for Changes to Process Controls	Non-Small	21	61	10	6	2	3	4	0	0	0	$7,832	$11,748	$15,664	$0	$0	$0
66.25	Training by Manager for Changes to Process Controls	Non-Small	21	61	1	11	2	3	4	0	0	0	$1,321	$1,982	$2,642	$0	$0	$0
66.26	Record of Training for Changes to Process Controls	Non-Small	21	61	11	11	0.05	0.05	0.05	0	0	0	$363	$363	$363	$0	$0	$0
66.27	Written Procedure for Process Validation	Small	32	955	1	14	2	4	6	1	2	3	$26,690	$53,379	$80,069	$13,345	$26,690	$40,035
66.28	Employee Training for Process Validation	Small	32	955	2	6	2	3	4	0	0	0	$24,665	$36,997	$49,329	$0	$0	$0
66.29	Training by Manager for Process Validation	Small	32	955	1	11	2	3	4	0	0	0	$20,803	$31,205	$41,606	$0	$0	$0
66.3	Record of Training for Process Validation	Small	32	955	3	11	0.05	0.05	0.05	0	0	0	$1,560	$1,560	$1,560	$0	$0	$0
66.31	Production Processes Control Activities	Small	10	298	1	11	0	0	0	52	104	156	$0	$0	$0	$169,025	$338,050	$507,075
66.32	Written Procedure for Process Validation	Non-Small	70	202	1	14	4	8	12	2	4	6	$11,300	$22,600	$33,900	$5,650	$11,300	$16,950
66.33	Employee Training for Process Validation	Non-Small	70	202	10	6	2	3	4	0	0	0	$26,107	$39,160	$52,213	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
66.34	Training by Manager for Process Validation	Non-Small	70	202	1	11	2	3	4	0	0	0	$4,404	$6,606	$8,808	$0	$0	$0
66.35	Record of Training for Process Validation	Non-Small	70	202	11	11	0.05	0.05	0.05	0	0	0	$1,211	$1,211	$1,211	$0	$0	$0
66.36	Production Processes Control Activities	Non-Small	10	29	1	11	0	0	0	104	208	312	$0	$0	$0	$32,715	$65,429	$98,144
68.1	Written Procedure for Laboratory Functions	Small	29	865	1	14	2	4	6	1	2	3	$24,188	$48,375	$72,563	$12,094	$24,188	$36,281
68.2	Employee Training for Laboratory Functions	Small	29	865	2	6	2	3	4	0	0	0	$22,352	$33,528	$44,704	$0	$0	$0
68.3	Training by Manager for Laboratory Functions	Small	29	865	1	11	2	3	4	0	0	0	$18,853	$28,279	$37,706	$0	$0	$0
68.4	Record of Training for Laboratory Functions	Small	29	865	3	11	0.05	0.05	0.05	0	0	0	$1,414	$1,414	$1,414	$0	$0	$0
68.5	Conducting Laboratory Control Activities	Small	10	298	1	11	0	0	0	52	104	156	$0	$0	$0	$169,025	$338,050	$507,075
68.6	Equipment Laboratory Materials	Small	5	149									$5,788,475	$5,788,475	$5,788,475	$0	$0	$0
68.7	Written Procedure for Laboratory Functions	Non-Small	19	55	1	14	4	8	12	2	4	6	$3,067	$6,134	$9,201	$1,534	$3,067	$4,601
68.8	Employee Training for Laboratory Functions	Non-Small	19	55	10	6	2	3	4	0	0	0	$7,086	$10,629	$14,172	$0	$0	$0
68.9	Training by Manager for	Non-Small	19	55	1	11	2	3	4	0	0	0	$1,195	$1,793	$2,391	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Laboratory Functions																	
68.1	Record of Training for Laboratory Functions	Non-Small	19	55	11	11	0.05	0.05	0.05	0	0	0	$329	$329	$329	$0	$0	$0
68.11	Conducting Laboratory Control Activities	Non-Small	10	29	1	11	0	0	0	104	208	312	$0	$0	$0	$32,715	$65,429	$98,144
68.12	Equipment Laboratory Materials	Non-Small	5	14									$1,121,794	$1,121,794	$1,121,794	$0	$0	$0
70.1	Written Procedure for Production Record Practices	Small	46	1373	1	14	2	4	6	1	2	3	$38,366	$76,733	$115,099	$19,183	$38,366	$57,550
70.2	Employee Training for Production Record Practices	Small	46	1373	2	6	0.5	1	2	0	0	0	$8,864	$17,728	$35,455	$0	$0	$0
70.3	Training by Manager for Production Record Practices	Small	46	1373	1	11	0.5	1	2	0	0	0	$7,476	$14,952	$29,904	$0	$0	$0
70.4	Record of Training for Production Record Practices	Small	46	1373	3	11	0.05	0.05	0.05	0	0	0	$2,243	$2,243	$2,243	$0	$0	$0
70.5	Review of Production Record	Small	10	298	1	11	0	0	0	52	104	156	$0	$0	$0	$169,025	$338,050	$507,075
70.6	Written Procedure for Production Record Practices	Non-Small	43	124	1	14	4	8	12	2	4	6	$6,941	$13,883	$20,824	$3,471	$6,941	$10,412
70.7	Employee Training for Production	Non-Small	43	124	10	6	0.5	1	2	0	0	0	$4,009	$8,018	$16,037	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Record Practices																	
70.8	Training by Manager for Production Record Practices	Non-Small	43	124	1	11	0.5	1	2	0	0	0	$676	$1,353	$2,705	$0	$0	$0
70.9	Record of Training for Production Record Practices	Non-Small	43	124	11	11	0.05	0.05	0.05	0	0	0	$744	$744	$744	$0	$0	$0
70.1	Review of Production Record	Non-Small	10	29	1	11	0	0	0	104	208	312	$0	$0	$0	$32,715	$65,429	$98,144
72.1	Written Procedure for Sampling Plans	Small	69	2059	1	14	2	4	6	1	2	3	$57,550	$115,099	$172,649	$28,775	$57,550	$86,324
72.2	Employee Training for Sampling Plans	Small	69	2059	2	6	2	3	4	0	0	0	$53,183	$79,774	$106,366	$0	$0	$0
72.3	Training by Manager for Sampling Plans	Small	69	2059	1	11	2	3	4	0	0	0	$44,857	$67,285	$89,713	$0	$0	$0
72.4	Record of Training for Sampling Plans	Small	69	2059	3	11	0.05	0.05	0.05	0	0	0	$3,364	$3,364	$3,364	$0	$0	$0
72.5	Written Procedure for Sampling Plans	Non-Small	72	208	1	14	4	8	12	2	4	6	$11,623	$23,246	$34,869	$5,811	$11,623	$17,434
72.6	Employee Training for Sampling Plans	Non-Small	72	208	10	6	2	3	4	0	0	0	$26,852	$40,279	$53,705	$0	$0	$0
72.7	Training by Manager for Sampling Plans	Non-Small	72	208	1	11	2	3	4	0	0	0	$4,530	$6,795	$9,059	$0	$0	$0
72.8	Record of Training for Sampling Plans	Non-Small	72	208	11	11	0.05	0.05	0.05	0	0	0	$1,246	$1,246	$1,246	$0	$0	$0
74.1	Written Procedure for Controlling Nonconforming Products	Small	36	1082	1	14	2	4	6	1	2	3	$30,244	$60,488	$90,731	$15,122	$30,244	$45,366

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
74.2	Employee Training for Controlling Nonconforming Products	Small	36	1082	2	6	2	3	4	0	0	0	$27,949	$41,923	$55,898	$0	$0	$0
74.3	Training by Manager for Controlling Nonconforming Products	Small	36	1082	1	11	2	3	4	0	0	0	$23,573	$35,360	$47,147	$0	$0	$0
74.4	Record of Training for Controlling Nonconforming Products	Small	36	1082	3	11	0.05	0.05	0.05	0	0	0	$1,768	$1,768	$1,768	$0	$0	$0
74.5	Control and Disposition of Nonconforming Products	Small	10	298	1	11	0	0	0	52	104	156	$0	$0	$0	$169,025	$338,050	$507,075
74.6	Written Procedure for Controlling Nonconforming Products	Non-Small	11	31	1	14	4	8	12	2	4	6	$1,752	$3,505	$5,257	$876	$1,752	$2,629
74.7	Employee Training for Controlling Nonconforming Products	Non-Small	11	31	10	6	2	3	4	0	0	0	$4,048	$6,073	$8,097	$0	$0	$0
74.8	Training by Manager for Controlling Nonconforming Products	Non-Small	11	31	1	11	2	3	4	0	0	0	$683	$1,024	$1,366	$0	$0	$0
74.9	Record of Training for Controlling Nonconforming Products	Non-Small	11	31	11	11	0.05	0.05	0.05	0	0	0	$188	$188	$188	$0	$0	$0
74.1	Control and Disposition of Nonconforming Products	Non-Small	10	29	1	11	0	0	0	104	208	312	$0	$0	$0	$32,715	$65,429	$98,144
76.1	Written Procedure for	Small	35	1044	1	14	2	4	6	1	2	3	$29,192	$58,384	$87,576	$14,596	$29,192	$43,788

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Controlling Returned Tobacco Products																	
76.2	Employee Training for Controlling Returned Tobacco Products	Small	35	1044	2	6	2	3	4	0	0	0	$26,977	$40,465	$53,954	$0	$0	$0
76.3	Training by Manager for Controlling Returned Tobacco Products	Small	35	1044	1	11	2	3	4	0	0	0	$22,753	$34,130	$45,507	$0	$0	$0
76.4	Record of Training for Controlling Returned Tobacco Products	Small	35	1044	3	11	0.05	0.05	0.05	0	0	0	$1,707	$1,707	$1,707	$0	$0	$0
76.5	Inspection and Evaluation of Returned Tobacco Products	Small	10	298	1	11	0	0	0	52	104	156	$0	$0	$0	$169,025	$338,050	$507,075
76.6	Written Procedure for Controlling Returned Tobacco Products	Non-Small	27	78	1	14	4	8	12	2	4	6	$4,359	$8,717	$13,076	$2,179	$4,359	$6,538
76.7	Employee Training for Controlling Returned Tobacco Products	Non-Small	27	78	10	6	2	3	4	0	0	0	$10,070	$15,105	$20,139	$0	$0	$0
76.8	Training by Manager for Controlling Returned Tobacco Products	Non-Small	27	78	1	11	2	3	4	0	0	0	$1,699	$2,548	$3,397	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
76.9	Record of Training for Controlling Returned Tobacco Products	Non-Small	27	78	11	11	0.05	0.05	0.05	0	0	0	$467	$467	$467	$0	$0	$0
76.1	Inspection and Evaluation of Returned Tobacco Products	Non-Small	10	29	1	11	0	0	0	104	208	312	$0	$0	$0	$32,715	$65,429	$98,144
78.1	Written Procedure for Reprocessing and Reworking Tobacco Products	Small	37	1104	1	14	2	4	6	1	2	3	$30,860	$61,720	$92,580	$15,430	$30,860	$46,290
78.2	Employee Training for Reprocessing and Reworking Tobacco Products	Small	37	1104	2	6	2	3	4	0	0	0	$28,518	$42,778	$57,037	$0	$0	$0
78.3	Training by Manager for Reprocessing and Reworking Tobacco Products	Small	37	1104	1	11	2	3	4	0	0	0	$24,054	$36,080	$48,107	$0	$0	$0
78.4	Record of Training for Reprocessing and Reworking Tobacco Products	Small	37	1104	3	11	0.05	0.05	0.05	0	0	0	$1,804	$1,804	$1,804	$0	$0	$0
78.5	Written Procedure for Reprocessing and Reworking Tobacco Products	Non-Small	30	85	1	14	4	8	12	2	4	6	$4,762	$9,524	$14,287	$2,381	$4,762	$7,143
78.6	Employee Training for Reprocessing and Reworking	Non-Small	30	85	10	6	2	3	4	0	0	0	$11,002	$16,503	$22,004	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
	Tobacco Products																	
78.7	Training by Manager for Reprocessing and Reworking Tobacco Products	Non-Small	30	85	1	11	2	3	4	0	0	0	$1,856	$2,784	$3,712	$0	$0	$0
78.8	Record of Training for Reprocessing and Reworking Tobacco Products	Non-Small	30	85	11	11	0.05	0.05	0.05	0	0	0	$510	$510	$510	$0	$0	$0
Total													**$9,445,703**	**$10,662,546**	**$11,900,414**	**$1,509,900**	**$3,019,801**	**$4,529,701**

(2020 USD)

Subpart F Costs

Table 6 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart F to foreign facilities only. Total estimated one-time costs range from $0.4 million to $1.3 million; total annual costs range from $45,000 to $135,000. These costs include:

- The one-time cost for the written procedure requirements for this subpart estimated to be between $90,000 and $270,000; and the annual cost estimated to be between $45,000 and $135,000 (in Table 6, sum of line items 92.1, 92.5, 94.1, 94.5, 98.1, and 98.5).
- The one-time cost for the training requirements for this subpart estimated to be between $0.3 million and $1.0 million (in Table 6, sum of line items 92.2-92.4, 92.6-92.8, 94.2-94.4, 94.6-94.8, 98.2-98.4, and 98.6-98.8).

Table 6: Detailed Calculation of Subpart F Costs - Packaging and Labeling Controls

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
92.1	Written Procedure for Controlling Packaging and Labeling	Small	34	1014	1	14	2	4	6	1	2	3	$28,358	$56,716	$85,073	$14,179	$28,358	$42,537
92.2	Employee Training for Controlling Packaging and Labeling	Small	34	1014	2	6	4	6	12	0	0	0	$52,412	$78,618	$157,236	$0	$0	$0
92.3	Training by Manager for Controlling Packaging and Labeling	Small	34	1014	1	11	4	6	12	0	0	0	$44,207	$66,310	$132,620	$0	$0	$0
92.4	Record of Training for Controlling Packaging and Labeling	Small	34	1014	3	11	0.05	0.05	0.05	0	0	0	$1,658	$1,658	$1,658	$0	$0	$0
92.5	Written Procedure for Controlling Packaging and Labeling	Non-Small	27	78	1	14	4	8	12	2	4	6	$4,359	$8,717	$13,076	$2,179	$4,359	$6,538
92.6	Employee Training for Controlling Packaging and Labeling	Non-Small	27	78	10	6	4	6	12	0	0	0	$20,139	$30,209	$60,418	$0	$0	$0
92.7	Training by Manager for Controlling Packaging and Labeling	Non-Small	27	78	1	11	4	6	12	0	0	0	$3,397	$5,096	$10,192	$0	$0	$0
92.8	Record of Training for Controlling Packaging and Labeling	Non-Small	27	78	11	11	0.05	0.05	0.05	0	0	0	$467	$467	$467	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
94.1	Written Procedure for Repacking and Relabeling Operations	Small	29	865	1	14	2	4	6	1	2	3	$24,188	$48,375	$72,563	$12,094	$24,188	$36,281
94.2	Employee Training for Repacking and Relabeling Operations	Small	29	865	2	6	4	6	12	0	0	0	$44,704	$67,057	$134,113	$0	$0	$0
94.3	Training by Manager for Repacking and Relabeling Operations	Small	29	865	1	11	4	6	12	0	0	0	$37,706	$56,558	$113,117	$0	$0	$0
94.4	Record of Training for Repacking and Relabeling Operations	Small	29	865	3	11	0.05	0.05	0.05	0	0	0	$1,414	$1,414	$1,414	$0	$0	$0
94.5	Written Procedure for Repacking and Relabeling Operations	Non-Small	30	87	1	14	4	8	12	2	4	6	$4,843	$9,686	$14,529	$2,421	$4,843	$7,264
94.6	Employee Training for Repacking and Relabeling Operations	Non-Small	30	87	10	6	4	6	12	0	0	0	$22,377	$33,566	$67,131	$0	$0	$0
94.7	Training by Manager for Repacking and Relabeling Operations	Non-Small	30	87	1	11	4	6	12	0	0	0	$3,775	$5,662	$11,324	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
94.8	Record of Training for Repacking and Relabeling Operations	Non-Small	30	87	11	11	0.05	0.05	0.05	0	0	0	$519	$519	$519	$0	$0	$0
98.1	Written Procedure for Implementing FDA-approved Warning Plan	Small	29	875	1	14	2	4	6	1	2	3	$24,457	$48,914	$73,372	$12,229	$24,457	$36,686
98.2	Employee Training for Implementing FDA-approved Warning Plan	Small	29	875	2	6	4	6	12	0	0	0	$45,203	$67,804	$135,608	$0	$0	$0
98.3	Training by Manager for Implementing FDA-approved Warning Plan	Small	29	875	1	11	4	6	12	0	0	0	$38,126	$57,189	$114,378	$0	$0	$0
98.4	Record of Training for Implementing FDA-approved Warning Plan	Small	29	875	3	11	0.05	0.05	0.05	0	0	0	$1,430	$1,430	$1,430	$0	$0	$0
98.5	Written Procedure for Implementing FDA-approved Warning Plan	Non-Small	23	66	1	14	4	8	12	2	4	6	$3,713	$7,426	$11,139	$1,856	$3,713	$5,569
98.6	Employee Training for Implementing FDA-approved Warning Plan	Non-Small	23	66	10	6	4	6	12	0	0	0	$17,156	$25,734	$51,467	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
98.7	Training by Manager for Implementing FDA-approved Warning Plan	Non-Small	23	66	1	11	4	6	12	0	0	0	$2,894	$4,341	$8,682	$0	$0	$0
98.8	Record of Training for Implementing FDA-approved Warning Plan	Non-Small	23	66	11	11	0.05	0.05	0.05	0	0	0	$398	$398	$398	$0	$0	$0
Total													**$427,898**	**$683,863**	**$1,271,923**	**$44,958**	**$89,917**	**$134,875**

(2020 USD)

Subpart G Costs

Table 7 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart G to foreign facilities only. Total estimated one-time costs range from $0.8 million to $1.2 million; total annual costs range from $41,000 to $79,000. These costs include:

- The one-time cost for the written procedure requirements for this subpart estimated to be between $82,000 and $245,000; and the annual cost estimated to be between $41,000 and $78,000 (in Table 7, sum of line items 102.1, 102.6, 104.1, and 104.5).
- The one-time cost for the training requirements for this subpart estimated to be between $0.2 million and $0.4 million (in Table 7, sum of line items 102.2-102.4, 102.7-102.9, 104.2-104.4, and 104.6-104.8).
- The one-time capital cost for this subpart estimated to be about $580,000 (in Table 7, sum of line items 102.5 and 102.10).

Table 7: Detailed Calculation of Subpart G Costs - Handling, Storage, and Distribution

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
102.1	Written Procedure for Preventing Adulteration During Handling and Storage	Small	43	1283	1	14	2	4	6	1	1.5	2	$35,864	$71,729	$107,593	$17,932	$26,898	$35,864
102.2	Employee Training for Preventing Adulteration During Handling and Storage	Small	43	1283	3	6	2	3	4	0	0	0	$49,714	$74,572	$99,429	$0	$0	$0
102.3	Training by Manager for Preventing Adulteration During Handling and Storage	Small	43	1283	1	11	2	3	4	0	0	0	$27,954	$41,931	$55,908	$0	$0	$0
102.4	Record of Training for Preventing Adulteration During Handling and Storage	Small	43	1283	4	11	0.05	0.05	0.05	0	0	0	$2,795	$2,795	$2,795	$0	$0	$0
102.5	Equipment Extra Storage Materials or Space	Small	5	149									$484,039	$484,039	$484,039	$0	$0	$0
102.6	Written Procedure for Preventing Adulteration During Handling and Storage	Non-Small	21	61	1	14	4	8	12	2	2	2	$3,390	$6,780	$10,170	$1,695	$1,695	$1,695

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
102.7	Employee Training for Preventing Adulteration During Handling and Storage	Non-Small	21	61	21	6	2	3	4	0	0	0	$16,447	$24,671	$32,894	$0	$0	$0
102.8	Training by Manager for Preventing Adulteration During Handling and Storage	Non-Small	21	61	2	11	2	3	4	0	0	0	$2,642	$3,963	$5,285	$0	$0	$0
102.9	Record of Training for Preventing Adulteration During Handling and Storage	Non-Small	21	61	23	11	0.05	0.05	0.05	0	0	0	$760	$760	$760	$0	$0	$0
102.1	Equipment Extra Storage Materials or Space	Non-Small	5	14									$93,685	$93,685	$93,685	$0	$0	$0
104.1	Written Procedure for Preventing Adulteration During Distribution	Small	47	1402	1	14	2	4	6	1	1.5	2	$39,200	$78,401	$117,601	$19,600	$29,400	$39,200
104.2	Employee Training for Preventing Adulteration During Distribution	Small	47	1402	3	6	2	3	4	0	0	0	$54,339	$81,509	$108,678	$0	$0	$0
104.3	Training by Manager for Preventing Adulteration During Distribution	Small	47	1402	1	11	2	3	4	0	0	0	$30,555	$45,832	$61,109	$0	$0	$0

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
104.4	Record of Training for Preventing Adulteration During Distribution	Small	47	1402	4	11	0.05	0.05	0.05	0	0	0	$3,055	$3,055	$3,055	$0	$0	$0
104.5	Written Procedure for Preventing Adulteration During Distribution	Non-Small	23	66	1	14	4	8	12	2	2	2	$3,713	$7,426	$11,139	$1,856	$1,856	$1,856
104.6	Employee Training for Preventing Adulteration During Distribution	Non-Small	23	66	21	6	2	3	4	0	0	0	$18,014	$27,020	$36,027	$0	$0	$0
104.7	Training by Manager for Preventing Adulteration During Distribution	Non-Small	23	66	2	11	2	3	4	0	0	0	$2,894	$4,341	$5,788	$0	$0	$0
104.8	Record of Training for Preventing Adulteration During Distribution	Non-Small	23	66	23	11	0.05	0.05	0.05	0	0	0	$832	$832	$832	$0	$0	$0
Total													**$869,893**	**$1,053,340**	**$1,236,787**	**$41,084**	**$59,850**	**$78,616**

(2020 USD)

Subpart H Costs

Table 8 provides a detailed breakdown of the components used to estimate the costs of proposed Subpart H to foreign facilities only. Total estimated one-time costs range from $120,000 to $360,000; total annual costs range from $60,000 to $123,000.

Table 8: Detailed Calculation of Subpart H Costs - Recordkeeping and Document Controls

							One-Time Hours			Annual Hours			One-Time Costs			Annual Costs		
Line Item	**Task**	**Entity Type**	**Percent Affected (%)**	**Number Affected**	**Units**	**Wage ($)**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**	**L**	**M**	**H**
124.1	Written Procedure for controlling documents	Small	65	1939	1	14	4	9	13	2	3	4	$115,431	$230,861	$346,292	$57,715	$86,573	$115,431
124.1	Written Procedure for controlling documents	Non-Small	15	43	1	14	9	17	26	4	9	13	$5,156	$10,311	$15,467	$2,578	$5,156	$7,734
Total													**$120,586**	**$241,173**	**$361,759**	**$60,293**	**$91,729**	**$123,164**

(2020 USD)

Appendix C - Wage Rates for Foreign Tobacco Product Manufacturing

To estimate wages in foreign tobacco product manufacturing establishments, we use the Occupational Wages around the World (OWW) Database: Update for 1983-2008. Relying on historical occupational and industry-level wages, we reviewed data for the most recent year available for the 20 foreign countries that exported the largest amount of tobacco products to the United States by total dollar value. With the exception of a few countries, the database does not report wages for employees of tobacco product manufacturers. We therefore use reported wages earned by laborers and foremen employed by other manufacturing industries such as chemical products manufacturing as proxy wages. We request comment on this assumption comparing wages for tobacco manufacturing to wages for the manufacture of other chemical products.

We then estimate wages for General and Operations Manager using the ratio of wages for production managers to general managers in the United States according to the Bureau of Labor Statistics. We further use Accountant wages reported in OWW as proxies for the wages of Legal Occupations. For other occupations where the OWW data do not include comparable staff descriptions, we use country-specific general manufacturing industry level wages for specific occupations such as plant and machine operators from the ILOSTAT database (and in the United Arab Emirates, wages from the Federal Competitiveness and Statistics Authority) as proxies.

To account for inflation, we adjust historical wages to their 2016 equivalents based on consumer price indices (CPI) for each country, obtained from the Federal Reserve Economic Data (FRED) database. We then used (2020) exchange rates to convert all currency units into U.S. dollars. Finally, we calculate weighted average wages for the occupations of production worker, manager, general manager, and legal staff across the 20 foreign countries, using as weights each country's share of their combined total dollar value of tobacco product exports to the United States (Table 1).

Table 1: Weighted Foreign Wage Estimates by Country and Values of Imports*

Country Of Origin Full Name (Top 20)	Base Wage Rate by Occupation and Country				Percent Value of Imported Tobacco Products	Wage rates weighted by share of imported tobacco product value (=Base wage * Present Value)			
	Productions Occupation	Industrial Production Manager	General and Operations Manager	Legal Occupations		Weighted Productions Occupation	Weighted Industrial Production Manager	Weighted General and Operations Manager	Weighted Legal Occuptions
Honduras	$1.20	$2.38	$3.04	$1.82	30%	$0.36	$0.72	$0.92	$0.55
Dominican Republic	$1.43	$3.75	$4.79	$1.43	18%	$0.26	$0.69	$0.88	$0.26
People's Republic of China	$1.34	$1.36	$1.73	$2.80	12%	$0.15	$0.16	$0.20	$0.32
Brazil	$1.93	$3.13	$4.00	$13.32	6%	$0.12	$0.20	$0.25	$0.84
Canada	$15.20	$19.29	$24.62	$25.29	6%	$0.84	$1.07	$1.36	$1.40
Turkey	$1.66	$1.94	$2.47	$3.37	4%	$0.07	$0.08	$0.11	$0.15
Spain	$19.22	$33.10	$42.28	$29.88	4%	$0.82	$1.41	$1.80	$1.27
Nicaragua	$0.67	$1.76	$2.25	$1.86	4%	$0.03	$0.07	$0.09	$0.08
Korea, Republic Of	$6.96	$10.63	$13.58	$23.91	3%	$0.21	$0.32	$0.41	$0.73
India	$0.31	$0.44	$0.56	$2.15	1%	$0.00	$0.01	$0.01	$0.03
Philippines, Republic of the	$0.93	$2.03	$2.60	$2.19	1%	$0.01	$0.03	$0.03	$0.03
Indonesia	$0.35	$0.95	$1.21	$0.49	1%	$0.00	$0.01	$0.01	$0.01
France	$19.22	$33.10	$42.28	$34.40	1%	$0.16	$0.28	$0.36	$0.29
Argentina	$0.12	$12.66	$16.17	$3.59	1%	$0.00	$0.09	$0.12	$0.03
Bulgaria	$1.25	$3.26	$4.16	$3.93	1%	$0.01	$0.02	$0.03	$0.02
Macedonia, The Former Yugoslav Republic Of	$6.61	$12.13	$15.49	$12.03	1%	$0.04	$0.07	$0.09	$0.07
Guatemala	$1.79	$1.97	$2.52	$5.86	1%	$0.01	$0.01	$0.01	$0.03
Malawi	$0.14	$0.14	$0.18	$4.97	1%	$0.00	$0.00	$0.00	$0.03
Germany	$19.22	$33.10	$42.28	$34.40	1%	$0.10	$0.17	$0.22	$0.18
United Arab Emirates	$3.66	$9.57	$19.44	$13.67	0%	$0.02	$0.04	$0.09	$0.06
Average	**$5.16**	**$9.34**	**$12.28**	**$11.07**	**0%**	**$3.23**	**$5.45**	**$6.99**	**$6.37**

*Values may not be exact due to rounding
(2020 USD)

Appendix C References

C1. Freeman, Richard B. and Remco H. Oostendorp (2020). *Occupational Wages Around the World 1953-2008 Database* [Data file and documentation]. Available from National Bureau of Economic Research website: https://www.nber.org/research/data/occupational-wages-around-world-oww-database.

C2. Bureau of Labor Statistics (2020). *May 2020 National Industry-Specific Occupational Employment and Wage Estimates* [Online database]. Available from BLS website: https://www.bls.gov/oes/current/oessrci.htm

C3. International Labour Organization. *ILOSTAT* [Online database]. Available from International Labour Organization website: https://ilo.org/ilostat

C4. UAE Federal Competitiveness and Statistics Authority (FCSA) (2008). *Paid Employees in Manufacturing Industry* [Data file]. Available from UAE Open Data Portal website: http://data.bayanat.ae/en_GB/dataset/paid-employees-in-manufacturing-industry

Appendix D. Recall Costs

We consider the costs of recalls to a recalling manufacturer (including reimbursement costs paid to retailers) to be private costs and the costs of recalls to manufacturers of competing and complementary products, along with unreimbursed costs to wholesalers, retailers and consumers to be external costs. Costs to recalling manufacturers are internal (private) costs because well-established, profit-maximizing tobacco product manufacturers may be able to consider in their decisions the costs associated with recalling a nonconforming tobacco product beyond the value of recalled units, to include expenses associated with notifying tobacco retailers and consumers, collection, shipping, disposal and legal costs. However, from Jarrell and Peltzman (Ref. 2), any recall, regardless of size, is followed by industry-wide asset loss. Their findings "help shed light on the degree to which the capital market might sub-optimally deter production of faulty products," and show that large costs exist in cross-company effects (Ref. 2). While the authors contend that losses spill over to competitors and their stocks, this negative externality may be larger in the aggregate than the losses to the producer of the recalled product. The authors measured losses using cumulative excess returns (CERs) and found that average stockholder losses beyond costs to the specific recalled product can range between 3% and 6% of market value (Ref. 2). The authors do not capture the external costs separately nor do they offer a clear way to separate social (external) costs from private (internal) costs.

As our first step to estimate any social costs due to recalls we estimate all costs due to recalls to further break down the share of social (external) and private (internal) costs. To estimate manufacturers' private costs of conducting recalls, we use the costs of recorded recalls of tobacco products and assign the estimated proportion of costs that would correspond to manufacturers of finished tobacco products.

To approximate the share of external costs associated with a recall across the supply chain, we use information on external costs of recalls from FDA's Requirements for Additional Traceability Records for Certain Foods (Final Rule) Regulatory Impact Analysis (RIA) (87 FR 70910, November 21, 2022)[70], hereinafter referred to as the Food Traceability Rule. In the Regulatory Impact Analysis, we estimated the benefits from avoiding overly broad recalls by estimating the forgone external costs associated with conducting a recall when following an FDA advisory. We use the estimated share of external recall costs applied to food industry sectors covered under the traceability rule as a proxy to estimate the share of external recall costs incurred by tobacco industry sectors affected under the TPMP proposed rule. Table 1 shows the series of calculations used to estimate the share of external recall costs by food industry sector. To assess the spillover costs to competitors due to recalls and market withdrawals, the Food Traceability Rule RIA uses the results of an expert elicitation estimating both labor and non-labor costs for different firm sizes and industry sectors. The reduction in spillover costs is the difference between total costs incurred by firms affected by an overly broad recall following an FDA advisory and total costs to firms affected by a more targeted recall. In the food traceability Rule we estimate the revenue of affected firms and the share of external costs by sector using Statistics of U.S. Businesses (SUSB) data from the U.S. Census data.[71] We use data on recall costs among a sample of 36 food manufacturers

[70] Regulatory Impact Analysis: Requirement for Additional Traceability Records for Certain Foods Final Regulatory Impact Analysis. Page 84. Viewed on 1/24/2021 at https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/requirements-additional-traceability-records-certain-foods-final-rule-regulatory-impact-analysis

[71] Statistics of U.S. Businesses SUSB is an annual series that provides national and subnational data on the distribution of economic data by enterprise size and industry. https://www.census.gov/programs-surveys/susb.html

from a 2011 study from Grocery Manufacturers Association to estimate the fraction of recall costs as a fraction of sales of about 0.0029.[72] We multiply the fraction by the total annual revenue of the industry covered by the Food Traceability Rule (row a) to obtain the cost of recalls representing internal costs of a recall (row b). To obtain the external costs of recalls we used input from an expert elicitation (row c,1, c2, and c3).[73] We addressed inherent uncertainty and variability using Monte Carlo simulations.[74] Finally, the percentage share of external costs is estimated by dividing external recall costs (row c_n by row d_n, (where n= 1,2,3).

Table 1.—Share of External Recall Costs of Traceability Covered Foods by Sector.

Calculation	Estimate Description / Sector		Manufacturers/ Processors	Wholesalers/ Distributors	Retail Food Establishments
a	Total Annual Revenue of Industry Covered by the Food Traceability Rule		$100,511,580	$454,500,999	$998,574,280
b = a x 0.03	Value of recalls based on 0.3% GMA fraction representing internal costs.		$289,094	$1,307,245	$2,872,121
c1	External Recall Costs from the Traceability Final Rule (1)	*Low Estimate*	$46,723	$7,273	$22,818
c2		*Middle Estimate*	$384,047	$55,937	$159,579
c3		*High Estimate*	$1,243,551	$160,565	$435,278
d1= b+c1	Total Cost of Recalls	*Low Estimate*	$335,817	$1,314,518	$2,894,938
d2=b+c2		*Middle Estimate*	$673,141	$1,363,182	$3,031,700
d3= b+c3		*High Estimate*	$1,532,644	$1,467,810	$3,307,398
e1= d1/c1	Percent Share of External Costs (2)	*Low Estimate*	14%	1%	1%
e2= d2/c2		*Middle Estimate*	57%	4%	5%
e3=d3/c3		*High Estimate*	81%	11%	13%

(1) Low, Middle and High Estimates for External Recall Costs are Based on Simulation Results from Requirements for Additional Traceability Records for Certain Foods (Final Rule) Regulatory Impact Analysis. Middle Estimates can be derived from Table 21 page 105.

(2) The calculation for percent share of external costs low, middle and high estimates are point estimates. To characterize variability and uncertainty we use these point estimates (e1,e2, and e3) as input parameter estimates in triangular distributions for each sector, shown in table 2.

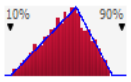
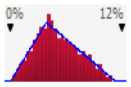
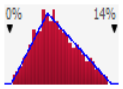
To account for variability and uncertainty about our estimate range we characterize external recall cost shares by sector as a triangular distribution (Table 2).

[72] GMA (Ref 4). From page 4 in the GMA study we estimate an average of 2.16 recalls in the past 5 years at an average cost per recall of $25.8 million (page 3). Over a five-year period, the product of the average 2.16 recalls in 5 years x $25.8 million x 36 manufacturers represents approximately $2,005 million USD lost to recalls by the whole sample or $400 million USD in lost recalls by the whole sample per year. The estimated fraction of the GMA sample's recall costs as a fraction of sales (revenues) is about 0.0029.

[73] Eastern Research Group (ERG), "Expert Elicitations to Estimate Traceability Costs and Costs Savings from Avoiding Overly Broad Recalls," Lexington, MA, 2022.

[74] Low, Middle and High Estimates for Total Costs of Recalls are based on simulation results from the Food Traceability Rule's RIA. Middle Estimates can be derived from Table 21 page 105 of the RIA.

Table 2.— Monte Carlo Simulation Input Parameter Estimates Characterizing the Share of External Costs by Sector (Triangular Distribution)

Name	Graph	Min	Mean	Max	5%	95%
Manufacturer Share		14%	51%	81%	26%	72%
Wholesaler Share		1%	5%	11%	2%	9%
Retailer Share		1%	6%	13%	2%	11%

To estimate revenue share by tobacco industry sector we estimate that the value that exists as of the point when manufacturers deliver products to wholesalers constitutes 68% of the retail value of cigarettes (excluding taxes) in the U.S. market (See Table 2). This percentage is derived from the price breakdown for a pack of a prominent brand of cigarettes with a 20% share of retail value corresponding to manufacturer operating profit, 18% to components, 4% to "other," 17% to both wholesalers and retailers and 42% share of the retail value corresponding to State and Federal Excise tax. The estimated percentage of the manufacturer operating profit over sales without taxes is about 34% = [20% ÷ (100% - 42%)], components 31% =[18% ÷ (100% - 42%)] and other 7% =[4% ÷ (100% - 42%)]. We assume that the estimated 7% category for "other" is divided equally between manufacturers and non-manufacturers (wholesalers and retailers). Therefore, as shown in Table 2, column (a) we further estimate manufacturers' share of total retail value excluding taxes as 68% =[(34% profit share + 31% components + (7% other x 50%)].

In a similar manner, we estimate the wholesaler and retailer share of total retail value without taxes is 32% =[17% ÷ (100% - 42%)+ (7% other x 50%)].[75] Of the 32%, we estimate the percent share for wholesalers as 11% = (32% x 33%) and retailers as 22% = (32% x 67%).[76]

To estimate the percentage external cost share of recalls by sector in column (c) of Table 3, we apply the simulated results for estimated percentage range for the share of external recall costs by sector from the Food Traceability Rule RIA (Table 3 column b) as a proxy to estimate the percentage share of external recall costs. The middle percentage for external cost share by revenue share and by sector (column c) is the product of both columns (a) Percentage Revenue Share and (b) Percent External Cost Share. The calculated results in column (c) reflect point estimates to illustrate the calculations steps. The simulated results for column (c) are in Table 4.

[75] Against All Odds, the U.S. Tobacco Industry Is Rolling in Money, Wall Street Journal - April 23, 2017, https://www.wsj.com/articles/u-s-tobacco-industry-rebounds-from-its-near-death-experience-1492968698.

[76] The percentage markup between retailers (33%) and wholesalers (66%) is estimated using information from "Total Cigarette Markup Across Standard Distribution Chain in Pricing States 2015) https://tobacconomics.org/research/total-cigarette-markup-across-standard-distribution-chain-in-pricing-states-2015/

Table 3.— Estimated Share of Internal and External Recall Costs Across Standard Tobacco Distribution Chain (Central Estimate)

Sector	Percentage of Revenue Share (a)	Percent External Cost Share (b)	Percent External Cost Share by Revenue Share and by Sector (c) = (a) x (b)
Manufacturer Share	68%	51%	34%
Wholesaler Share	11%	5%	0.6%
Retailer Share	22%	6%	1.4%

Table 4 shows the simulation output results representing column (c) in table 3, for the percentage share of external costs by revenue share and by sector.

Table 4.— Monte Carlo Simulation Output Results for the Percentage Share of External Costs by Revenue Share and by Sector

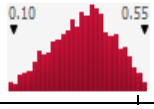
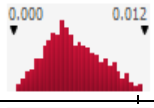
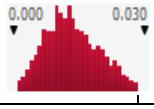
Name	Graph	Min	Mean	Max	5%	95%
Manufacturer Share		10%	34%	54%	18%	49%
Wholesaler Share		0.1%	0.6%	1.1%	0.2%	1.0%
Retailer Share		0.2%	1.4%	3%	1%	2%

Table 5a shows the steps we use in estimating average costs of recalls and market withdrawals potentially associated with insufficient TPMP controls. We first estimate the annual average retail value and the estimated annual maximum retail value of all recalls and market withdrawals. Of these recalls and market withdrawals, we estimate the total and average annual retail value of voluntarily initiated recalls and market withdrawals handled and classified by FDA since 2011 (lines a through e).

Table 5a.— Calculated Values Used in Estimating Benefits from Avoiding External Costs of Recalls and Market Withdrawals*

Calculations	Calculation Description	Value
a	Sample Sum - Retail Value Recalled	**$114,053,625**
b = a / 9	Annual average retail value	$12,672,625
c	Annual maximum	$69,624,532
d	Sum of retail value of FDA classified recalls	$85,994,393
e = d / 9	Annual average classified retail value	$9,554,933

*Copied from Section D.1, Table 4b.

Table 5b below shows the relationship between the calculations for the total value of recalls, private costs, and external costs. The columns in Table 5b show the estimated potential share of external recall costs by sector across a standard tobacco distribution chain as explained in Table 4. Table 5b is the same as Table 5a (Section D. 1) and we included it in this appendix to help clarify how the other calculations from tables 1 through 4 fit in the overall estimate.

One important step to account for other recall associated costs beyond the retail value of recalled products, is the extrapolation from food manufacturers' recall costs as a proportion of annual revenues to estimate total recall costs incurred by tobacco manufacturers or line g or the GMA fraction or row g (Refs. R1, R2, R7, R8, R9, R10, R11, R12, R13, R14). Results in table 5b show middle expected value estimates using the GMA fraction of 0.29%.

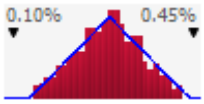
Table 5b.— Calculations for Low, Middle and High Benefits Estimates from Avoided Recalls and Market Withdrawals, 2011-2019 (2020 U.S. Dollars, using GMA fraction*)

Calculation	Calculation Description		(A) Value	Percent External Cost Share by Revenue Share by Sector			(E) External Costs due to Recalls or Market Withdrawals = B + C + D
				(B) Manufacturing Share = A x (34%)	(C) Wholesaler Share = A x (0.6%)	(D) Retailer Share = A x (1.4%)	
f	Retail value of tobacco products sold by sector in U.S.		$128,474,990,000	$44,161,696,264	$712,234,061	$1,772,218,847	$46,646,149,172
g	Fraction of recall costs over retail value per sector		0.29%				
h= f x g	Annual costs of tobacco recalls per sector		$369,522,489	$127,018,807	$2,048,543	$5,097,293	$134,164,643
i = h / c	Multipliers for estimating other recall associated costs	low	5				
j = k - ((k-i)/2)		middle	17				
k = h / b		high	29				
e	Annual average classified retail value from Table 5a		$9,554,933	$3,284,390	$52,970	$131,803	$3,469,164
l = e x i	**Estimated Annual Costs of FDA classified recalls from TPMP**	**low**	**$50,711,471**	**$17,431,444**	**$281,132**	**$699,528**	**$18,412,104**
m = e x j		**middle**	**$164,555,101**	**$56,563,790**	**$912,253**	**$2,269,918**	**$59,745,962**
o = e x k		**high**	**$278,398,732**	**$95,696,137**	**$1,543,375**	**$3,840,308**	**$101,079,819**

*This table presents an example calculation using the GMA fraction. See Tables 6 through 10 for additional calculations using a range of 50% and 150% of the GMA fraction and the full range of results.

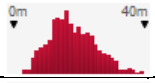
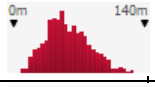
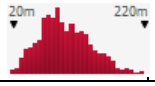
We characterize variability about our uncertainty using probabilistic techniques representing the GMA fraction of 0.29% (line g) as a triangular distribution with parameter estimates 0.15%, and 0.42% representing the lower and upper bound around 0.29% (Table 6).[77]

Table 6.— Monte Carlo Simulation Input Parameter Estimates Characterizing the Fraction of Recall Costs over Retail Value (Triangular Distribution)

Name	Graph	Min	Mean	Max	5%	95%
(g) Fraction of recall costs over retail value (From GMA)		0.15%	0.29%	0.42%	0.19%	0.38%

Results in Table 7 show the full simulation results. Due to the overlap between the Minimum, Mean and Maximum (columns) across the Low, Middle and High results in rows, we use as a primary estimate the Middle/Mean of $59 million with $4 million (Min/Low) and $213 million as the lower and upper bound estimates respectively.

Table 7.— Monte Carlo Simulation Output Results for the Range of Potential External Costs due to Recalls or Market Withdrawals (Full Range of Results for Table 5b, Column E)

Name	Graph	Min	Mean	Max	5%	95%
Low Estimate		**$4,230,726**	$18,383,910	$38,758,660	$8,670,684	$29,809,290
Middle Estimate		$13,728,400	**$59,654,480**	$125,769,100	$28,135,750	$96,729,020
High Estimate		$23,226,080	$100,925,100	**$212,779,500**	$47,600,820	$163,648,800

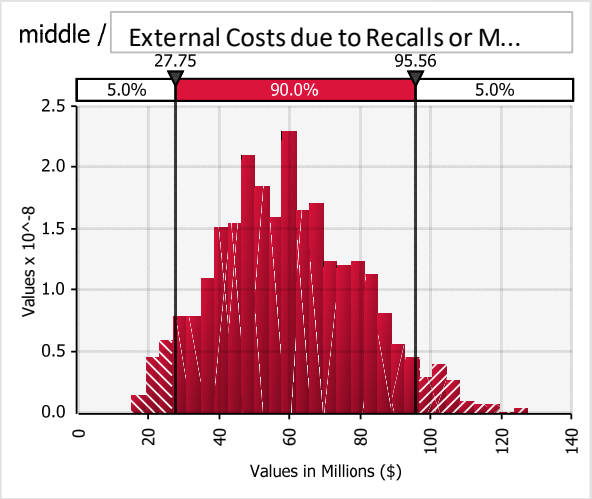
Tables 8, 9 and 10 show detailed results from the three simulated results. The inputs as ranked by their effect on output mean, show that variation in results is mostly driven by our two input distributions. The first one, characterizing the estimated manufacturers share of external costs from Table 2 and the second one, characterizing the fraction of recall costs over retail value of the estimated range for (g) in Table 5b.

[77] We note that this fraction range is significantly smaller than the 3% and 6% average stockholder losses beyond costs to the specific recalled product as discussed by Jarrell and Peltzman (Ref. 2).

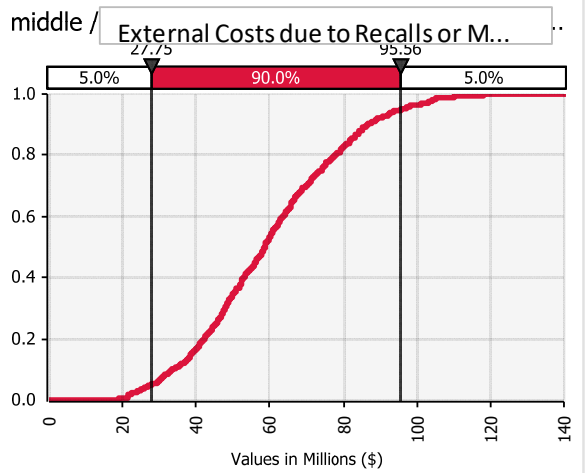
Table 8.--@RISK Output Report for middle / External Costs due to Recalls

Performed By: FDA ECON

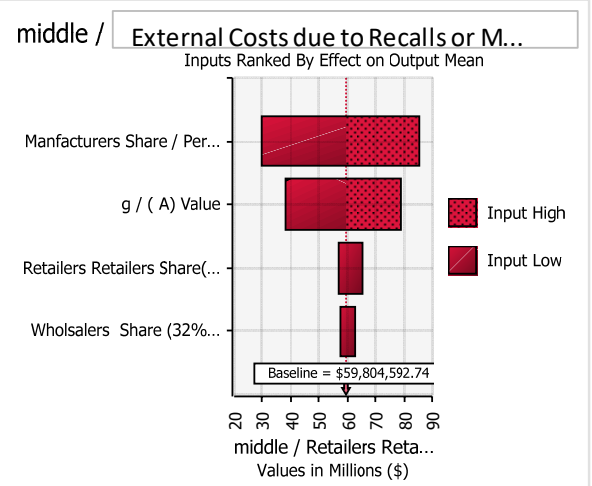
Date: Wednesday, January 25, 2023 4:13:45 AM



Simulation Summary Information	
Workbook Name	TPMP Benefit Tables.xlsx, Copy of
Number of Simulations	1
Number of Iterations	800
Number of Inputs	18
Number of Outputs	19
Sampling Type	Latin Hypercube
Simulation Start Time	1/25/2023 4:11
Simulation Stop Time	1/25/2023 4:11
Simulation Duration	00:00:17
Random # Generator	Mersenne Twister
Random Seed	628115339
Total Errors	0
Collect Distribution Samples	All
Convergence Testing	Enabled
Smart Sensitivity Analysis	Enabled



Summary Statistics for middle / Retailers Retailers Share(3			
Statistics		**Percentile**	
Minimum	$15,307,997	**1.0%**	$21,366,736
Maximum	$127,653,909	**2.5%**	$23,625,295
Mean	$59,804,593	**5.0%**	$27,749,237
Std Dev	$20,275,813	**10.0%**	$33,570,225
Variance	4.11109E+14	**20.0%**	$42,039,594
Skewness	0.314607676	**25.0%**	$45,256,257
Kurtosis	2.723895534	**50.0%**	$58,553,347
Median	$58,553,347	**75.0%**	$73,910,184
Mode	$66,039,575	**80.0%**	$77,833,954
Left X	$27,749,237	**90.0%**	$86,440,604
Left P	5%	**95.0%**	$95,558,987
Right X	$95,558,987	**97.5%**	$103,855,929
Right P	95%	**99.0%**	$107,254,708
#Errors	0		

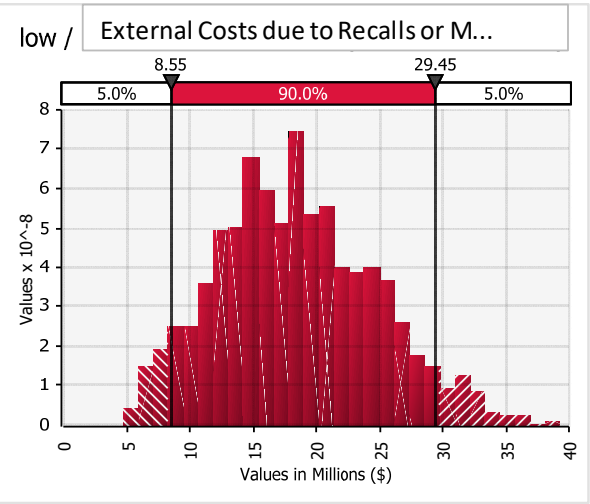


Change in Output Statistic for middle / Retailers Retailers S			
Rank	**Name**	**Lower**	**Upper**
1	Manfacturers Sh	$29,957,910	$85,734,241
2	g / (A) Value	$37,868,729	$79,274,493
3	Retailers Retaile	$56,846,661	$65,450,560
4	Wholsalers Shar	$57,588,857	$62,931,535

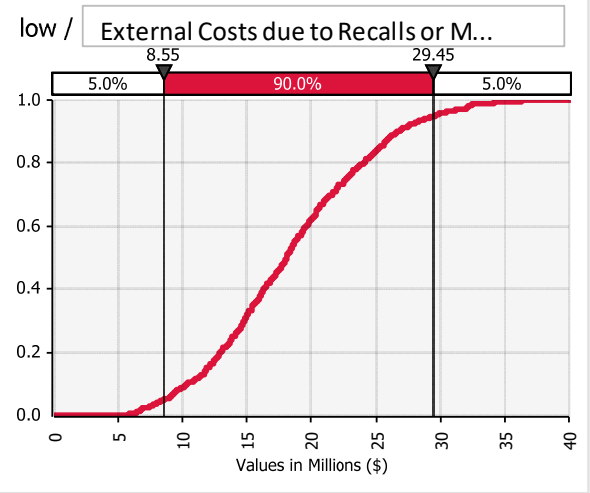
Table 9.--@RISK Output Report for low / External Costs due to Recalls

Performed By: FDA ECON

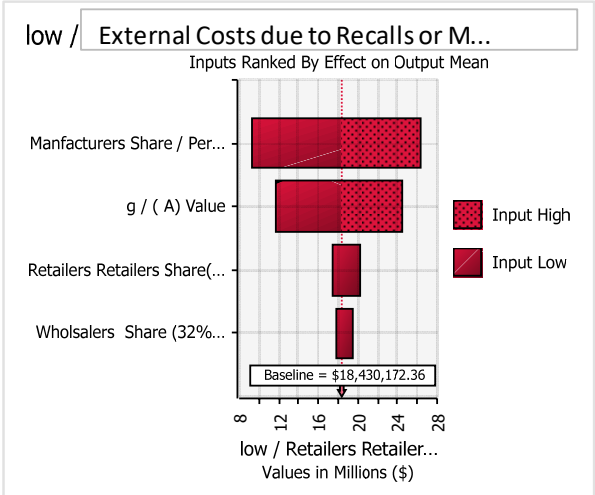
Date: Wednesday, January 25, 2023 4:13:41 AM



Simulation Summary Information	
Workbook Name	TPMP Benefit Tables.xlsx, Copy of
Number of Simulations	1
Number of Iterations	800
Number of Inputs	18
Number of Outputs	19
Sampling Type	Latin Hypercube
Simulation Start Time	1/25/2023 4:11
Simulation Stop Time	1/25/2023 4:11
Simulation Duration	00:00:17
Random # Generator	Mersenne Twister
Random Seed	628115339
Total Errors	0
Collect Distribution Samples	All
Convergence Testing	Enabled
Smart Sensitivity Analysis	Enabled



Summary Statistics for low / Retailers Retailers Share(32$			
Statistics		**Percentile**	
Minimum	$4,717,514	**1.0%**	$6,584,655
Maximum	$39,339,513	**2.5%**	$7,280,683
Mean	$18,430,172	**5.0%**	$8,551,571
Std Dev	$6,248,462	**10.0%**	$10,345,443
Variance	3.90433E+13	**20.0%**	$12,955,476
Skewness	0.314607676	**25.0%**	$13,946,765
Kurtosis	2.723895534	**50.0%**	$18,044,572
Median	$18,044,572	**75.0%**	$22,777,138
Mode	$20,351,627	**80.0%**	$23,986,338
Left X	$8,551,571	**90.0%**	$26,638,677
Left P	5%	**95.0%**	$29,448,718
Right X	$29,448,718	**97.5%**	$32,005,613
Right P	95%	**99.0%**	$33,053,026
#Errors	0		

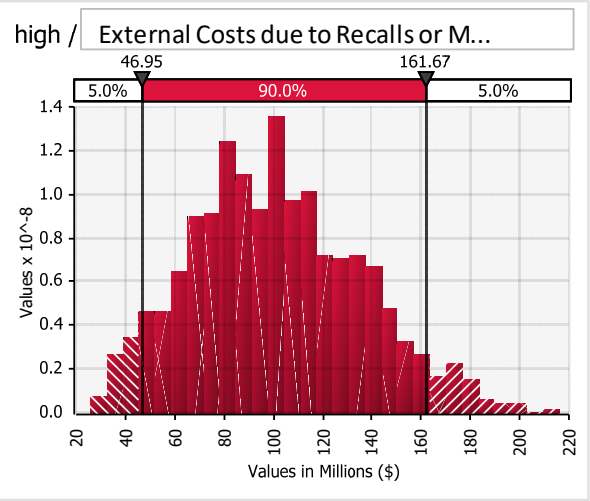


Change in Output Statistic for low / Retailers Retailers Sha			
Rank	**Name**	**Lower**	**Upper**
1	Manfacturers Sh	$9,232,225	$26,420,995
2	g / (A) Value	$11,670,127	$24,430,274
3	Retailers Retaile	$17,518,617	$20,170,108
4	Wholsalers Shar	$17,747,342	$19,393,812

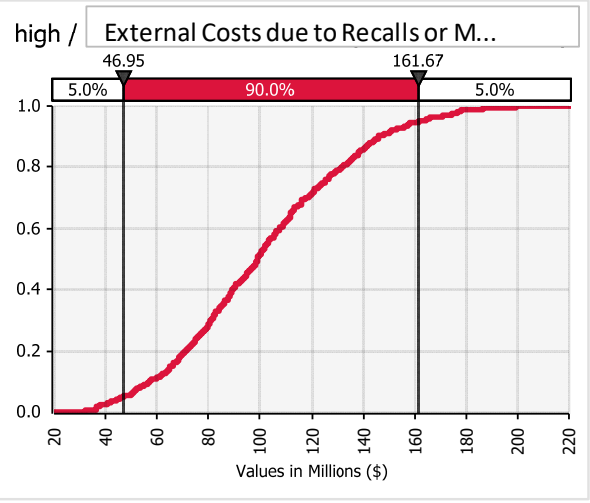
Table 10.--@RISK Output Report for high / External Costs due to Recalls

Performed By: FDA ECON

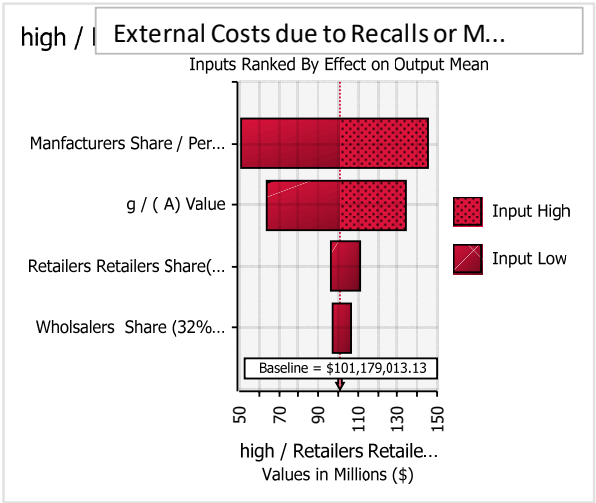
Date: Wednesday, January 25, 2023 4:13:49 AM



Simulation Summary Information	
Workbook Name	TPMP Benefit Tables.xlsx, Copy of
Number of Simulations	1
Number of Iterations	800
Number of Inputs	18
Number of Outputs	19
Sampling Type	Latin Hypercube
Simulation Start Time	1/25/2023 4:11
Simulation Stop Time	1/25/2023 4:11
Simulation Duration	00:00:17
Random # Generator	Mersenne Twister
Random Seed	628115339
Total Errors	0
Collect Distribution Samples	All
Convergence Testing	Enabled
Smart Sensitivity Analysis	Enabled



Summary Statistics for high / Retailers Retailers Share(32$			
Statistics		**Percentile**	
Minimum	$25,898,479	**1.0%**	$36,148,817
Maximum	$215,968,305	**2.5%**	$39,969,908
Mean	$101,179,013	**5.0%**	$46,946,902
Std Dev	$34,303,164	**10.0%**	$56,795,006
Variance	1.17671E+15	**20.0%**	$71,123,712
Skewness	0.314607676	**25.0%**	$76,565,749
Kurtosis	2.723895534	**50.0%**	$99,062,123
Median	$99,062,123	**75.0%**	$125,043,231
Mode	$111,727,524	**80.0%**	$131,681,571
Left X	$46,946,902	**90.0%**	$146,242,531
Left P	5%	**95.0%**	$161,669,257
Right X	$161,669,257	**97.5%**	$175,706,245
Right P	95%	**99.0%**	$181,456,390
#Errors	0		



Change in Output Statistic for high / Retailers Retailers Sha			
Rank	**Name**	**Lower**	**Upper**
1	Manfacturers Sh	$50,683,595	$145,047,487
2	g / (A) Value	$64,067,331	$134,118,713
3	Retailers Retaile	$96,174,705	$110,731,012
4	Wholsalers Shar	$97,430,372	$106,469,257