

Outline of Presentation to OMB-OIRA by  
The Cigar Association of America

December 5, 2013

I. Introduction/Recap

A. Two previous meetings with OMB/OIRA

1. November 7, 2012

- a. background on cigar industry
- b. size of industry
- c. product description
- d. category make up
- e. historical/current cigar regulation
- f. application of Executive Order 12866 and 13563
- g. requests

1. proper observance of EOs

2. recognition of difference between cigarettes and cigars,  
and between and among various types of cigars

3. ensure that any proposed regs for cigars are tailored to  
unique nature of product, industry

4. oppose any effort to instantly or automatically apply  
"tobacco product" regs to cigars

2. March 19, 2013

- a. requested after publication of proposed rule on data collection for  
user fees
- b. provided updated information on cigar industry
- c. discussion of "tobacco buyout" (FETRA) methodology
- d. discussion of FDA user fees



B. Four meetings with CTP

1. June 23, 2011
2. October 17, 2012
3. April 25, 2013
4. May 14, 2013

C. Current meeting request – what’s changed?

1. FDA announcement that proposed deeming reg under review at OMB/OIRA
2. GAO Report on CTP progress in implementing Tobacco Control Act
3. papers by private individuals (not government agencies) purporting to discuss public health issues (i.e., youth usage of cigars)
4. appellate court decision in lawsuit over tobacco buyout methodology
5. CDC statement on youth usage of flavored cigars

II. Issues of Primary Concern

A. Path to Market (Substantial Equivalence)

1. according to GAO, 3,800 SE applications filed as of January 2013
  - a. as of June 2013, 6 had been decided
  - b. important to recognize CTP gets no additional user fees by regulating additional products
2. cigar manufacturers typically have wide variety of products on the market, regularly introduce /withdraw products
  - a. approximately 8,000 active SKUs for just three leading companies in both mass market and premium; estimate well over 10,000 for entire category
  - b. as many as 1,000 SKUs are introduced/withdrawn annually by these companies
3. these changes are direct response to adult consumer preferences
  - a. brand loyalty not primary consideration in purchase
  - b. adult consumers often buy more than one brand at a time
  - c. contrast to cigarettes



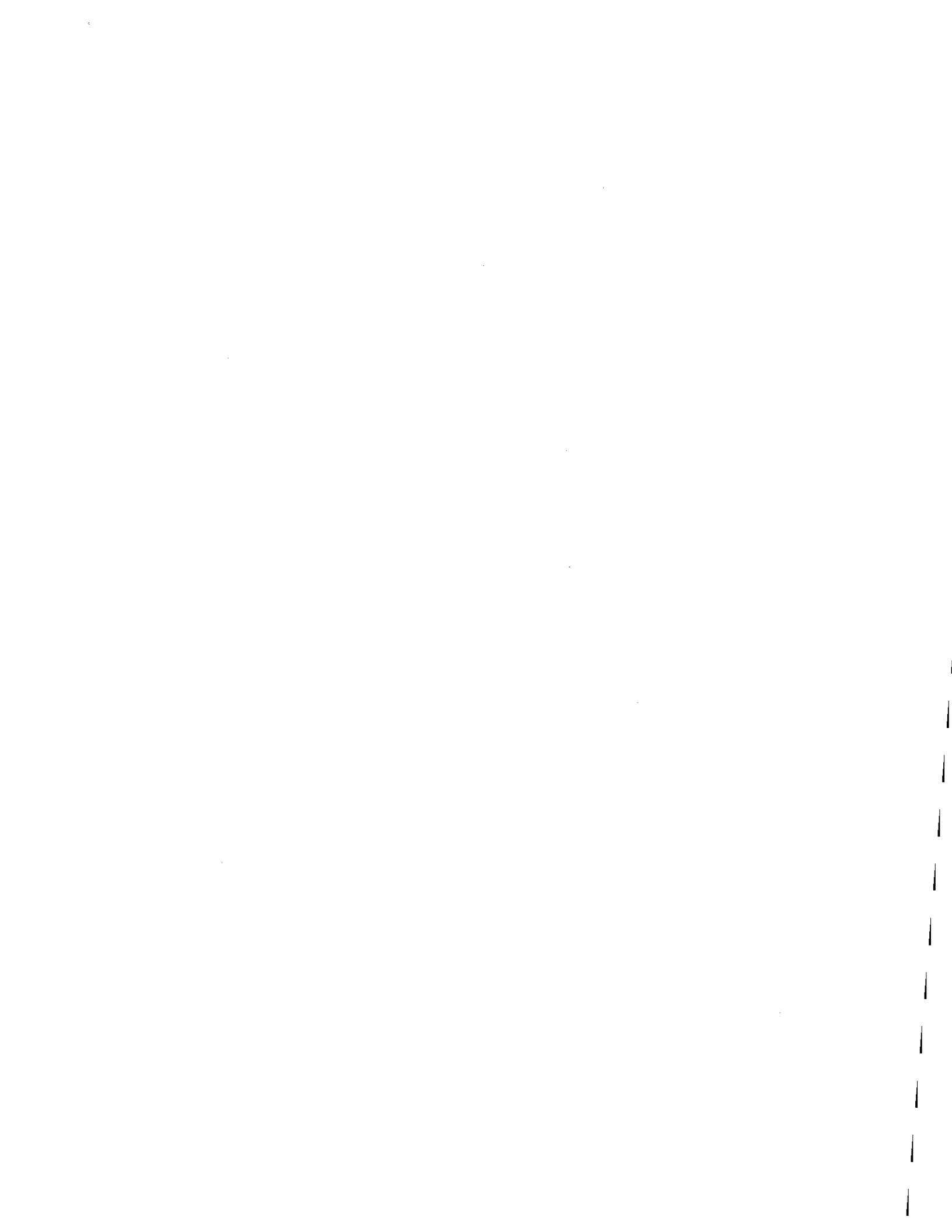
4. other possible reasons for changes (outside manufacturer control)
  - a. tobacco availability, demand, price
  - b. growing conditions – suitability of particular crop
  - c. natural variations in tobacco
5. nature of changes
  - a. exact same cigar may be made in different size, shape
  - b. limited edition cigars – seasonal, geographic
  - c. blend may change – result of different filler
  - d. wrapper may change
6. any SE process for cigars must recognize unique nature of industry/products and have grandfather/transition dates different than those for cigarettes – FDA has direct authority and/or enforcement discretion

B. Flavors

1. used in cigars since there have been cigars
2. depending on how “flavored” is defined, as much as 80% of cigar category may be “flavored”
3. approximately 50% of cigar market has flavor “descriptor”
4. critical for cigars, which use air-cured tobacco – lower in sugar
  - a. smokeless tobacco – also lower in sugar, flavor allowed
  - b. cigarettes use flue-cured tobacco – higher in sugar
5. no accepted/recognized definition of “characterizing flavor” – not needed for flavored cigarette ban
6. every flavor used in cigars made by CAA member companies also used in other consumer products for both children and adults
7. no evidence that flavors cause increased “initiation” or reduced “cessation”
8. before any action taken by FDA on flavors in cigars, issue should go to TPSAC, as product standard question under 907(d)(5)(A) of TCA

C. Non- Face-to-Face (Remote) Sales

1. important distribution channel for cigars, particularly premium
  - a. in contrast to cigarettes, many convenience stores do not carry cigars or have limited selection due to limited space, typically purchased by cigarettes



- b. estimates are that 50% of premium sales are through NFTF
- 2. many mail order companies already have stringent age verification procedures in place
  - a. subject of discussion/presentation to CTP
  - b. no reason to believe, or evidence to support, contention that youth buy cigars through NFTF sales

D. User fees

- 1. CTP proposes that only six specified tobacco products will be assessed user fees, even if other tobacco products are regulated
- 2. such an approach is inequitable and subject to legal challenge
- 3. under TCA, FDA must collect user fees "from each manufacturer or importer subject to" the Act
- 4. impact – e-cigarette sales estimated to surpass cigar sales in five years

E. Impact on Small Business

- 1. majority of cigar category made up of small businesses
  - a. cigarettes – "Blg 3" have 90% of the market
  - b. cigars - according to FETRA assessments, 25 to 30 companies have 90% of the market; most are "small"
  - c. government estimates that 89% of OTP manufacturers are "small" and that over 90% of retail tobacconists are "small"
- 2. Difficult to quantify costs
  - a. clearly will require additional employees
  - b. cigar companies do not have in-house testing facilities: out sourcing for testing very expensive
  - c. underscores need for gradual role out of any regulatory structure, including compliance dates

III. Conclusions/Recommendations

A. Adopt GAO recommendation to set time frames for decisions on SE applications

- 1. procedure should clear up backlog of SE applications by currently regulated product manufacturers
- 2. SE application process for any newly-regulated tobacco products should commence after existing backlog is addressed





- B. Establish Path-to-Market (SE) process for cigars
  - 1. grandfather/transition dates should reflect date cigar regulations become effective
  - 2. give consideration to unique nature of cigars and tremendous product/SKU turnover
  - 3. address issues of natural variations in tobacco and limited/seasonal products
- C. Allow continued use of flavors in cigars
  - 1. CTP currently considering use of menthol flavor in cigarette
  - 2. no basis for allowing flavors in some tobacco products but not in others
- D. Allow continued Non-Face-To-Face sales of cigars, subject to government-mandated age verification process
- E. Establish framework for calculation/assessment of user fees on all products regulated under the TCA
- F. Prioritize any cigar regulation, taking into account industry resources, as required by the TCA
- G. Include allowance for small businesses (i.e., longer phase in periods) as required by the TCA

