

**Summary of the Manager's Amendment
to H.R. 1108 Committee Print**
Committee on Energy and Commerce
April 1, 2008

Please note text in italics indicates changes from previous draft.

The Manager's amendment to the March 27, 2008, Committee Print does the following:

Tobacco Product Retailers

- Adds a new **Section 906(d)(4)** to require the Secretary, within 18 months of enactment, to issue regulations regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products to minors. The Secretary would also be required, within 2 years of enactment, to issue regulations to protect minors from the promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and a consumer.
- Adds a new **Section 102(a)(5)** to direct the Secretary to enforce provisions of the Act, including those relating to retail sales, with respect to the United States and Indian Tribes.
- Amends **Section 103(q)(1)(B)** to require the Secretary to send each notice of retailer violation to the location specified on the retailer's registration or the retailer's registered agent.
- Adds a new **Section 103(q)(1)(G)** to require the Secretary to consider whether a retailer has taken effective steps to prevent violations of the minimum age requirements for the sale of tobacco products in determining whether to compromise, modify, or terminate a no-tobacco-sale order.
- Amends **Section 103(q)(2)(A)** to clarify the time period within which a retailer shall be subject to a civil penalty not to exceed \$10,000 in the case of a sixth or subsequent violation.
- Adds a new **Section 103(q)(2)(C)** to direct the Secretary to coordinate with the States in enforcing this Act and to consider any penalty paid by a retailer to a State when determining the amount of the Federal penalty for the same violation.
- Amends **Title II** to ensure retailer liability for warning labels and advertising is consistent between cigarettes and smokeless tobacco products.

Small Tobacco Product Manufacturers

- Adds a new **Section 900(15)** to provide a definition for ‘small tobacco product manufacturer’ as a manufacturer with fewer than 350 employees.
- Amends **Section 906(e)(1)(A)** to clarify that the Secretary shall, through regulation, require tobacco product manufacturers to comply with good manufacturing practices or hazard analysis and critical control point methodology.
- Adds a new **Section 906(e)(1)(B)(v)** to prohibit the Secretary from requiring small tobacco product manufacturers to comply with good manufacturing practices or hazard analysis and critical control point methodology for at least 4 years following the effective date of the regulations establishing the requirements.
- Adds a new **Section 916(d)** to provide small tobacco product manufacturers additional time to comply with testing and reporting requirements under Section 916. The Secretary shall not require small tobacco product manufacturers to begin complying with the testing and reporting requirements for at least 2 years following the promulgation of the regulation establishing the requirements. Small manufacturers will then have 4 years thereafter to finish testing all of their products. The Secretary may grant a small manufacturer additional time to fully comply on a case-by-case basis. The Secretary is also required to allow small tobacco product manufacturers to join together to purchase laboratory testing services. The Secretary may also grant additional time to comply in instances where there is limited laboratory capacity.

Tobacco Growers

- Adds a new **Section 907(a)(1)(B)** to prohibit foreign-grown tobacco from having a level of pesticide, insecticide, herbicide, or fungicide in excess of any level that is applicable to domestically grown tobacco or from being grown or processed using any pesticide, herbicide, or fungicide not approved by the Environmental Protection Agency.
- Adds a new **Section 907(a)(4)(D)** to require tobacco products containing foreign-grown tobacco to meet the same standards applicable to products containing domestically grown tobacco.
- Amends **Section 907(b)(1)(B)** to further clarify what is required in establishing or amending a proposed tobacco product standard. Among other things, the proposed product standard notice shall to invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco, and invite the Secretary of Agriculture to provide information or analysis which the Secretary of Agriculture believes is relevant.

- Amends **Section 907(b)(1)(D)** to require the Secretary to consider, in connection with a proposed tobacco product standard, the technical achievability of compliance with the standard.
- *Amends Section 907(b)(2)(B) to require the Secretary to consider, when establishing the effective date of the proposed standard, (1) technical achievability of compliance with a tobacco product standard, and (2) the existence of patents that could make it impossible to comply in the timeframe.*

Modified Risk Products

- Amends **Section 911(b)(2)(C)** to ensure the use of the following phrases do not constitute a modified risk claim: ‘smokefree’, ‘smoke-free’, ‘without smoke’, ‘no smoke’, and ‘not smoke’.
- Adds a new **Section 911(l)(1)(F)** to direct the Secretary to issue regulations or guidance within 2 years after enactment to establish a timeline to review modified-risk product applications.

Additional Changes

- Amends **Section 2(46)** to clarify a finding relating to how consumers can be misled if manufacturers state or imply that a tobacco product is approved or inspected by the Food and Drug Administration.
- *Amends Section 3(1) to clarify that FDA will be recognized as the primary Federal regulatory authority with respect to tobacco products as provided for under the Family Smoking Prevention and Tobacco Control Act.*
- Amends **Section 102(a)** to require the Secretary to publish the final rule regarding cigarettes and smokeless tobacco 6 months after enactment. The final rule shall become effective 1 year after enactment.
- Amends **Section 102(a)(2)(F)** to clarify that no samples of smokeless tobacco products may be distributed to any person younger than the minimum age established by applicable law for the purchase of smokeless tobacco products.
- *Adds a new Section 104 to require the Secretary to (1) convene an expert panel to conduct a study on the public health implications of raising the minimum age to purchase tobacco products, and (2) submit a report to the Congress on the results of such study not later than 5 years after enactment.*

- Adds a new **Section 900(19)** to provide a definition for ‘tobacco warehouse’, which includes any person who, with respect to tobacco leaf, removes foreign material from tobacco leaves through nothing other than a mechanical process; humidifies the leaf with nothing other than potable water in the form of steam or mist; or de-stems, dries, and packs leaf tobacco for storage and shipment.
- *Adds a new **Section 901(g)** to require FDA to endeavor to consult with other Federal agencies as appropriate prior to promulgating rules.*
- Amends **Section 907(a)(1)** to clarify what a “characterizing flavor” is as it relates to tobacco product standards.
- Amends **Section 907(a)(3)(B)** to clarify that in adopting a tobacco product standard, the Secretary shall consider, among other things, scientific evidence concerning the risks and benefits to the population as a whole, of the proposed standard.
- *Amends **Section 907(a)(3)(B)(ii)** to clarify that a person objecting to a proposed tobacco product standard in a proposed rule on the ground that the standard will not reduce or eliminate the risk of illness or injury may provide scientific evidence to that effect.*
- Amends **Section 920** to ensure Congressional Budget Office adjustments are accurately reflected in the user fee amounts included in the bill.
- *Adds a new **Section 920(g)** requiring the Government Accountability Office to conduct a study on youth tobacco use and the feasibility of structuring the user fee based on a manufacturers’ share of the youth market.*