Annual Submission of the Ingredients Added to and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S.

Extension: OMB No. 0929-0338

Supporting Statement A

Program Official/Contact
Kathy Gallagher
Associate Director
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
P: 678.733.5349
F: 770.488.5767
khg5@cdc.gov

3/29/2022

TABLE OF CONTENTS

ATTACHMENTS

1. Comprehensive Smokeless Tobacco Health Education Act of 1986 15 U.S.C. ' [4401 seq.; Public Law 99-252]
2. Federal Register Notice (2021)
3. Smokeless Tobacco Submission Requirement (1994)

4a. Recommended Smokeless Tobacco Ingredient Reporting Format

4b. Recommended Smokeless Tobacco Nicotine Data Reporting Format

4c. Request for Additional Information from Manufacturers, Packagers, and Importers of Smokeless Tobacco Products

4d. Human subjects document non-research determination

5. Federal Register Notice Revisions to the Laboratory Protocol to Measure (2009)

6a. OSH Comprehensive Smokeless Tobacco Health Education Act Web Page

6b. OSH Tobacco Ingredient and Nicotine Reporting Instructions Web Page
7. Certificate of Compliance to Manufacturers, Packagers, and Importers of Smokeless Tobacco Products
8a. Guidelines to Control Protect Documents that Contain Privileged Information Obtained in Accordance with Sec. 5 (a) of Public Law 98-474
8b. Civil Penalties for Disclosure of Confidential Information (18 U.S.C. 1905)
9. Federal Register Notice (2020)

JUSTIFICATION SUMMARY

Goal of the project: This Information Collection Request (ICR) supports Extension of a Congressionally mandated information collection, "Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S." (OMB control no. 0920-0338, exp. April 30, 2022).

Intended use of the resulting data: The information collection is used to certify tobacco industry compliance with the terms of the Comprehensive Smokeless Tobacco Health Education Act 15 U.S.C. 4403 (CSTHEA).

Methods to be used to collect: To comply with CSTHEA, manufacturers, packagers, and importers must submit annually to HHS (through CDC) a list of ingredients added to tobacco in the manufacture of smokeless tobacco products and a specification of the quantity of nicotine contained in each product. Following receipt of the required information, CDC sends a Certificate of Compliance to each entity that submitted a report.

The subpopulation to be studied: The data collected do not contain data on human subjects. The data that are collected are required for submission by smokeless tobacco product manufacturers, packagers, or importers.

How data will be analyzed: The Department of Health and Human Services (HHS) is authorized, but not required, to analyze submitted data and to submit a report to Congress. Reports are submitted only at such times as the Secretary of HHS considers appropriate.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

This Information Collection Request (ICR) supports Extension of a Congressionally mandated information collection, “Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S.” (OMB control no. 0920-0338, exp. April 30, 2022). A 3-year approval is requested.

Smokeless tobacco products (SLT) are associated with many health problems. Using smokeless tobacco: can lead to nicotine addiction; causes cancer of the mouth, esophagus, and pancreas; is associated with diseases of the mouth; can increase risks for early delivery and stillbirth when used during pregnancy; can cause nicotine poisoning in children; and may increase the risk for death from heart disease and stroke.

The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health (OSH) has the primary responsibility for the Department of Health and Human Services (HHS) smoking and health program. OSH promotes tobacco control interventions, including actions to prevent youth from starting to use tobacco, smoke-free environments, programs to help tobacco users quit, and steps to eliminate tobacco-related health disparities in different population groups.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. '4401 et seq. or P.L. 99-252), hereinafter referred to as CSTHEA, requires each person who manufactures, packages, or imports smokeless tobacco products to annually provide the Secretary of Health and Human Services with a list of ingredients added to tobacco in the manufacture of smokeless tobacco products, as well as the nicotine data report for each product. Commonly known as the SLT Nicotine and Ingredient Report, this report is due to the CDC annually by March 31. This legislation also authorizes HHS to undertake research, and to report to the Congress, as deemed appropriate, on the health effects of SLT products. A copy of the statute is provided in **Attachment 1**. Section 4403 relates specifically to ingredient reporting.

The legislative requirements for reporting were published in the Federal Register in 1994 (**Attachment 3**, Federal Register, Volume 59, Number 215, November 8, 1994).

Annually, OSH sends a certificate of compliance letter to each entity that has submitted the required information. The letter includes a reminder of responsibilities related to future reporting. If a submission contains incomplete entries or possible errors, CDC will follow up by sending a request for additional information **(Attachment 4c)**.

Privacy Impact Assessment

Overview of the Data Collection System

Respondents are commercial manufacturers, packagers, and importers (collectively called “commercial entities” throughout this ICR) of smokeless tobacco (SLT) products. Respondents are required to report both the ingredients in, and the nicotine content of, their SLT products. CDC accepts SLT Nicotine and Ingredient Reports in any format that meets the legislation’s reporting requirements. The recommended format for the SLT Ingredient Report is included as **Attachment 4a**. The recommended format for the SLT Nicotine Report is included as **Attachment 4b**. Typically, commercial entities submit information for multiple products in summary (aggregate) form, often through a designated entity such as legal counsel. The submission must be received on letterhead from the commercial entity or its designated representative. Reports may be submitted via mail or facsimile, but all faxed lists should be followed up with a mailed original. Electronic mail submissions are not accepted.

Nicotine and ingredient reports for new products are due at the time of first importation. Thereafter, nicotine and ingredient reports are due annually on March 31. Respondents are required to submit a new list or a statement that there are no changes to their previously submitted ingredient report every year.

Items of Information Collected

Commercial entities are required to provide CDC with an itemized list of all ingredients in each SLT product. CDC requires the list of ingredients be submitted by chemical name and Chemical Abstract Service (CAS) Registration Number. This is consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products. OMB previously approved this format for reporting of smokeless tobacco products ingredients. In addition, respondents are required to submit information about the nicotine content of their products. Nicotine content is determined based on a standard laboratory protocol for analyzing SLT product samples. The laboratory protocol was revised and re-published in 2009 (see **Attachment 5**, Federal Register, Vol.

74, No. 4, pp. 712-719, January 7, 2009). As of 2010, nicotine data reports provided to CDC reflected the minor change in the nicotine analysis protocol.

This information collection involves information in identifiable form (IIF). For each commercial entity required to report, the name and contact information of a contact person is collected. No personal information about the contact person is collected.

Since 2003, background information about the requirements of the law, nicotine and ingredient reporting requirements, and instructions have been available to commercial entities through a CDC/OSH web site, Tobacco Ingredient and Nicotine Reporting, http://www.cdc.gov/tobacco/basic_information/tobacco_industry/reporting/instructions/index.htm (See **Attachments 6a and 6b**).

There is no website content directed at children less than 13 years of age.

A2. Purpose and Use of the Information Collection

This information collection is used to certify tobacco industry compliance with the terms of the CSTHEA. To comply with CSTHEA, manufacturers, packagers, and importers must submit annually to HHS (through CDC) a list of ingredients added to tobacco in the manufacture of smokeless tobacco products and a specification of the quantity of nicotine contained in each smokeless tobacco product. Following receipt of the required information, CDC sends a Certificate of Compliance **(Attachment 7)** to each entity that submitted a report.

To import smokeless tobacco products into the United States for introduction into domestic commerce, one must certify to U.S. Customs and Border Protection that the original manufacturer has complied with CSTHEA's requirements. The Certificate of Compliance from CDC can serve as proof of compliance.

HHS also has the authority under CSTHEA to use the information submitted to conduct research on the health effects of ingredients added to tobacco in the manufacture of smokeless tobacco products. If and when the Secretary of HHS considers it appropriate, HHS will report to Congress information regarding its current and proposed research relative to the health effects of the ingredients; information pertaining to any such ingredient which, in the judgment of the Secretary poses a health risk to users of smokeless tobacco products; and any other information which the Secretary determines to be in the public interest.

Of note, on April 27, 2020, a Federal Register Notice was published Vol. 85, No. 84, pp. 23359-23360, **(Attachment 9)**, to indicate the CDC/OSH was extending the March 31st deadline for submissions required under CSTHEA. Within the April 2020 Federal Register Notice, CDC/OSH stated that due to the unforeseen circumstances in light of COVID-19, OSH was rendered unable to accept any ingredient submissions or to issue Certificates of Compliance. This same language was provided on OSH's website under the webpage entitled Tobacco Ingredient and Nicotine Reporting | CDC.

HHS is authorized, but not required, to analyze submitted data and to submit a report to the Congress. Reports are only submitted to Congress when requested. Requested reports only were prepared and submitted to Congress in February 1990, July 1990, and March 1993.

A3. Use of Improved Information Technology and Burden Reduction

In order to reduce burden to the respondents, only the minimum information necessary to comply with provisions of the CSTHEA is being requested. The CSTHEA requires annual reporting.

To date, data submissions are received via courier, mail, or facsimile to ensure confidentiality of the information included. At present, CDC/OSH is working to assess the feasibility of establishing an electronic means to receive information while adhering to confidentiality requirements.

A4. Efforts to Identify Duplication and Use of Similar Information

No other information collection activity of the Federal government or private sector has compiled the information necessary to certify compliance with the CSTHEA.

As stated in the previous terms of clearance for the Center for Disease Control (OMB Control No.: 0920-0338) and FDA's Center for Tobacco Products (OMB Control No. 0910-0650), the data to be collected overlap in terms of the similar tobacco product ingredient collections being conducted. However, at this time, the CTP data cannot currently be used by CDC due to both logistical reasons and restrictions on the use of information collected.

The CSTHEA contains certain requirements that differ from the statutory requirements for submission of information in the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Family Smoking Prevention and Tobacco Control Act (TCA). For instance, the CSTHEA requires ingredients to be provided annually whereas the TCA only mandates annual submissions detailing lists of products, but not ingredients. In addition, the TCA only requires submission of ingredients prior to a Tobacco product's delivery for introduction into commerce and thereafter if certain changes are made to such product. Further, the CSTHEA allows for the submission of the list of ingredients in a way that does not identify the company which uses the ingredients or the brand of smokeless tobacco which contains the ingredients. The TCA, on the other hand, requires submission of all ingredients by quantity, brand, and sub-brand.

Also, FDA collects user fees from each manufacturer and importer of regulated tobacco products which may only be used for the purpose of funding the costs for FDA to regulate tobacco products under the TCA. FDA cannot use other funds for performing these duties, nor use tobacco product user fees to perform duties falling outside the regulation of tobacco products under the TCA.

A5. Impact on Small Businesses or Other Small Entities

Some of the companies affected by the reporting requirements are small businesses. The burden on these companies has been considered. To ease potential burden on both small and large entities, the data collection process does

not require respondents to use a cumbersome format or to complete an unwieldy form or questionnaire. Each respondent may select and use the response option that is most convenient for their organization.

A6. Consequences of Collecting the Information Less Frequently

CSTHEA stipulates those respondents shall report ingredient information annually. If the data collection were less frequent, the collection and reporting provisions would not satisfy statutory requirements.

A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5

There are no special circumstances for this request.

A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency

Part A: PUBLIC NOTICE
A 60-day Federal Register Notice was published in the *Federal Register* on September 27, 2021, vol.86 No.184, pp. 53305-53306 **(Attachment 2)**.

CDC did not receive any public comments in response to this federal register notice.

Part B: CONSULTATION

Table 1. External Consultations

No individuals/entities were consulted for purposes of this OMB submission. Please note, however, that consultations were held in 1989 and 1990 to inform a prior OMB submission to assist with estimating the approximate time burden for complying with the requirements pursuant to CSTHEA. All burden estimates remain the same as those provided in previous OMB submissions.

Table 2. Consultations within CDC

Name	Title	Affiliation	Phone	Email	Role
Kathy Gallagher	Public Health	OSH, Policy	678-733-5349	Khg5@cdc.gov	Project Officer
Ruth Hayes	Contractor	Katmai Government Services OSH, Policy	770-488-5743	aro5@cdc.gov	Data Collection

A9. Explanation of Any Payment or Gift to Respondents

N/A

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent

This ICR has been reviewed by staff in CDC's Information Collection Review Office, who determined that the Privacy Act is not applicable.

Respondents are commercial entities, not individuals. No personal information is being collected. All information is filed and retrieved by name of the responding commercial entity or the attorney representing the respondent, therefore, the information does not fall under the purview of the Privacy Act.

The authorizing legislation for this information collection requires HHS to establish written procedures to assure the confidentiality of the information provided. Consistent with these statutory provisions, HHS has developed strict procedures for treating and protecting relevant documents, including secured file storage, and strictly limiting access to the information. A copy of the HHS Guidelines for Maintaining and Releasing Privileged Information in Accordance with Sec. 4 (b) (2) (a) of Public Law 99-252, is included in the 1994 Federal Register Notice, **Attachment 3**. In accordance with provisions in the CSTHEA, the collected information is to be treated as trade secret or confidential information subject to 5 U.S.C. ' 552 (b)(4) (Freedom of Information Act) and 18 U.S.C. '1905 (Criminal Code) **(Attachments 8a and 8b)** and shall not be revealed except as authorized in the statute.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This data collection does not involve research with human subjects and does not require IRB review and approval. There is no consent process comparable to participation in research. **(Attachment 4d)**

A12. Estimates of Annualized Burden Hours and Costs

The burden estimate is based on experience with the information collection in the prior approval period. Ingredient and reporting for smokeless tobacco products

are more complex than ingredient reporting for cigarette products. First, there is a broad range of SLT products, and ingredients must be reported for each product (including each formulation of the product, e.g., chew, pouch, etc.) and each combination of formulation and flavoring, etc. Second, the burden estimate includes time for determining the nicotine content of samples through laboratory analysis.

The total annual response burden reported for all 11 companies is estimated at 18,843 hours at a total cost of $12,529. The average cost per response burden for each company is estimated at 1,713 hours at a cost of $1,139 per company. Because some respondents report on only one product or brand, and other respondents report on 20 or more products or brands, burden and cost for an individual respondent may differ from the overall averages.

Table A12A: Estimated Annualized Burden (Hours)

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Smokeless Tobacco Product Manufacturers, Packagers, and Importers	SLT Ingredient Report	11	1	6.5	71.5
Smokeless Tobacco Product Manufacturers, Packagers, and Importers	SLT Nicotine Report	11	1	1,706.5	18,771.5
Total					18,843

Table A12B: Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Annual Burden Hours	Average Cost per Respondent	Estimated Total Respondent Labor Cost
Smokeless Tobacco	SLT Nicotine	1,713	$1,139	$12,529

Type of Respondents	Form Name	Total Annual Burden Hours	Average Cost per Respondent	Estimated Total Respondent Labor Cost
Product Manufacturers, Packagers, and Importers	and Ingredient Report			

Average cost for compiling each report, per respondent, is estimated at $1,139.

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs. The collection tool requires no special hardware or software and is free to respondents.

A14. Annualized Cost to the Federal Government

The estimated annualized cost to the government is $66,250. The table below describes itemized cost components.

Table A14. Estimated Annualized Federal Government Cost Distribution

Item	Annualized Cost
CDC Supervisor (3% FTE)	$3,250
Contractor for data collection, data management, communications and logistical support related to compilation and analysis of ingredient reports	$54,500
Computing equipment and maintenance	$8,500
Total	$66,250

A15. Explanation for Program Changes or Adjustments

This ICR is an extension. There is no change in burden.

A16. Plans for Tabulation and Publication and Project Time Schedule

Information collection occurs annually; smokeless tobacco ingredient and nicotine information is to be submitted by March 31 of each year for ingredients used in the previous calendar year. Because the information collection occurs annually, in accordance with the CSTHEA, we request a maximum (3-year) clearance.

Of note, on April 27, 2020, a Federal Register Notice was published Vol. 85, No. 84, pp. 23359-23360, **(Attachment 9)**, to indicate the CDC/OSH was extending the March 31st deadline for submissions required under the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA). Within the April 2020 Federal Register Notice, CDC/OSH stated that due to the unforeseen circumstances related to COVID-19, OSH was rendered unable to accept any ingredient submissions or to issue Certificates of Compliance. This same language was inserted on OSH's website under the webpage entitled Tobacco Ingredient and Nicotine Reporting | CDC.

HHS is authorized, but not required, to analyze submitted data and to submit a report to the Congress. Reports are only submitted to Congress when requested. Requested reports only were prepared and submitted to Congress in February 1990, July 1990, and March 1993.

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate. As discussed in Section A.3, respondents are required to report information but are not required to use a standardized form. The OMB approval number, expiration date and burden estimate are displayed on the recommended formats for reporting (**Attachments 4a and 4b**) which are available on the CDC website. This information is also displayed on the needs additional information letter (**Attachment 4c**).

A18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification statement.