summaries of the meeting and a roster of Commission members may be obtained from Edward (Chip) Malin, Room 118–F, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, telephone 202–205–3333.

Dated: April 28, 1997.

Janet M. Corrigan,

Executive Director, Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

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BILLING CODE 4110–60–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[INFO–97–09]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Wilma Johnson, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

1. Annual Submission of the Quantity of Nicotine Contained in Smokeless Tobacco Products Manufactured, Imported, or Packaged in the United States—New—Oral use of smokeless tobacco represents a significant health risk which can cause cancer and a number of noncancerous oral conditions, and can lead to nicotine addiction and dependence. The Centers for Disease Control and Prevention's (CDC) Office on Smoking and Health (OSH) has been delegated the authority for implementing major components of the Department of Health and Human Services' (HHS) tobacco and health program, including collection of tobacco ingredients information. HHS's overall goal is to reduce death and disability resulting from cigarette smoking and other forms of tobacco use through programs of information, education and research.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 et seq., Pub. L. 99–252) requires that each person who manufactures, packages, or imports smokeless tobacco provide the Secretary of HHS annually with a report on the quantity of nicotine contained in smokeless tobacco products. This notice implements this nicotine reporting requirement. CDC is requesting OMB clearance to collect this information for three years. A standard methodology for measurement of quantity of nicotine in smokeless tobacco has been developed. The methodology (''Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products'') is intended to provide standardized measurement of nicotine, total moisture, and pH in smokeless tobacco products.

Background

In 1989, the smokeless industry submitted a business review letter to the Department of Justice (DOJ), in accordance with 28 CFR 50.6. This letter requested approval of a collaborative industry effort to determine standard nicotine reporting. In January 1993, DOJ extended permission to the smokeless industry to begin the development of uniform methods for analyzing smokeless tobacco products for nicotine or moisture content. The first meeting of the work group, which represented the ten major domestic manufacturers of smokeless tobacco, was convened on July 7, 1993. After a series of meetings of the joint industry work group, a standard methodology was approved by the work group and submitted to OSH for approval. The protocol was revised by OSH based on individual comments received from peer reviewers and the Division of Environmental Health Laboratory Sciences, National Center for Environmental Health, CDC. The total cost to respondents is $467,500.*

Respondents	No. of respondents	No. of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Tobacco manufacturers	11	1	1,706	18,766

*Please note that these figures are based on the average reporting time and cost estimations for six major smokeless tobacco manufacturers are reported by Patton Boggs, LLP.

*Please note that these figures are based on the average reporting time and cost estimations for six major smokeless tobacco manufacturers as reported by Patton Boggs, LLP.

Note: The annual reporting of the quantity of nicotine contained in smokeless tobacco products for calendar year 1997 is due on July 31. In future years, the annual report will be due on March 31 of each year; this is the same date that lists the ingredients added to tobacco in the manufacture of smokeless tobacco products are due.

Dated: April 24, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–11348 Filed 5–1–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Protocol to Measure the Quantity of Nicotine Contained in Smokeless Tobacco Products Manufactured, Imported, or Packaged in the United States

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Request for comments.

SUMMARY: CDC's Office on Smoking and Health (OSH) is requesting comments from all interested parties on a standard methodology for measurement of quantity of nicotine in smokeless tobacco. The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 *et seq.*, Pub. L. 99–252) requires that each person who manufactures, packages, or imports smokeless tobacco provide the Secretary of HHS annually with a report on the quantity of nicotine contained in smokeless tobacco products; OSH has been delegated the authority to implement the nicotine reporting provisions of this law. The methodology (''Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products'') is the basis for such nicotine reporting and is intended to provide standardized measurement of nicotine, total moisture, and pH in smokeless tobacco products.

DATES: Written comments to this notice should be submitted to Patricia Richter, Centers for Disease Control and Prevention (CDC), Office on Smoking and Health, 4770 Buford Highway, NE., Mailstop K50, Atlanta, Georgia 30341–3724 on or before June 2, 1997. Comments may also be faxed to Patricia Richter at (770) 488–5848 or submitted by email to pir1@cdc.gov as WordPerfect 5.0, 5.1/5.2, 6.0/6.1 or ASCII files.

FOR FURTHER INFORMATION CONTACT: Patricia Richter, Centers for Disease Control and Prevention (CDC), Office on Smoking and Health, 4770 Buford Highway NE., Mailstop K50, Atlanta, Georgia 30341–3724; telephone: (770) 488–5703.

SUPPLEMENTARY INFORMATION: In 1989, the smokeless tobacco industry submitted a business review letter to the Department of Justice (DOJ), in accordance with 28 CFR 50.6. This letter requested approval of a collaborative industry effort to determine standard nicotine reporting. Previous to this, each company employed different methods of nicotine and moisture analysis; however, HHS requested that a standard methodology be developed to ensure the accuracy and reliability of the information on nicotine and moisture, as well as to ensure comparability of the data. HHS did not have the resources to develop such a standardized methodology thus necessitating a collaborative industry process to develop the methodology.

In January 1993, DOJ extended permission to the smokeless industry to begin the development of uniform methods for analyzing smokeless tobacco products for nicotine and moisture content. The smokeless tobacco industry formed a work group, which represented the ten major domestic manufacturers of smokeless tobacco. The first meeting of the work group was on July 7, 1993 and the group continued to meet throughout 1993 and 1994. After this series of meetings, a standard methodology was approved by the work group and submitted to OSH. The protocol was revised by OSH based on individual comments received from peer reviewers and the Division of Environmental Health Laboratory Sciences, National Center for Environmental Health, CDC. Once OSH has received comments, it will review the comments, make the necessary changes to the methodology, and publish the final methodology in the **Federal Register**. Once the final methodology has been published, OSH will implement the nicotine reporting requirements of the Act.

Dated: April 24, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

Standardized methodology: Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products

I. Requirements [1, 2]

A. Reagents [3]
1. 2 N Sodium hydroxide (NaOH)
2. Methyl t-butyl ether (MTBE)
3. (-)-Nicotine (Fluka 72290) >99% purity [4]
4. Quinoline (Aldrich)
5. Standard pH buffers; 7.00 and 10.00
6. Deionized distilled water

B. Glassware and supplies
1. Volumetric flasks
2. 25 mm x 200 mm Pyrex culture tubes with Teflon lined screw caps (Mfr #982625X)
3. Pasteur pipettes
4. Repipettors (10 mL and 50 mL)
5. Linear shaker (configured to hold tubes in horizontal position) [5, 6]
6. Moisture dish—Al, diam. 45–65 mm, depth 20–45 mm, with tight fitting cover
7. Teflon-coated magnetic stirring bar
8. 50 mL polypropylene container

C. Instrumentation
1. Robot Coupe Model RSI 6V Scientific Batch Processor or equivalent
2. Capillary gas chromatograph with modified split capability (splitless/split), flame ionization detector, integrator, a 4 mm split/splitless glass liner and a 30 m × 0.32 mm ID fused silica column crosslinked and coated with 5% phenyl and 95% methyl silicone at 1 m film thickness.
3. Orion Model SA 720 pH meter equipped with Orion 8103 Ross Combination pH electrode.

D. Additional Equipment

Forced-draft oven, regulated to 99.5 ± 0.5 °C. Suggested dimensions: 19×19×19″ (48 cm). Approx. oven settings: fresh air intake vent ⅕ open; air control damper ¼ open; air exhaust vent ⅓ open.

E. Chromatographic Conditions [7, 8]
1. Detector temperature: 250 °C
2. Injector temperature: 250 °C
3. Flow rate at 100 °C—1.7 mL/min; with split ratio of 40:1 [9]
4. Injection volume: 2 µl
5. Column conditions: 110–185 °C at 10 °C min-1; 185–240 °C at 6 °C min $^{-1}$, hold at final temperature for 10 min. Equil. time: 5 min.

F. Sample Preparation [10]

There exist six different categories of commercial smokeless tobacco products:
1. Dry snuff;
2. Wet snuff;
3. Wet snuff portion packs;
4. Plug;
5. Twist; and
6. Loose leaf.

Because of their physical characteristics, samples of three of the six product categories must be ground before nicotine, total moisture, and pH analyses can be conducted. The objective of grinding the samples is to obtain a homogeneous sample with particles measuring approximately 4 mm. Grinding to achieve this particle size should take no more than 3 minutes. To ensure proper grinding and an adequate amount of the ground sample for analysis, the minimum sample size of all commercial products to be ground should not be less than 100 grams.

To ensure precision of analyses for nicotine, total moisture, and pH, the samples