

Proposed Project

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 No. 0920-0338, exp. 4/30/2011)—Extension—Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

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. HHS's overall goal is to reduce death and disability resulting from the use of smokeless tobacco products and other forms of tobacco use through programs of information, education and research.

Since 1994, as required by the Comprehensive Smokeless Tobacco

Education Act of 1986 (CSTHEA, 15 U.S.C. 4401 *et seq.*, Public Law 99-252), CDC has collected information about the ingredients used in smokeless tobacco products and their nicotine content. Respondents are commercial smokeless tobacco product manufacturers, packagers, or importers (or their representatives), who are required by the CSTHEA to submit ingredient reports to HHS on an annual basis.

Respondents are not required to submit specific forms; however, they are required to meet reporting guidelines and to submit the ingredient report by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products. Typically, respondents submit a summary report to CDC with the ingredient information for multiple products, or a statement that there are no changes to their previously submitted ingredient report.

Ingredient reports for new products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to OSH by mailing a written report on the respondent's letterhead, by CD, three-inch floppy disk, or thumb drive. Electronic mail submissions are not accepted.

Upon receipt and verification of the annual ingredient and nicotine data reports, OSH issues a Certificate of Compliance to the respondent. OSH also uses the information to report to the Congress (as deemed appropriate) discussing the health effects of these ingredients.

In this Extension request, there are no changes to the estimated number of respondents, the estimated burden per response, or the information collection methods. There are no costs to respondents other than their time. The total estimated annualized burden hours are 18,843.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Smokeless Tobacco Manufacturers, Packagers, and Importers	11	1	1,713

Dated: March 10, 2011.

Carol E. Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2011-0002]

Draft Action Plan—A Public Health Action Plan To Combat Antimicrobial Resistance

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

ACTION: Notice of availability and request for public comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) is publishing this notice requesting public comment on the draft *A Public Health Action Plan to Combat Antimicrobial Resistance*.

HHS/CDC is publishing this notice on behalf of the HHS Interagency Task Force on Antimicrobial Resistance. The draft Action Plan and supporting documents can be found at <http://www.regulations.gov>.

DATES: Written comments must be received on or before April 15, 2011. Comments received after April 15, 2011 will be considered to the fullest extent possible.

ADDRESSES: Written comments may be submitted to the following address: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion, Office of Antimicrobial Resistance, Attn: Antimicrobial Resistance Action Plan, Docket No. CDC-2011-0002, 1600 Clifton Rd., NE., Mailstop A-07, Atlanta, Georgia 30333.

You may also submit written comments electronically to: <http://www.regulations.gov>. All comments received will be posted publicly without change, including any personal or proprietary information provided. To download an electronic version of the plan, access <http://www.regulations.gov>.

Written comments, identified by Docket No. CDC-2011-0002 will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Daylight Time, at 1600 Clifton Road, NE., Atlanta, Georgia 30333. Please call ahead to (404) 639-4000 and ask for a representative from the Office of Antimicrobial Resistance to schedule your visit. Comments may also be viewed at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Rachel Wolf, Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion, Office of Antimicrobial Resistance; 1600 Clifton Road, NE., Mailstop A-07, Atlanta, Georgia 30333, (404) 639-4000.

SUPPLEMENTARY INFORMATION: The HHS Interagency Task Force on Antimicrobial Resistance (hereafter referred to as the Task Force) was created in 1999 to coordinate the activities of Federal agencies in addressing antimicrobial resistance (AR) in recognition of the increasing importance of AR as a public health threat. The Task Force is co-chaired by

the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). The Task Force also includes the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), the HHS Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR), the Department of Agriculture (USDA), the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the Environmental Protection Agency (EPA).

In 2001, the Task Force developed an initial Action Plan, outlining specific issues, goals, and actions important for addressing the problem of AR. This document, entitled *A Public Health Action Plan to Combat Antimicrobial Resistance, Part I: Domestic Issues*, reflected a broad-based consensus of participating Federal agencies, which was reached with individual input from State and local health agencies, universities, professional societies, pharmaceutical companies, healthcare delivery organizations, agricultural producers, consumer groups, and other members of the public. Continued collaboration with these partners has been vital to achieving successful implementation of the Action Plan.

This draft document, *A Public Health Action Plan to Combat Antimicrobial Resistance*, is a revision of the 2001 interagency action plan. The revised Action Plan provides an updated blueprint for specific, coordinated Federal action to address emerging threats in AR. The document covers a broad spectrum of AR issues, addressing resistance in a wide range of pathogens (bacteria, viruses, fungi, and parasites) and settings (human medicine, veterinary medicine, agriculture, animal production, and others).

The Action Plan includes action items organized into four focus areas: Surveillance, Prevention and Control, Research, and Product Development. The Action Plan contains specific action items, projects, and implementation steps. Wherever possible, action items are populated with specific projects or implementation steps to provide greater specificity for planned Federal activities. The action items, projects,

and implementation steps do not represent an exhaustive list of activities.

Dated: March 11, 2011.

Tanja Popovic,

*Deputy Associate Director for Science,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Comment Request

Title: Personal Responsibility Education Program (PREP) Multi-Component Evaluation.

OMB No.: New collection.

Description: The Family Youth Services Bureau (HHS/ACF/ACYF/FYSB) and the Office of Planning Research and Evaluation (HHS/ACF/OPRE) in the Administration for Children and Families (ACF) are proposing three data collection activities to be undertaken for the Personal Responsibility Education Program (PREP) Multi-Component Evaluation.

The impact study included in the PREP Multi-Component Evaluation is a random assignment evaluation which will expand available evidence on whether the replication of evidence-based effective programs, or the substantial incorporation of elements of these programs, funded as part of the Personal Responsibility Education Program, are effective at delaying sexual activity, increasing condom or contraceptive use for sexually active youth, or reducing pregnancy among youth. The evaluation will document and test a range of pregnancy prevention approaches in up to five program sites. The findings from the evaluation will be of interest to the general public, to policy-makers, and to organizations interested in teen pregnancy prevention.

This **Federal Register** Notice is to notify the public regarding Data Collection for the Baseline, Field Collection, and In-Depth Implementation Components of the Impact and In-Depth Implementation Evaluation of the Personal

Responsibility Education Program (PREP) Multi-Component Evaluation.

Field Collection: The field collection activity involves the collection of information from observations of program activities and interviews with a range of experts and persons involved with programs about various aspects of existing prevention programs and topics the experts view as important to address through evaluation. These data will be used to help enhance decisions about the types of programs to be evaluated in the studies.

In-Depth Implementation: The implementation data collection activity as part of the in-depth implementation portion of the PREP Multi-Component Evaluation involves the collection of information from program records and site visits at two to three points in the program implementation period. Understanding the programs, documenting their implementation and context, and assessing fidelity of implementation will allow for description of each implemented program and the treatment-control contrast evaluated in each site. It will also help in interpreting impact findings, differences in impacts across programs, and differences in impacts across locations or population subgroups.

Baseline: The baseline data collection activity will present respondents with carefully selected questions about demographics and risk and protective factors related to teen pregnancy. Also proposed is a collection of school records, performance, and program participation for the youth. Information from this data collection will be used to perform meaningful analysis to determine significant program effects.

Respondents:

Field Clearance: Researchers; Policy Experts; State Level Coordinators; Program Directors; Program Staff; Program Participants; School Administrators.

In-Depth Implementation: General Staff; Community Members; Frontline Staff; Participating Youth; and Control Group Schools.

Baseline: Study participants (*i.e.*, adolescents, and schools and organizations responsible for administrative data); Schools and Organizations.