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Tobacco Product Ingredient Listing Collections by CDC and FDA

Issue: Whether tobacco product ingredient listing information collected by the Food and Drug Administration (FDA) (OMB Control Number 0910-0650) and the Center for Disease Control (CDC) (OMB Control Numbers 0920-0210 and 0920-0338) are duplicative.

Resolution: As discussed and agreed upon by OMB, FDA, and CDC at a June 6, 2013, meeting, the FDA and CDC data collections for tobacco product ingredient listing are similar but are not duplicative (as described in greater detail below). However, both agencies have continued to discuss opportunities for collaboration to enhance the overall usefulness of both agencies' tobacco product data collections and elimination of future duplicative collections of information.

FDA and CDC have agreed upon a Memorandum of Understanding (MOU) which primarily addresses sharing of data and test methods between both agencies. There are also two interagency agreements in place in which CTP funds either cycles of existing surveys such as the National Youth Tobacco Survey (NYTS) or leverages existing CDC surveys such as the Pregnancy Risk Assessment Monitoring System (PRAMS) survey and the National Health Interview Survey (NHIS) by funding additional FDA drafted survey questions.

Background: The CDC and FDA each rely on different statutory authorities to collect their respective data. CDC collects certain product ingredient information authorized under the Federal Cigarette Labeling and Advertising Act (FCLAA) (OMB Control Number 0920-0210) and the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) (OMB Control Number 0920-0338). FDA collects product ingredient information under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (OMB Control Number 0910-0650). FDA also 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 Tobacco Control Act (OMB Control Number 0910-0749). 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 Tobacco Control Act.

- FCLAA, 15 U.S.C. 1335, requires individuals who manufacture, package, or import cigarettes to submit annually to HHS a list of ingredients added to tobacco in the manufacture of cigarettes. CDC's Office of Smoking and Health (OSH) has the primary responsibility for this aspect of HHS's tobacco and health program. The information collected includes company name(s), brand(s), and an aggregated list of ingredients (name and Chemical Abstract Services (CAS) Registry Number) for any ingredient found in any of the listed brands. No quantities or brand/sub-brand-specific information is provided. Under FCLAA, reporting on tobacco type/blends used or ingredients used in the paper or filters of tobacco products is not required.

CSTHEA, 15 U.S.C. 4403, requires individuals who manufacture, package, or import smokeless tobacco products in the United States to report annually to HHS an aggregated list of ingredients across all brands, but also brand-specific quantities of nicotine for each smokeless tobacco product. CDC/OSH is also responsible for administering this aspect of HHS's program. The information collected includes the data elements collected under FCLAA (above), plus identification of a list of product categories that the product may fit under. Under CSTHEA, reporting on tobacco type/blends used or ingredients used in the composition of tobacco product wrappings is not required.

- The Tobacco Control Act, 21 U.S.C. 387, amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) and establishes FDA's authority to regulate tobacco products. Section 904(a) and (c) of the FD&C Act requires each tobacco product manufacturer or importer to submit ingredient lists initially when the product is first introduced to the market (new submission) and then at the time of any product changes (updating a previous submission). For new submissions, the manufacturer provides submitter and point-of-contact information; submits a detailed listing of all ingredients and additives to tobacco, inclusive of tobacco, paper, and filter; and provides the quantity of the additive by brand and sub-brand. For updates, the manufacturer also indicates whether the quantity of the ingredient was added, increased, decreased, or eliminated. Additional information on the content, form, and delivery of nicotine is also requested. The submitter also certifies that the information submitted is true and accurate, and that any changes to this information will be reported under section 904(c) of the FD&C Act (21 U.S.C. 387d(c)). Reporting of ingredients under the Tobacco Control Act has a larger scope because it includes collecting data on tobacco type/blends used and ingredients used in the composition of paper or filters of tobacco products.

- Section 919(a) of the FD&C Act (21 U.S.C. 387s(a)) requires FDA to "assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products" subject to the tobacco provisions of the FD&C Act (chapter IX of the FD&C Act). Section 919(c)(2)(A) states that "Fees appropriated under paragraph (3) are available ***only for the purpose of paying the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under this chapter and the Family Smoking Prevention and Tobacco Control Act (referred to in this subsection as "tobacco regulation activities….")*** Section 919(c)(2)(B)(i) states "fees collected under subsection (a) are the only funds authorized to be made available for tobacco regulation activities."

Analysis: In consultation with each of their agency's attorneys, CDC and FDA have determined that although the product information being submitted to CDC and FDA is similar, the data collections are not duplicative due to factors such as the timing of the information collection, its

content, and its use. For example, manufacturers of tobacco products submit product ingredient information to CDC annually to fulfill CDC's requirements to produce a report to Congress, when requested, on ingredient content. CDC also uses the information to provide certification to States' Attorneys General that tobacco manufacturers have met the requirements of FCLAA and CSTHEA and can therefore legally sell tobacco products in their states. In contrast to the annual submission of information provided to CDC, product ingredient information is initially submitted to FDA when a tobacco product is first introduced to the market, and then only upon a change in product ingredients. There is no specific periodic reporting required under the Tobacco Control Act. FDA uses this information internally under its premarket product review authorities. Also, user fees collected from tobacco manufacturers and importers for FDA may only be used to fund the costs of the activities for FDA's Center for Tobacco Products (CTP), and these funds are the only ones authorized to be made available for tobacco regulation activities at CTP. Therefore, FDA could not implement CDC's data collection activities using its tobacco user fees and those are the only funds authorized to be made available to FDA for tobacco regulation activities.

Key Distinctions Between CDC and FDA's Data Collection

	FCLAA/CSTHEA (1969/1986)	**Tobacco Control Act (2009)**
HHS Program Administration	CDC	FDA
Reference Section of U.S. Code	15 U.S.C. 1335 / 15 U.S.C. 4403	21.U.S.C. 387
Cigarette Data Collected: Ingredients	Yes; however, no quantities collected; brands and subbrands are not specified. Also, reporting not required for tobacco types/brands or reporting of ingredients used in paper and filters.	Yes; quantities collected; brand and subbrands are specified. Reporting is required for tobacco types/brands and reporting of ingredients used in paper and filters.
Cigarette Data Collected: Nicotine[1]	Not collected	Yes; quantities are collected, brands and subbrands are specified

[1] FDA is also required to collect information on harmful and potentially harmful constituents (such as nicotine) by brand and sub-brand and notes that not every constituent is harmful/potentially harmful and therefore on the list. Since constituents are what are inhaled/absorbed/ingested by the person, some ingredients may also be constituents, other ingredients are not constituents (cigarette paper), and some constituents are not ingredients (e.g., lead since it comes from the tobacco itself or CO since it is produced by burning the tobacco). Thus, the reporting of harmful and potentially harmful constituents is also not duplicative of CDC ingredient reporting requirements

Smokeless Tobacco Data Collected: Ingredients	Yes; however, no quantities collected; brands and subbrands are not specified. Also, reporting not required for tobacco types/brands.	Yes; quantities are collected; brands and subbrands are specified. Reporting ist required for tobacco types/brands.
Smokeless Tobacco Data Collected: Nicotine	Yes; quantities are collected; brands and subbrands are specified	Yes; quantities are collected; brands and subbrands are specified
Timeline of Collection	Annual, regardless of changes to product	Baseline collection when tobacco product is first introduced to market, with additional disclosure to FDA upon any changes to product
Confidentiality Provisions and Information Sharing	Information submitted is considered trade secret and confidential. Disclosures permitted only as authorized by legislation.	Information submitted is considered confidential and may contain trade secrets. Other disclosures as permitted to other officers or employees concerned with carrying out the tobacco control provisions of the FD&C Act or when relevant in a proceeding under the tobacco control provisions of the FD&C Act

As the chart above implies, a legislative fix would be needed to allow the collection of product ingredient information by only one of the two agencies. Currently, FDA cannot not rely on CDC's information collection because quantities of ingredients for cigarettes are not required, and CDC is not required to report on tobacco types/blends or ingredients in paper and filters. FDA does require reporting on tobacco types/blends and ingredients in paper and filters. In addition, FDA might be seen as using funds other than those generated by user fees (i.e., CDC appropriated funds) for FDA's activities relating to tobacco regulation. CDC could not rely on FDA's information because the data are not collected annually. To ensure that data collected by FDA and CDC are not duplicative and burdening the public needlessly, both agencies meet regularly and collaborate on tobacco surveys, ingredient reporting, data analysis, and publications. For example, FDA works with CDC on the National Youth Tobacco Survey

(NYTS) and the National Adult Tobacco Survey (NATS) data collection efforts (within the restrictions on the use of FDA's user fees). For NYTS, both agencies have agreed on a unified core set of questions of interest to both agencies but alternate years of data collection/funding to accommodate each agency's data needs. For NATS, FDA is working on a mechanism for CDC to add funding and questions to the survey. FDA also works with CDC on the National Health Interview Survey (NHIS) to use existing survey systems rather than to develop new ones.

Summary:

- Although FDA and CDC's tobacco ingredient data collections are similar, the underlying authorities found in the Tobacco Control Act, FCLAA, and CSTHEA to collect such information would not allow either agency's data collection (in solo) to fulfill both agencies' needs. A legislative fix would be needed to allow one agency to collect the ingredient information that both FDA and CDC require.

- In light of the potential benefits of sharing information, CDC and FDA will continue to discuss opportunities for collaboration to enhance the overall usefulness of both CDC's and FDA's tobacco industry reporting programs.

- Section 919(a) of the FD&C Act requires FDA to collect user fees from each manufacturer and importer of regulated tobacco products, and these fees are available only for the purpose of paying the costs of the activities of the FDA related to the regulation of tobacco products. Section 919(c) indicates that these user fees are the only funds authorized to be made available for tobacco regulation activities.