

Reporting Instructions

The requirements for submission and the format for submitting the Ingredient Report for cigarettes and the Ingredient and Nicotine Reports for smokeless tobacco, and a specification of the quantity of nicotine for smokeless tobacco, are available in the <u>Federal Register. (http://www.gpoaccess.gov/fr/index.html)</u>

Certification

Deadline:

As detailed in 64 FR 14086, March 23, 1999 (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi? dbname=1999 register&docid=99-7022-filed); and 66 FR 17559, April 2, 2001 (http://www.access.gpo.gov/su_docs/fedreg/a010402c.html), all submissions required under the Federal Cigarette Labeling and Advertising Act (FCLAA) and Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) for cigarettes and smokeless tobacco are due upon initial importation and annually thereafter by March 31. Submissions to CDC's Office on Smoking and Health are reflective of ingredient information required by FCLAA and CSTHEA during the previous calendar year.

Once an accurate submission of an Ingredient Report and Nicotine Report (where applicable) have been received, CDC will issue a Certificate of Compliance valid until March 31 of the following year.

Note: All faxed submissions should be immediately followed with a mailed original.

Report Format:

CDC requests all submissions be on letterhead of the manufacturer, packager, importer, respective counsel, or designated individual or entity.

Because CDC cannot ensure the confidentiality of information submitted via e-mail, that is not an acceptable format. However, submission of data by way of mailing a CD, 3-inch floppy disk, or thumb drive is acceptable.

Reports may also be submitted via facsimile, but all faxed lists should be followed-up with a mailed original.

To the best of our knowledge, laboratory analysis is not available that will provide a complete representation of the ingredients added to tobacco in the manufacture of cigarettes or smokeless tobacco. Laboratory analysis in lieu of the Ingredient Report is not acceptable.

Note: If no ingredients are added to tobacco in the manufacture of cigarettes or smokeless tobacco, a statement to that effect must be submitted in writing.

Recommended Formats for Reporting

(/tobacco/basic information/tobacco industry/reporting/formats/)

Contact information for submissions to OSH

(/tobacco/basic information/tobacco industry/reporting/contacts/)

Categories:

The reporting status of manufacturers, packagers, and importers will be coded by CDC as either "compliant (#Compliant)," "noncompliant (#Noncompliant)," or "inactive (#Inactive)."

Compliant

Importers of cigarettes and smokeless tobacco products must submit a list of ingredients added to tobacco in the manufacture of the product upon initial importation of said product. Additionally, all manufacturers, packagers, and importers must annually submit by March 31 a list of ingredients added to tobacco in the manufacture of cigarettes and smokeless tobacco products during the previous calendar year.

A Certificate of Compliance will be issued for submissions that meet all of the following requirements:

- The submission clearly states on whose behalf the submission is made.
- The list of ingredients, including chemical names and corresponding Chemical Abstract Service (CAS) registry numbers, added to tobacco in the manufacture of cigarettes and/or smokeless tobacco products is complete and without error.

Example:

Chemical Name: Menthol CAS Number: 89–78–1

- The submission is signed and certified as correct by the submitter.
- The submission for smokeless tobacco products contains a specification of the quantity of nicotine through the reporting of the amount of total nicotine, amount of unionized nicotine and percentage of unionized nicotine, total moisture, and pH for each smokeless product.

Noncompliant

Failure to provide the annual Ingredient Report and Nicotine Report (for smokeless tobacco) by the March 31 deadline and failure to correct inadequacies or errors in a submission within 60 days of notification will result in CDC deeming the manufacturer, packager, or importer noncompliant.

In addition, if a report is submitted by a designated individual, the manufacturer, packager, or importer on whose behalf the report is submitted must be identified with the submission. Otherwise, the company will be deemed noncompliant.

Noncompliant status will be changed upon receipt of required information.

Inactive

Companies are encouraged to inform CDC if they are no longer manufacturing, packaging, or importing tobacco products. CDC communicates with other federal agencies involved in the regulation of tobacco products and will share the information of a company's status as appropriate.

Other Requirements

In addition to the requirements detailed here, manufacturers, packagers, and importers of tobacco products may have additional legal obligations to consider. Although not an exhaustive list, other federal agencies that may have applicable laws include the Alcohol and Tobacco Tax and Trade Bureau (TTB), U.S. Customs (Customs), and the Federal Trade Commission (FTC).

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