# **26-239 OFFICE OF THE MAINE ATTORNEY GENERAL**

 **HEALTH AND HUMAN SERVICES DIVISION**

**Chapter 10: Rules for Exemptions to the Ban on Flavored Cigarettes and Cigars**

**SUMMARY:** This chapter describes the procedures under which tobacco manufacturers may file statements for flavored cigarette or flavored cigars first on the market prior to January 1, 1985 and for the verification of those statements. This chapter also describes the procedures under which tobacco manufacturers may apply for exemption from the flavored cigarette and cigar ban for those flavored products first on the market after January 1, 1985 and the criteria by which those applications will be evaluated. Pursuant to 22 M.R.S.A. §1560-D, the Office of the Attorney General is responsible for administering the exemptions to the ban on flavored cigarettes and cigars, and for promulgating these Rules.

SECTION 1. PURPOSE

These Rules are promulgated pursuant to the Flavored Cigarettes and Cigars Subchapter of the Retail Tobacco Sales Law, 22 M.R.S.A. §1560-D. They set forth guidelines for manufacturers of flavored cigarettes and flavored cigars regarding the criteria and processes for obtaining exemptions for flavored cigarettes and flavored cigars from the ban on those products. 22 M.R.S.A §1560-D(2).

SECTION 2. Definitions

Unless otherwise stated, the following terms have the following meanings.

1. ”Brand” means a cigarette or cigar brand name (*e.g.,* Marlboro). A brand may have more than one brand style including but not limited to: lights, blunts, or a specified flavor.

2. ”Brand Style” means a variety of cigarettes or cigars distinguished by the tobacco used, flavoring used, size of, or filtration on the cigarette or cigar.

3. “Candy” means the generic name of a confection made from sugar or sugar substitute (*e.g.,* toffee) and the brand name of such a confection, this includes but is not limited to chocolate, cocoa, cacao, mocha, vanilla, honey, maple, cinnamon, licorice, and mint (*e.g.*, spearmint and peppermint, but excluding menthol).

4. ”Characterizing flavor” means a distinguishable taste or aroma that is imparted to tobacco or tobacco smoke either prior to or during consumption, other than a taste or aroma from tobacco, menthol, clove, coffee, nuts or peppers.

5. “Cigar” means: any roll of tobacco wrapped in leaf tobacco or in any substance containing tobacco, which is not a cigarette as that term is defined at subsection 6 below.

6. “Cigarette” has the same meaning as that term is defined in 22 M.R.S.A. §1580-H(4).

7. ”Component part” includes but is not limited to the tobacco, filter and paper in a cigarette or cigar.

8. ”Constituent” means any ingredient, substance, chemical or compound, other than tobacco, water or reconstituted tobacco sheet, that is added by the manufacturer to the tobacco, paper or filter of a cigarette or cigar during the processing, manufacture or packing of the cigarette or cigar. “Constituent” includes a smoke constituent.

9. ”Flavored cigar” means a cigar or any component part thereof that contains a constituent that imparts a characterizing flavor.

10. ”Flavored cigarette” means a cigarette or any component part thereof that contains a constituent that imparts a characterizing flavor.

11. “Fruit” means the generic name of a specific fruit (*e.g*., orange) or a type of fruit (*e.g.,* berry)

12. “Person” means an individual, corporation, partnership or unincorporated association.

13. ”Smoke constituent” means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette or cigar to the smoke or that is formed by the combustion or heating of tobacco, additives or other component of the tobacco product.

**SECTION 3. PROHIBITION**

 Beginning July 1, 2009, a person may not sell or distribute or offer to sell or distribute in this State any flavored cigarette or flavored cigar unless:

1. The flavored cigarette or flavored cigar was first on the market prior to January 1, 1985, based on a statement to that effect filed with the Attorney General pursuant to 22 M.R.S.A. §1560-D(2)(A) and Section 4 of these Rules by the current manufacturer and verified by the Attorney General;

2. The flavored cigarette or flavored cigar has been granted an exemption by the Attorney General pursuant to 22 M.R.S.A. §1560-D(5) and Section 5 of these Rules; or

3. The sale is allowed under the transition provisions of 22 M.R.S.A. §1560-D(7).

**SECTION 4. EXEMPTIONS FOR FLAVORED CIGARETTES AND FLAVORED CIGARS FIRST ON THE MARKET PRIOR TO JANUARY 1, 1985**

1. **Statement of Manufacturer that Flavored Cigarette or Flavored Cigar was First on the Market prior to January 1, 1985**

The current manufacturer of a flavored cigarette or flavored cigar first on the market prior to January 1, 1985 wishing to apply for an exemption pursuant to 22 M.R.S.A. §1560-D(2)(A) and Section 3(1) of these Rules shall, on or with a form provided by the Attorney General, submit a statement for verification supported by the following:

A. The brand and brand style/s of the flavored cigarette or flavored cigar;

B. The original manufacturer of the flavored cigarette or flavored cigar;

C. The current manufacturer of the flavored cigarette or flavored cigar;

D. The original flavor of the flavored cigarette or flavored cigar;

E. The length and diameter of the flavored cigarette or flavored cigar prior to January 1, 1985;

F. A digital photo or other color image of the pre-1985 packaging of the flavored cigarette or flavored cigar;

G. A digital photo of the current packaging;

H. The number of flavored cigarettes/cigars, per package, prior to January 1, 1985;

I. The number of flavored cigarettes/cigars per current package;

J. The flavor imparting constituents that impart a characterizing flavor or aroma to the flavored cigarette or flavored cigar prior to January 1, 1985;

K. The current flavor imparting constituents that impart a characterizing flavor or aroma to the flavored cigarette or flavored cigar;

L. Any constituent ingredients other than flavor imparting constituents prior to January 1, 1985; and

M. Current constituent ingredients other than flavor imparting constituents.

2. **Confidentiality of Information**

Subject to the provisions of the Freedom of Access Act, Title 1 M.R.S.A. §§ 401-521, information submitted to the Attorney General pursuant to these rules may be designated as confidential. Any manufacturer claiming confidentiality pursuant to 1 M.R.S.A. §§ 401-521 must indicate such claim clearly on its reporting form, specifically identifying the information to be treated as confidential and citing to the specific privilege/s claimed. Any portion of an application for which such privilege is asserted will be treated as confidential until such time as a Freedom of Access request is made for that information. Upon receipt of such request for any of the information designated by the manufacturer as confidential, the Office of the Attorney General shall notify the manufacturer within 10 days of the request. The Office of the Attorney General may accommodate the public access request unless the manufacturer notifies the Office of Attorney General of its objection to the release of the data within 10 days of receiving notification of the public access request. Upon receipt of a manufacturer’s objection, the Attorney General will make a determination whether the requested data falls within the claimed privilege. Upon making a determination the Attorney General will notify the data submitter and the data requester of that determination. Determinations under this provision are final agency action and subject to the appeal rights found in the Maine Administrative Procedure Act, 5 M.R.S.A. §§ 8001‑11008. The burden shall be upon the manufacturer to demonstrate that any data claimed as confidential is not a public record and not subject to disclosure pursuant to 1 M.R.S.A. §§ 401-521. During any appeal of its determination, the Office of the Attorney General will treat the data for which confidentiality was asserted as confidential until a final judicial decision is rendered.

3. **Verification-** Upon verification based on the above submissions that the current flavored cigarette or flavored cigar was first on the market prior to January 1, 1985, the Office of Attorney General shall add the product to a list of flavored cigarettes and flavored cigars that are authorized for distribution and sale in the State.

4. **Request for Reconsideration-** Within 30 days of receipt of the determination of the Office of Attorney General refusing to grant an exemption for a product under 22 M.R.S.A. §1560-D(2)(A), an applicant may request reconsideration by submitting a written request for reconsideration.

A. The applicant must clearly state its reasons for requesting reconsideration.

B. The applicant must attach any additional or supplementary information it wishes to have considered in addition to its original submissions to its request for reconsideration.

C. Within 30 days of the receipt of a reconsideration request, the Office of Attorney General shall affirm, modify or reverse its original exemption determination.

D. Exemption determinations are considered final agency action for purposes of the Maine Administrative Procedure Act, 5 M.R.S.A. §§ 8001-11008, once the Office of the Attorney General has made its determination on the request for reconsideration.

**SECTION 5. EXEMPTIONS FOR FLAVORED CIGARETTES AND FLAVORED CIGARS FIRST ON THE MARKET AFTER JANUARY 1, 1985**

1. **Application for Exemption.** The current manufacturer of a flavored cigarette or flavored cigar wishing to apply for an exemption pursuant to 22 M.R.S.A. §1560-D(2)(B) and (5), and Section 3(2) of these Rules shall, on or with a form provided by the Office of Attorney General, submit the following:

A. The brand and brand style/s of the flavored cigarette or flavored cigar;

B. The manufacturer of the flavored cigarette or flavored cigar;

C. The name of an authorized manufacturer’s representative;

D. The characterizing flavor of the flavored cigarette or flavored cigar; and

E. The constituent/s that imparts a characterizing flavor or aroma to the flavored cigarette or flavored cigar

2. **Confidentiality of Information**

Subject to the provisions of the Freedom of Access Act, Title 1 M.R.S.A. §§ 401-521, information submitted to the Attorney General pursuant to these rules may be designated as confidential. Any manufacturer claiming confidentiality pursuant to 1 M.R.S.A. §§ 401-521 must indicate such claim clearly on its reporting form, specifically identifying the information to be treated as confidential and citing to the specific privilege/s claimed. Any portion of an application for which such privilege is asserted will be treated as confidential until such time as a Freedom of Access request is made for that information. Upon receipt of such request for any of the information designated by the manufacturer as confidential, the Office of the Attorney General shall notify the manufacturer within 10 days of the request. The Office of the Attorney General may accommodate the public access request unless the manufacturer notifies the Office of Attorney General of its objection to the release of the data within 10 days of receiving notification of the public access request. Upon receipt of a manufacturer’s objection, the Attorney General will make a determination whether the requested data falls within the claimed privilege. Upon making a determination the Attorney General will notify the data submitter and the data requester of that determination. Determinations under this provision are final agency action and subject to the appeal rights found in the Maine Administrative Procedure Act, 5 M.R.S.A. §§ 8001‑11008. The burden shall be upon the manufacturer to demonstrate that any data claimed as confidential is not a public record and not subject to disclosure pursuant to 1 M.R.S.A. §§ 401-521. During any appeal of its determination, the Office of the Attorney General will treat the data for which confidentiality was asserted as confidential until a final judicial decision is rendered.

3. **Complete Application**

Within 30 days of receipt of an exemption application, the Office of Attorney General shall review the exemption application for completeness. A complete application is one that contains the information and materials identified above in Section 5(1) of this Rule.

A. Upon finding an application complete, the Office of Attorney General shall so notify the applicant and proceed with a determination of whether the flavored cigarette or flavored cigar meets the criteria for an exemption.

B. In the event an application is determined incomplete, the Attorney General shall notify the applicant of the additional information or submissions required and allow an additional 30 days in which to submit an amended application.

C. If an applicant needs time beyond the additional 30 days to gather and supply the requested submissions, the applicant may request an extension of no more than 60 days.

D. Unless granted an extension, if an applicant fails to submit required additional submissions within the initial 30 day extension, the application shall be denied.

E. In the event an application is denied for incompleteness, an applicant may submit a new exemption application.

4. **Evaluation of Exemption Applications**

A. Within 60 days of finding an application complete, the Office of Attorney General shall either grant or deny the exemption application for the brand style of flavored cigarette or flavored cigar.

B. In determining whether “the characterizing flavor is not one known to or likely to appeal to youth” as required by 22 M.R.S.A. §1560-D(5) the Office of Attorney General shall consider:

* + 1. whether the characterizing flavor of the flavored cigarette or flavored cigar is a flavor generally associated with those used in candy, fruit, liquor or fermented alcohol flavored products, or other flavors known or likely to appeal to youth; and
		2. whether the characterizing flavor is one that was used in flavored cigarettes or flavored cigars prior to January 1, 1985.

C. Findings of Fact

 The Office of Attorney General shall make findings of fact in support of its determination to grant or deny an exemption for each flavored cigarette or flavored cigar application.

D. Request for Reconsideration

Within 30 days of receipt of the determination of the Office of Attorney General, an applicant may request reconsideration by submitting a written request for reconsideration.

(1) The applicant must clearly state its reasons for requesting reconsideration.

(2) The applicant must attach any additional or supplementary information pertaining to its original submissions to its request for reconsideration.

(3) Within 30 days of the receipt of a reconsideration request, the Office of Attorney general shall affirm, modify or reverse its original exemption determination.

(4) Upon completion of the reconsideration process, the Office of the Attorney General exemption determinations are considered final agency action for purposes of 5 M.R.S.A. §§ 8001-11008.

E. Material Changes to Characterizing Flavor

1. After an exemption has been granted for a flavored cigarette or flavored cigar under Section 5 of these Rules, a manufacturer to whom an exemption has been granted has an affirmative duty to inform the Attorney General at the time that a material change is made in the characterizing flavor of the flavored cigarette or flavored cigar. A violation of the duty to inform imposed by this paragraph constitutes a civil violation for which a fine of not more than $10,000 may be adjudged.
2. If the Attorney General determines a material change has been made to a product’s characterizing flavor, the Attorney General may, after providing the manufacturer to whom an exemption has been granted notice and an opportunity to respond within 30 days, revoke a previously granted exemption.

**SECTION 6. SEVERABILITY**

Should any provision of these Rules be determined to be unconstitutional or unenforceable, such a determination shall not invalidate any other provision of these rules.

STATUTORY AUTHORITY: 22 M.R.S.A. §1560-D

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