

Food and Flavors with Standards of Identity

Vanilla – Standards and Labeling

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Federal Food Standards – FD&C Act Section 401

Food standards are not safety standards.

- Purpose is to “promote honesty and fair dealing in the interest of consumers.”

Food standards are intended to assist consumers by requiring that descriptions of specific food meet consumers’ expectations, i.e. when a consumer purchases a “standardized” food, the food is what the consumer expects it to be.

- The “standardized” food must match its recipe.

Vanilla – Standards and Labeling

Federal food standards relevant to vanilla:

1. Vanilla standard – 21 CFR 169.175-182
 - Vanilla extract
 - Vanilla flavoring
 - Vanilla powder
 - Vanilla-vanillin extract, flavoring, powder

2. Ice cream and frozen custard – 21 CFR 135.110

Vanilla – Standards and Labeling

Vanilla standard: Key definitions

1. Vanilla beans – 21 CFR 169.3(a)

Properly cured and dried fruit pods of two vanilla species.

2. Unit weight of vanilla beans – 21 CFR 169.3(b)

Specific amount of beans with specific moisture content.

3. Unit of vanilla constituent – 21 CFR 169.3(c)

Total sapid and odorous principles extractable from one unit weight of vanilla beans using alcohol/water solution >35% alcohol.

Vanilla – Standards and Labeling

Vanilla extract – 21 CFR 169.175

To be called “vanilla extract” or “extract of vanilla” the product must meet the following recipe:

- Sapid and odorous principles from one unit weight of vanilla beans per gallon suspended in alcohol solution containing >35% alcohol.

May contain certain optional ingredients:

- Glycerin, propylene glycol, sugar, dextrose, corn syrup.

Also recipes for:

- Vanilla flavoring, vanilla powder, and vanilla-vanillin extract, flavoring, powder.

Vanilla – Standards and Labeling

How can we interpret the vanilla standards?

- FDA has issued a substantial body of regulatory correspondence that, in addition to the standards, facilitate understanding and interpretation.

Regulatory correspondence issued in response to an inquiry from:

- Industry
- Another agency – TTB (BATF)
- Public

Advisory opinion for vanilla – 1983.

Regulatory correspondence = advisory opinion.

FDA/TTB Relationship

FDA jurisdiction – food.

TTB (BATF) jurisdiction – alcohol use (drawback)/alcoholic beverages.

TTB is involved because:

1. Some vanilla standardized products **must** contain alcohol.
2. Alcohol drawback for non-potable uses (e.g. extracts).
3. Use of flavors in alcoholic beverages.

TTB generally defers to FDA's expertise

- Some important interpretations involve TTB (BATF).

Ice Cream – Standards and Labeling

FDA requirements for specific standardized frozen desserts, ice cream and frozen custard – 21 CFR 135.110

Key provisions – Nomenclature for “Categories 1, 2, and 3”:

21 CFR 135.110(f)

1. No artificial flavor = common or usual name of the characterizing flavor, i.e. vanilla ice cream.
2. Natural characterizing flavor (predominant) + artificial simulating it = vanilla flavored ice cream.
3. Natural characterizing flavor + artificial simulating it (predominant) OR only artificial flavor = artificially flavored vanilla ice cream.

In the case of vanilla, artificial predominates if it contains >1 oz vanillin per unit of vanilla constituent.

21 CFR 135.110(f)(5)

Ice Cream – Standards and Labeling

Ice cream labeling

Categories 1, 2, 3 apply to principal display panel – the front label.

- Category 2 – must also include explicit disclosure “artificial flavor added” or if other non-characterizing or non-simulating artificial flavor included.

21 CFR 135.110(f)(3)(i)

Ingredient statement

- Must include statement of the common or usual name of ingredients.

Ice Cream – Standards and Labeling

How can we interpret the ice cream standard?

As with vanilla, there is FDA regulatory correspondence, much of it about vanilla ice cream.

- Correspondence
- 1983 advisory opinion

Vanilla and Ice Cream Standards and Labeling

Putting it all together

Key to interpretation and proper labeling is putting the two standards, vanilla and ice cream, together for evaluation and analysis and making use of readily available resources:

- FEMA compilation of regulatory correspondence plus annotated index available on the FEMA website.
- FEMA Flavor Labeling Handbook.
- General food/flavoring labeling regulations at 21 CFR 101.22.

Food Labeling Regulations – 21 CFR 101.22

What is the role of these regulations in the context of the ice cream standard?

“The general flavor regulations (21 CFR 101.22) are not applicable to this standardized food (ice cream).”

FDA, 1983.

The food/flavor labeling regulations may be used to interpret several important concepts such as the “characterizing” concept.

FDA, 1983.

- Concepts of simulate, resemble, or reinforce (enhance).

Food Labeling Regulations and Vanilla Labeling

Key concepts of “simulate, resemble, or reinforce.”

Key context is the inclusion of non-vanilla bean derived “natural” flavors, e.g. vanillin.

FDA awareness back in 1983:

- “The non-vanilla flavor is deemed to simulate vanilla if the addition of the non-vanilla flavor results in a reduction of the amount of vanilla bean derived flavor that would otherwise be used. . . . Thus, a flavor that permits less of the characterizing flavor to be used than would otherwise be the case simulates that flavor.

FDA, 1983.

Interpretation of vanilla standards – 21 CFR 169

Definitions:

Unit weight of vanilla beans – 21 CFR 169.3(b)

- Specific amount of beans with specific moisture content.

Unit of vanilla constituent – 21 CFR 169.3(c)

- Total sapid and odorous principles extractable from one unit weight of vanilla beans using alcohol/water solution >35% alcohol.

TTB(BATF) Guidance on moisture content

- Describes “flexible” approach on moisture content requirements for vanilla extract for TTB “approved” formulas.

BATF Industry Memorandum, 1987.

Interpretation of vanilla standards – 21 CFR 169

Key principle:

Use of the descriptive term “vanilla” in **any** context of flavor or food labeling including bulk and retail flavors including vanilla extract and foods including ice cream will cause FDA (and TTB) to evaluate labeling in light of the vanilla and ice cream standards.

FDA policy is not to prohibit the use of non-vanilla bean derived flavors but rather to require clear labeling declarations of the presence of these flavors.

- Only if one complies with the standard recipes can one label the product with the “standardized” name.

Interpretation of vanilla standards – 21 CFR 169

“(T)he standards do not infer that the vanilla products covered by these sections may be made from other than the flavoring principles actually extracted by aqueous alcohol solution from vanilla beans. Other flavoring ingredients, whether natural or synthesized, are not permitted except for vanillin as provided for in 21 CFR 169.180 through 169.182. . . . Accordingly, the addition of any flavoring substance (other than vanillin) to the standardized vanilla products . . . Would result in articles which no longer conform to the standards and which would not be entitled to be identified or labeled as the standardized products.”

FDA, 1979(1).

Interpretation of vanilla standards – 21 CFR 169

“The combination of vanilla-vanillin extract or vanilla-vanillin flavoring with natural flavors not derived from vanilla beans . . . may be marketed . . . However, such a combination should in no way imply or suggest that this combination is one of the standardized flavors covered under 21 CFR 169.”

FDA, 1979(2).

Appropriate labeling could be:

“Vanilla-vanillin extract with other natural flavors” and “each ingredient of the natural non-vanilla flavoring should be declared by its specific common or usual names.”

FDA, 1979(2).

Interpretation of vanilla standards – 21 CFR 169

“Vanilla extract and vanilla flavoring are standardized foods and these products are expensive” and should be distinguished from similar products. Therefore:

- “A flavoring composed of 50% vanilla extract and 50% natural flavors not derived from vanilla beans intended for retail sale may be identified as vanilla flavor with other natural flavors.”
- **Plus** a labeling declaration that the product “contains 50% vanilla extract and 50% non-vanilla flavors.”

FDA, 1980.

Interpretation of vanilla standards – 21 CFR 169

In the context of an issue on secondary extractives from vanilla beans:

“(T)he term ‘vanilla flavor’ tends to be deceptive, leading one to believe the product is standardized vanilla extract or vanilla flavoring. We suggest that the product be labeled by a truthful, descriptive term such as ‘extractives from spent vanilla beans.’”

Vanilla extract plus extractives from spent beans – labeled as “vanilla WONF”? Yes, but must be labeled also with “Vanilla extract with added extractives from spent beans.”

FDA, 1987.

Interpretation of vanilla standards – 21 CFR 169

So, where are we?

FDA policy is to not allow confusion between standardized vanilla products and other flavor formulations that impart a vanilla flavor.

If the common or usual name for a flavor formulation contains “vanilla” then FDA will look at compliance with the appropriate standard.

- Some flavor formulations that don’t meet the standard may be allowed to use “vanilla” in the flavor name but descriptive terms must accompany it to prevent confusion with standardized vanilla products.

Interpretation of vanilla standards – 21 CFR 169

Issues associated with “natural” vanillin:

- Before early 1990’s, vanillin (lignin) was widely recognized as a synthetic (“artificial”) flavoring substance.

New processes allowed production of vanillin meeting the definition of “natural flavor” at 21 CFR 101.22(a)(3).

BUT

Such vanillin “would not qualify as natural vanillin as defined in 21 CFR 101.22(a)(3) because the vanillin is not obtained from vanilla beans whose flavor it simulates.”

FDA, 1991.

Interpretation of vanilla standards – 21 CFR 169

Natural vanillin issues - Ferulic acid/fermentation process:

- Common or usual name is “vanillin” and should be labeled as “vanillin derived naturally through fermentation.”

FDA, 2004.

- Labeling “should not imply that the vanillin is a natural flavor or that a finished food containing it is natural.”

FDA, 2005.

- Such vanillin “may not be used to make natural vanilla flavors in such standardized foods.”

FDA, 2005.

Interpretation of vanilla standards – 21 CFR 169

Natural vanillin issues - Fermentation process, starting material not identified:

- May meet definition of natural flavor at 21 CFR 101.22(a)(3) and common or usual name is “vanillin” and label may indicate elsewhere “natural” or “vanillin derived naturally through fermentation.”

BUT

- “When vanillin manufactured through a natural process . . . is used . . . in a finished food it should be listed in the ingredient list as ‘vanillin’ or ‘natural flavor’ but it should not be done in a way to imply that it is a natural vanilla flavor because it is not derived from vanilla beans.

FDA, 2008.

Interpretation of vanilla standards – 21 CFR 169

Natural vanillin issues - Fermentation process, starting material not identified (2):

- Meets definition of natural flavor at 21 CFR 101.22(a)(3) and common or usual name is “vanillin” but not “natural vanillin.”
- Food ingredient label “can bear the term ‘vanillin,’ ‘natural flavor,’ or ‘contains natural flavor,’ but the term natural flavor must not be used in such a way to imply that it is a ‘natural vanilla flavor’ because it is not derived from vanilla beans.”

FDA, 2009.

Interpretation of vanilla standards – 21 CFR 169

TTB and “natural” vanillin:

“Because it is not included in 21 CFR Part 169, TTB has not approved nonbeverage formulas for standard of identity vanilla extract that include Rhovanil. Similarly, unless there is a natural source of vanilla (extract, oleoresin, etc.) we will not approve formulas containing Rhovanil where the product is being called ‘Natural Vanilla’ . . .”

TTB, 2007.

Interpretation of ice cream standard – 21 CFR 135

Key issues involve interpretation of the characterizing flavor concept, specifically the concept of “simulate, resemble or reinforce” as they relate to “categories 1, 2 and 3” ice cream and non-vanilla bean source flavoring substances.

- “It is our understanding that there are available in the market place, natural flavoring compounds that resemble, simulate and/or enhance vanilla flavor but are not derived from vanilla bean. These flavor compounds would not comply with the intent of the flavor provisions of Category I ice cream. However, they would qualify for Category II labeling (vanilla flavored ice cream) provided that the flavor derived from vanilla beans predominates.”

FDA, 1979.

Interpretation of ice cream standard – 21 CFR 135

Ice cream and “WONF” labeling:

“Labeling requirements for the declaration of flavors in the name of ice cream are specifically provided for by the standard and is separate and apart from the general flavor regulations. Therefore, the standard for ice cream does not provide for the label designation of ‘with other flavors’ (WONF). A product identified as ‘Vanilla Ice Cream’ is subject to the category I ice cream requirements and therefore must contain only the characterizing flavor derived from vanilla beans.”

FDA, 1979(2).

Interpretation of ice cream standard – 21 CFR 135

Characterizing flavor – predominance issue for categories 2 and 3 ice cream:

- “The addition of a flavor agent not derived from vanilla bean to the standardized flavor ‘Vanilla-Vanillin Extract’ could not qualify as a flavor for category II Vanilla Flavored Ice Cream since the vanillin and flavor not derived from the vanilla bean would predominate. However, this flavor combination when used in ice cream would qualify as flavor in the category III product.”

FDA, 1980.

Interpretation of ice cream standard – 21 CFR 135

Key document – 1983 FDA Formal Advisory Opinion:

- Issued within FDA’s formal administrative law processes.
- Context was controversy over previously issued “informal” advisory opinion on vanilla ice cream labeling.
- 1983 advisory opinion affirmed previously issued FDA policies and interpretations.

Interpretation of ice cream standard – 21 CFR 135

Key 1983 advisory opinion affirmations of existing policies and interpretations:

- “The general flavor regulations are not applicable to this standardized food (ice cream).”
- “FDA must treat all natural flavors that simulate the characterizing flavor as artificial flavors when deciding what name should appear on the principal display panel. Thus, the addition of a flavor that simulates vanilla to ice cream that contains one ounce of vanillin per unit of vanilla constituent would mean that the balance at which the natural characterizing flavor-vanilla- predominates would no longer obtain. In such circumstances, the artificial flavor-including natural flavors simulating vanilla- will be deemed to predominate.”

Interpretation of ice cream standard – 21 CFR 135

Key 1983 advisory opinion affirmations of existing policies and interpretations:

- “FDA will treat natural flavor compounds that simulate vanilla but are not derived from vanilla beans as artificial flavors that simulate the natural characterizing flavor.”
- “A flavor that permits less of the characterizing flavor to be used than otherwise would be the case simulates that flavor. . . . If an ice cream manufacturer added a small amount of a natural flavor not derived from the vanilla bean to his mix to permit the use of a smaller amount of vanilla-vanillin flavor, the natural flavor would simulate the characterizing flavor.”

Interpretation of ice cream standard – 21 CFR 135

2008 FDA Guidance:

- “The common or usual name of an ice cream product that does not contain artificial flavors would be ‘vanilla ice cream’ and it should be made from vanilla beans.”
- If ice cream “does not contain enough of the characterizing ingredient, vanilla beans, to characterize the food or it does not contain such ingredient and contains vanilla flavor, the product must be labeled ‘natural vanilla flavored ice cream’ or ‘vanilla flavored ice cream.’ However, flavors used to make such product must be derived from vanilla beans such as vanilla extract or vanilla flavor that are subject to the standards of identity.”

Interpretation of ice cream standard – 21 CFR 135

2008 FDA Guidance:

Ice cream “made from vanillin should not be named ‘vanilla ice cream’ or ‘vanilla flavored ice cream’ because these products are not made from vanilla beans or vanilla flavors made from vanilla beans. If a food contains any artificial flavor which resembles or reinforces the characterizing flavor, the name of the food on the label should be accompanied by the common or usual name of the characterizing flavor and the word(s) ‘artificial,’ or ‘artificially flavored,’ e.g. ‘artificial vanilla,’ ‘artificially flavored vanilla’ or ‘vanilla artificially flavored.’”

Spent (Exhausted) Vanilla Beans

TTB regulations on denaturing:

- 27 CFR 17.183(c)

BATF policy statement:

- “Exhausted vanilla beans do not constitute a legitimate article of commerce for food use in that the valuable constituents, the flavoring principles, have been omitted or abstracted therefrom. . . . Any vanilla product consisting in whole or in part of ground extracted vanilla beans would be adulterated . . . This type of adulteration cannot be corrected by any form of labeling.”

BATF, 1960.

Summary and Conclusions

If the term “vanilla” is used, FDA will review product labeling in the context of the vanilla standards at 21 CFR 169, and the ice cream standard at 21 CFR 135.

- Must meet the recipes in the standard to be labeled with the standardized common or usual names.

“Vanillin” is the common and usual name for all vanillin whether produced from lignin or with a process consistent with the definition of natural flavor at 21 CFR 101.22(a)(3).

- There is no such thing as “natural vanillin” unless derived from vanilla beans.
- In the context of vanilla products, all vanillin is artificial unless produced from vanilla beans.

Summary and Conclusions

“Categories 1, 2, and 3” Ice Cream - 21 CFR 135.110(f):

1. No artificial flavor = common or usual name of the characterizing flavor, i.e. vanilla ice cream.
2. Natural characterizing flavor (predominant) + artificial simulating it = vanilla flavored ice cream.
3. Natural characterizing flavor + artificial simulating it (predominant) OR only artificial flavor = artificially flavored vanilla ice cream.

Vanilla – Standards and Labeling Resources

Annotated index available on the FEMA website

- Collection of regulations and regulatory correspondence.

Confidential assistance available:

- Contact John Hallagan at FEMA (202.331.2333 or Hondobear@aol.com).

Thank you!