

§ 5.45

substance found within the distilled spirits, and a disease or health-related condition.

(C) *Health-related directional statement* is a type of health-related statement that directs or refers consumers to a third party or other source for information regarding the effects on health of distilled spirits or alcohol consumption.

(ii) *Rules for labeling*—(A) *Health-related statements*. In general, labels may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects on health of alcohol consumption. TTB will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement.

(B) *Specific health claims*. (1) TTB will consult with the Food and Drug Administration (FDA), as needed, on the use of a specific health claim on a distilled spirits label. If FDA determines that the use of such a labeling claim is a drug claim that is not in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, TTB will not approve the use of that specific health claim on a distilled spirits label.

(2) TTB will approve the use of a specific health claim on a distilled spirits label only if the claim is truthful and adequately substantiated by scientific or medical evidence; sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and outlines the categories of individuals for whom any levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim.

(C) *Health-related directional statements*. A statement that directs consumers to a third party or other source for information regarding the effects on health of distilled spirits or alcohol consumption is presumed misleading unless it—

(1) Directs consumers in a neutral or other non-misleading manner to a third party or other source for bal-

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anced information regarding the effects on health of distilled spirits or alcohol consumption; and

(2)(i) Includes as part of the health-related directional statement the following disclaimer: “This statement should not encourage you to drink or to increase your alcohol consumption for health reasons;” or

(ii) Includes as part of the health-related directional statement some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading impression conveyed by the health-related directional statement.

(26 U.S.C. 7805 (68A Stat. 917, as amended); 27 U.S.C. 205 (49 Stat. 981, as amended))

[T.D. 7020, 34 FR 20637, Dec. 30, 1969, as amended by T.D. ATF-62, 44 FR 71621, Dec. 11, 1979; T.D. ATF-180, 49 FR 31673, Aug. 8, 1984; 49 FR 35768, Sept. 12, 1984; T.D. ATF-198, 50 FR 8464, Mar. 1, 1985; 50 FR 23410, June 4, 1985; TTB T.D.-1, 68 FR 10104, Mar. 3, 2003]

Subpart E—Standards of Fill for Bottled Distilled Spirits

§ 5.45 Application.

No person engaged in business as a distiller, rectifier, importer, wholesaler, or warehouseman and bottler, directly or indirectly, or through an affiliate, shall sell or ship or deliver for sale or shipment, or otherwise introduce in interstate or foreign commerce, or receive therein or remove from customs custody any distilled spirits in bottles unless such distilled spirits are bottled and packed in conformity with §§ 5.46 through 5.47a.

(Sec. 5, 49 Stat. 981, as amended (27 U.S.C. 205); 26 U.S.C. 5301)

[T.D. ATF-25, 41 FR 10221, Mar. 10, 1976; T.D. ATF-146, 48 FR 43321, Sept. 23, 1983]

§ 5.46 Standard liquor bottles.

(a) *General*. A standard liquor bottle shall be one so made and formed, and so filled, as not to mislead the purchaser. An individual carton or other container of a bottle shall not be so designed as to mislead purchasers as to the size of the bottles.

(b) *Headspace*. A liquor bottle of a capacity of 200 milliliters or more shall be held to be so filled as to mislead the

purchaser if it has a headspace in excess of 8 percent of the total capacity of the bottle after closure.

(c) *Design.* A liquor bottle shall be held (irrespective of the correctness of the stated net contents) to be so made and formed as to mislead the purchaser, if its actual capacity is substantially less than the capacity it appears to have upon visual examination under ordinary conditions of purchase or use.

(d) *Exceptions—(1) Distinctive liquor bottles.* The headspace and design requirements in paragraphs (b) and (c) of this section do not apply to liquor bottles that are specifically exempted by the appropriate TTB officer, pursuant to an application filed by the bottler or importer.

(2) *Cross reference.* For procedures regarding the issuance, denial and revocation of distinctive liquor bottle approvals, as well as appeal procedures, see part 13 of this chapter.

(Sec. 5, 49 Stat. 981, as amended (27 U.S.C. 205); 26 U.S.C. 5301)

[T.D. 7020, 34 FR 20337, Dec. 30, 1969, as amended by T.D. ATF-25, 41 FR 10221, Mar. 10, 1976; 41 FR 11022, Mar. 16, 1976; T.D. ATF-62, 44 FR 71622, Dec. 11, 1979; T.D. ATF-146, 48 FR 43321, Sept. 23, 1983; T.D. ATF-406, 64 FR 2129, Jan. 13, 1999]

§ 5.47 Standards of fill (distilled spirits bottled before January 1, 1980).

(a) *Authorized standards of fill.* The standards of fill for all distilled spirits, whether domestically bottled, or imported, subject to the tolerances allowed in this section, shall be as follows:

1 gallon.	4/5 pint.
1/2 gallon.	1/2 pint.
1 quart.	1/3 pint.
4/5 quart.	1/10 pint.
1 pint.	1/16 pint (brandy only).

(b) *Tolerances.* The following tolerances shall be allowed:

(1) Discrepancies due to errors in measuring which occur in filling conducted in compliance with good commercial practice.

(2) Discrepancies due to differences in the capacity of bottles, resulting solely from unavoidable difficulties in manufacturing such bottles to a uniform capacity: *Provided*, That no greater tolerance shall be allowed in case of bottles which, because of their design, cannot

be made of approximately uniform capacity than is allowed in case of bottles which can be manufactured so as to be of approximately uniform capacity.

(3) Discrepancies in measure due to differences in atmospheric conditions in various places and which unavoidably result from the ordinary and customary exposure of alcoholic beverages in bottles to evaporation. The reasonableness of discrepancies under this paragraph shall be determined on the facts in each case.

(c) *Unreasonable shortages.* Unreasonable shortages in certain of the bottles in any shipment shall not be compensated by overages in other bottles in the same shipment.

(d) *Limitations.* This section does not apply after December 31, 1979.

(Sec. 5, 49 Stat. 981, as amended (27 U.S.C. 205); 26 U.S.C. 5301)

[T.D. 7020, 34 FR 20337, Dec. 30, 1969, as amended by T.D. ATF-25, 41 FR 10221, Mar. 10, 1976; T.D. ATF-146, 48 FR 43321, Sept. 23, 1983]

§ 5.47a Metric standards of fill (distilled spirits bottled after December 31, 1979).

(a) *Authorized standards of fill.* The standards of fill for distilled spirits are the following:

(1) For containers other than cans described in paragraph (a)(2), of this section—

- 1.75 liters
- 1.00 liter
- 750 milliliters
- 500 milliliters (Authorized for bottling until June 30, 1989)
- 375 milliliters
- 200 milliliters
- 100 milliliters
- 50 milliliters

(2) For metal containers which have the general shape and design of a can, which have a closure which is an integral part of the container, and which cannot be readily reclosed after opening—

- 355 milliliters
- 200 milliliters
- 100 milliliters
- 50 milliliters

(b) *Tolerances.* The following tolerances shall be allowed: