

product that will undergo special processing or filtration, or undergo any other process not used in traditional brewing. The use of reverse osmosis, ion exchange treatments, filtration that changes the character of beer or removes material from beer, concentration or reconstitution of beer, and freezing or superchilling of beer, are examples of processes for which you must file a formula with TTB. You are not required to file a formula for traditional brewing processes such as pasteurization, filtration prior to bottling, filtration in lieu of pasteurization, centrifuging (for clarification), lagering, carbonation, and the like.

You must currently file your formula prior to producing the fermented product at your brewery. Proposed § 25.55(c) permits you to produce certain fermented beverages for research and product development purposes without receiving formula approval. Under proposed § 25.55(c), you could not sell or market these products until receiving formula approval.

2. Filing Formulas

Under the proposed rule, you must file your formula in duplicate directly with TTB's Advertising, Labeling and Formulation Division in Washington, DC. After approval, we will return one copy to you. You may make copies of this approved formula for use at any of your breweries where the formula is valid. A copy of this formula will become part of the required records kept at any individual brewery where you make products using the formula. These proposed regulations do not require a Government form for your formula, although we are considering use of a form like ATF Form 5120.29, Formula and Process for Wine, or requiring both beer and wine formulas to be filed on this form.

Under the proposed rule, you may file one formula to cover production of a fermented product made at any brewery that you own or operate. You may not use your approved formula to cover production of a fermented product at a brewery that you do not operate, such as when you have beer produced for you under contract by another brewer. Also, when you file a formula to cover production of a fermented product at more than one of your breweries, you must identify each brewery where the formula is valid by including each brewery's name, address, and brewery registry number on the formula.

3. Information Required in Formulas

Proposed § 25.57 lists the information that you must include in a formula. This section spells out this information in

more detail than does existing §§ 25.62 and 25.67 relating to statements of process. Proposed § 25.57 also requires you to provide information required in your statements of process by Rulings 94-3, 96-1, and 2002-2.

Under the proposed rule, your formula must list each ingredient used in the production of a fermented product and the quantity of that ingredient or a range of the quantity. If you indicate use of a range of an ingredient, the range may not be so wide as to render the formula meaningless. For example, a formula that indicates use of ingredients as "water 0-100 gallons, flavors 0-10 gallons, beer base 0-500 gallons," has limited value in determining what kind of product will be made. Therefore any range of ingredients indicated in a formula must be "reasonable." We seek comment on means to quantify in the regulations what a "reasonable" range of ingredients should be.

If flavors are present in your fermented product, you must include: (1) The name of the flavor; (2) the product number, if any; (3) the name and location of the flavor manufacturer; (4) the TTB or ATF formula number and approval date, if any, of the flavor; (5) and the alcohol content of the flavor.

If you use flavors containing alcohol, or other ingredients containing alcohol, proposed § 25.57 imposes additional requirements. You must indicate in your formula: (1) The volume and alcohol content of the beer base; (2) the maximum volumes of flavors or other ingredients containing alcohol; (3) the alcohol strength of flavors or other materials containing alcohol; (4) the alcohol contribution to the finished product made by flavors and ingredients containing alcohol; and (5) the final volume and alcohol strength of the finished product. We will use this information to determine the amount of alcohol in a fermented product that is not derived from fermentation at the brewery and whether the proposed product meets the proposed definition of beer in this notice.

Under the proposed rule, you must also describe in detail any special process that you use in producing your fermented product. This information will help us to determine whether a particular process may be distillation and thus not eligible to be conducted on brewery premises. It will also help us determine the product classification of a proposed brewery product.

4. Superseding Formulas

Under proposed § 25.58, you must file a formula superseding an existing formula if you change a product's

ingredients or production process. In this case, "change" means to add a new ingredient or process, to eliminate an ingredient or process, or to change the quantity of an ingredient outside of an approved range. When you file a superseding formula you may give it the same serial number as the superseded formula, but you must indicate that it is a superseding formula, such as "Formula No. 2, Superseding, 3-04-2003." We will cancel a formula that you supersede.

5. Previously Approved Statements of Process

Your previously approved statements of process (SOP) will remain valid after the adoption of these regulations provided the finished product under the SOP is in compliance with the new requirements relating to the definition of beer in proposed § 25.15. You will not need to notify us or take any other action regarding these documents. After these regulations become effective, you must comply with the formula requirements or supercede statements of process for any new formulas that you intend to use.

C. Comments Sought on Formula Proposal

We welcome comments on the proposed regulations for the preparation and filing of formulas. We are especially interested to know if the proposed system will be easier and less confusing than the present statement of process requirement.

X. Samples

We propose to add a new section, § 25.53, regarding the submission of samples. This section recognizes our authority to require a brewer to submit a sample of a beer or an ingredient used for producing beer. We occasionally examine samples of beer or ingredients in conjunction with our review of statements of process or formulas and in order to determine the proper tax classification of fermented products. This proposal merely incorporates this existing statutory authority in our part 25 regulations.

XI. Formulas and Samples for Imported Malt Beverages

We propose amending § 7.31 by placing in the part 7 regulations our statutory authority to require an importer to submit a formula to us in conjunction with the filing of a certificate of label approval, ATF Form 5100.31. Similarly, we propose to place in the part 7 regulations our authority to require importers to submit samples of a malt beverage or samples of