translate to 13.0 grams (g) of total fat, 4.0 g of saturated fat, 60 mg of cholesterol, and 480 mg of sodium per reference amount customarily consumed, per label serving size, and for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. The regulations make additional allowances for main dish products and meal-type products. The disqualifying levels for main dish and meal products are 30 percent and 40 percent of the DV, respectively. These different levels are consistent with the legislative history, which states, ''a particular level of fat in a frozen dinner might not trigger the provision, whereas the same amount of fat in a snack food might trigger it.''

A food that exceeds the disqualifying level for any of the four disqualifying nutrients may not bear a health claim unless the agency has granted an exemption ''based on a finding that such a claim would assist consumers in maintaining healthy dietary practices.'' (Section 403(r)(3)(A)(ii) of the act.) To date, the agency has received no petitions for an exemption from this provision.

The NFPA petition requested that the defined disqualification levels be converted to disclosure levels under certain circumstances. More specifically, the petition suggested that ''the presence of one of these nutrients at the prescribed level would require disqualification *only* if the nutrient was found in another health claim regulation to be directly and adversely related to the disease mentioned in the claim.'' The petition went on to state that ''[i]f the nutrient is not so directly related to the disease to which the claim refers, the regulations would require only disclosure by an appropriate referral statement in conjunction with the health claim on the label, as the regulations now require for nutrient content claims.''

As stated in the May 11, 1995, letter to NFPA, FDA concludes that a generic change in its regulations would not be consistent with the underlying goals of the NLEA. The current disqualifying levels assist consumers in constructing total daily diets that meet dietary guidelines. The agency considered the role a food plays in the daily diet when it calculated the disqualifying levels. Health claims on foods with levels of fat, saturated fat, cholesterol, or sodium that exceed the disqualifying levels would encourage increased intake of these foods and would make it difficult for consumers to follow the Surgeon General's recommendations and to construct a healthful diet. Even with the current disqualification levels, consumers could reach the DV's for total fat, saturated fat, cholesterol, or sodium by eating as few as five foods that bear health claims.

The agency considers the current disqualification rules to be consistent with congressional intent. Congress contemplated that health claims would be reserved for those foods that can contribute to a healthful diet. As the House Report states, ''Health claims supported by a significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet.'' (See H. Rept. 101–538, 101st Cong., 2d sess. pp. 9–10 (1990).)

Nevertheless, the agency tentatively finds that there may be some instances where disclosure rather than disqualification is appropriate. While FDA continues to believe that exceptions should be granted on a case-by-case basis, using a petition process, the agency recognizes that further guidance on the criteria that it will use to evaluate petitions for exceptions would be useful. FDA is, therefore, proposing to amend its regulations to give such guidance.

Proposed § 101.70(f) provides guidance for petitioners requesting an exception to the prohibition in § 101.14(e)(3) against health claims for foods exceeding the disqualifying levels identified in § 101.14(a)(5). This proposed amendment to the petition procedures sets out some of the factors that the agency will consider when evaluating a petition.

The first factor that FDA is proposing to list is whether the risk of the disease or health-related condition is of such public health significance, and the role of the diet so critical, that disqualification is not appropriate (proposed § 101.70(f)(1)). The agency recognizes that there may be instances where extraordinary efforts are needed to address a particular public health problem. In such cases, the agency would consider providing for disclosure rather than disqualification levels.

The second factor is whether the availability of foods that qualify for a health claim is adequate to address the public health concern that is the subject of the health claim (proposed § 101.70(f)(2)). The agency intends to consider whether the application of the claim is so limited because of the disqualification levels that it will not be possible to meet the public health goal of the health claim. If only a limited number of food products qualify to bear the claim because of the disqualifying levels, the agency would consider providing for disclosure rather than disqualification levels.

The third factor that FDA intends to consider is whether there is some evidence that the population to which the health claim is targeted is not at risk for the disease or health-related condition associated with the disqualifying nutrient (proposed § 101.70(f)(3)). Although the current disqualifying nutrients are associated with diseases or health-related conditions that pose risks to the general population, there may be some categories of foods that are targeted to specific subpopulations that are not at particular risk for the disease or health-related condition associated with the disqualifying nutrient (toddlers, for example). The agency would be willing to look at data and to consider whether an exception to the disqualifying levels should be made for foods intended for such subgroups.

Related to this criterion, is the question of whether there is evidence that consumers can identify themselves as being at risk for a particular disease or health-related condition associated with the disqualifying levels. For instance, some individuals can already identify themselves as being sensitive to sodium and, therefore, would recognize the risk of a high sodium food if it were disclosed. If the ability to self-identify for these risks becomes widespread, disclosure might be sufficient to reduce the risk from the disqualifying nutrient. FDA would expect to receive data that demonstrate that this ability exists, however, before it would be willing to grant an exemption on this basis.

Finally, the agency intends to consider whether there are any other public health reasons for providing for disclosure rather than disqualification (proposed § 101.70(f)(4)). The agency does not consider the above list of criteria exhaustive. There may be other criteria that would be useful in determining whether the agency should provide for disclosure rather that disqualification levels for health claims, and the agency is open to considering such factors.

The agency requests comments on the appropriateness of these criteria.

The agency notes that there are ways to convey important health information other than through health claims. A food may still be able to bear a nutrient content claim or a structure/function claim in order to highlight a particular attribute even if it exceeds the disqualification level for a health claim. For example, while whole milk may not be able to bear a calcium and osteoporosis health claim, it can still bear a ''high calcium'' nutrient content claim, so long as the levels of fat and saturated fat are disclosed. Similarly,