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Factors to Consider in Setting Adequate Overages of Vitamins and Minerals in Dietary Supplements

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- Provide readers with general information regarding regulatory requirements on the labelled claim for dietary supplements
- Describe factors to consider in establishing adequate overages of dietary ingredients to meet regulatory requirements
- Discuss basic approaches to determine major factors that affect overages of dietary ingredients based on scientific data
- Discuss strategies to minimize overages

- Regulatory requirements on the labelled claim for dietary supplements
- IOM's Tolerable Upper Limits (UL)
- Factors affecting overages - stability, process & test variabilities
- Determination of stability losses, processing variabilities, and testing variabilities
- Determination of total overage based on scientific data
- Strategies for minimizing overages

USP Stimuli Article *PF 42(3)*

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ABSTRACT

Currently, U.S. law requires that all fortified foods, including dietary supplements, containing a Class I nutrient, e.g., vitamin, mineral, protein, or dietary fiber must contain, at minimum, 100% of the label-claimed amount of the Class I nutrient. Thus, it is important for dietary supplement manufacturers to ensure that the content of nutrients in a dietary supplement meets the requirement of 100% of the label-claimed amount throughout the shelf life of the product. Dietary supplement manufacturers typically formulate products to contain nutrients in amounts greater than the label-claimed amount (i.e., overage amounts or overages) to compensate for loss due to degradation of the nutrients during the product's shelf life, and to compensate for the inherent variability of the manufacturing process and product testing. However, it is desirable for manufacturers to minimize overages, to help prevent individuals from consuming higher amounts of nutrients than desired, especially amounts that exceed, without warning, the tolerable upper intake levels (ULs). The use of USP public quality standards, detailed in compendial monographs, can assist manufacturers in reducing overages. This *Stimuli* article discusses factors, such as nutrient degradation, analytical testing, and manufacturing process variabilities, for dietary supplement manufacturers to consider when determining overages of nutrients in products. Furthermore, this *Stimuli* article recommends several strategies, such as the use of stabilized ingredients, formulation adjustment by strength, and improved manufacturing processes, to minimize manufacturing variability that may assist manufacturers reduce nutrient overages in their products.

- **Ensure** nutrient contents meet the label claims.
- **Keep** overages below the ULs
- **Assess** stability profile and variabilities of process & testing
- **Determine** overages based on scientific data (stability & testing/process variabilities)
- **Consider** strategies for minimizing overages
- **Work** with SMEs



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Thank You