

## INS & OUTS OF INGREDIENT LABELING

### 2% or Less and Incidental Additives

Food labelers are aware that FDA regulations require that every ingredient be listed by common name in order of predominance in the final product. There are, however, circumstances that allow flexibility in this general requirement. Two scenarios for ingredient lists are: 1) ingredients in small amounts (2% of the formulation or less), and 2) incidental additives present at insignificant levels.

**Small amounts** – The 1st scenario that allows flexibility in creating the ingredient list is when there are small amounts of ingredients in the final formulation. There is a choice to either: 1) list in order of predominance like any other ingredient, or 2) at the end of the ingredient statement with a clause such as "2% or less of the following" and then list the minor ingredients in any order. Note: if the minor ingredients are even less than 2%, it is acceptable to use 1.5%, 1% or 0.5% in the clause.

There are several reasons why it could be advantageous to us the "2% or less" clause.

- Proprietary formula – Often it is strategic to keep the exact formulation concealed so that competitors cannot easily duplicate it. Using the "2% or less" clause enables the specific formulation to stay proprietary.
- Functional ingredients at varying levels – Some ingredients are used for a functional purpose, such as adjusting pH or acting as a preservative, and their levels can vary depending on the specific batch. For example, if citric acid is used to adjust pH and there are other ingredients in the 2% or less category, the "2% or less" clause enables a single ingredient statement to be used without concern for exact ingredient levels and batch-to-batch variances.
- Marketing support – For some foods, ingredients may have a somewhat negative consumer perception and detract from a brand's positioning. Using the "2% or less" clause reassures consumers that there is a very minimal amount of such ingredients in the product.

**Incidental additives** – The 2nd scenario that allows flexibility in creating the ingredient list is when there are trace amounts of ingredients in the final formulation. Per **21 CFR 101.100**, if ingredients are present in a food at insignificant levels and provide no technical or functional effect, these ingredients do not have to be listed in the ingredient statement. FDA defines incidental additives as:

- Ingredients that are incorporated in the food as an ingredient of another food; an example is alcohol in a natural flavor
- Processing aids added during processing but removed, converted to a normal constituent of the food present at normal levels, or are present at insignificant levels; a common example is a chlorine wash used on fruits and vegetables
- Substances migrating from equipment or packaging, such as canola oil used to lubricate a production line

NOTE: Incidental additives should always be included in the ingredient list when they are:

- Allergens, such as soy lecithin used as a lubricant on equipment
- Sulfiting agents at detectable levels (greater than 10ppm), such as sulfur dioxide
- Functional in the finished product, such as a preservative in another ingredient that also functions as a preservative in the finished food