Citizen Petition

Date: 09/24/2019

The undersigned submits this petition under Title 21 Part 10 Section 20 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of the Food and Drugs to amend a regulation.

A. Action Requested

In order to combat the widespread and deceptive practice of neglecting to declare the caloric value of amino acids in dietary supplements, this petition proposes the following amendment:

Amend CFR Title 21 101.36 b ii 2 (shown verbatim not bolded) to say

"Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contains only individual amino acids. **For the purposes of calorie calculations, however, individual amino acids shall be given the same Atwater factor (4 calories per gram) as protein.**"

The amendment shown bolded above will address all the arguments put forth by supplement manufacturers regarding why they think current regulations exempt them from declaring the calories in their amino acid ingredients.

B. Statement of Grounds

There is a current dietary supplement industry practice of not declaring the calorie content of amino acids. This is illogical and deceptive, and not within the spirit of the relevant regulations. Unfortunately, a few clauses within the FDA CFR Title 21 have been interpreted in a way to provide a loophole for this practice.

First, it is clear that amino acids do possess caloric value. We all acknowledge that protein contains calories; the only way for amino acids to not have calories then would be for the metabolizable energy to be within the peptide bonds themselves. This is not the case. For proteins to be utilized as energy, they must first be hydrolyzed down to individual amino acids and then deaminated to keto acids, as shown in the figure below (Palmer, Accessed 2019).

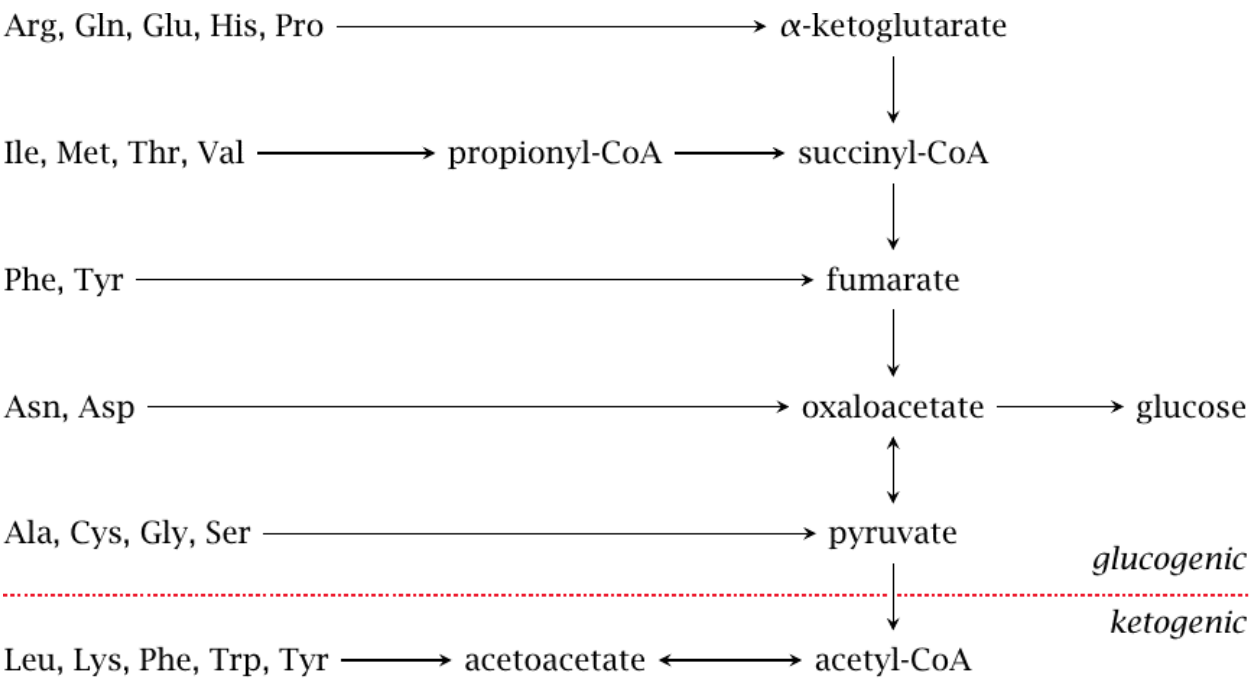


Figure 1: Utilization of amino acids for energy

Thus, if anything, free form amino acids are a better, more direct source of calories than protein. Some amino acids can be converted into tricarboxylic acid cycle intermediates, whereas some are converted into acetyl CoA (Wagenmakers , 1998). These are both sources of calories.

The perceived rationalization for declaring amino acids as zero-calorie starts with CFR Title 21 101.36 b 2. This passage has the sentence “Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contains only individual amino acids”. This passage states that free-form amino acids may not be declared as protein; it says nothing about declaring calories from free-form amino acids. This sentence had led some to claim that you cannot declare calories from amino acids. This is based on the incorrect assumption that the only way of determining calorie content is through the Atwater factors system. The Atwater’s system states that protein and carbohydrate contain 4 kcal per gram while fat contains 9 kcal per gram. If this system were the only way of determining calorie content of food and supplements, then we would be forced to declare amino acids as 0 calorie. However, according to CFR Title 21 101.9 c 1 i, Atwater’s factors are just one method of many that may be used to determine calories. In subsection E, bomb calorimetry is specifically listed as an acceptable method for calorie calculations. Bomb calorimetry data and various other calculation methods are available for amino acids (O'Hill, 1990) (Raquel, 2007) (Yang, 1999). Figures 2 shows some of the energy content data from O’Hill 1990.

Compound	Heat of combustion
	kcal/g
Alanine	4.341
Arginine	5.129
Asparagine	3.488
Aspartic acid	2.875
Cysteine	3.256
Cystine	3.015
Glutamic acid	3.646
Glutamine	4.207
Glycine	3.097
Histidine	4.851
Isoleucine	6.523
Leucine	6.524
Lysine	6.038
Methionine	4.456
Ornithine	5.493
Phenylalanine	6.723
Proline	5.681
Serine	3.308
Threonine	4.120
Tryptophan	6.588
Tyrosine	5.859
Valine	5.963

Figure 2: Heat of combustion of amino acids according to O'Hill 1990

Supplement manufacturers are given the option of using the Atwater's factors method, and thus do so in order to hide the real calorie content of their products. This is in spite of obvious inaccuracy and the fact that the regulations also allow for other, more realistic methods of calorie determination.

Finally, the requirements for a Supplement Facts panel include calories if calories are "present in measurable amounts…as specified in 21 CFR 101.9"(FDA, Dietary Supplement Labeling Guide: Chapter IV. Nutrition Labeling , 2018). Measurable amounts are defined as an "amount that exceeds the amount that can be declared as "zero" in the nutrition label of conventional foods". The loophole involves the attitude that you "may" use the Atwater's factors method, and thus you "can" declare the calorie content as 0, even though the Atwater's factors are inappropriate for isolated amino acids. There is no rational basis for not declaring the calorie content of amino acids. Amino acids are often supplemented by individuals who are acutely interested in their calorie intake and overall nutrition status, and this is something they certainly would want to be made aware of. The serving size for these products is almost always in the multiple gram amount, ensuring that they do not fall under the 5 calorie mark that may be declared as 0 on nutrition facts panels.

The only unfavorable response to the position described above is the fact that supplement facts panels for amino acid products will have to be revised, placing some obligations on the businesses involved.

References

FDA. (2018). *Dietary Supplement Labeling Guide: Chapter IV. Nutrition Labeling .* Retrieved from US FDA: https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide-chapter-iv-nutrition-labeling#4-6

FDA. (2019). FDA CFR Title 21.

O'Hill, J. (1990). Energy content of diets of variable amino acid composition. *American Journal of Clinical Nutrition*, 770-776.

Palmer, M. (Accessed 2019). *Metabolism Lecture Notes*. Retrieved from University of Waterloo: http://watcut.uwaterloo.ca/webnotes/Metabolism/AminoAcids.html

Raquel, F.-L. (2007). Estimation of the metabolizable energy equivalence of dietary proteins. *European Jornal of Nutrition*.

Wagenmakers , A. (1998). Muscle amino acid metabolism at rest and during exercise: role in human physiology and metabolism. *Exercise Sports Science Reviews*, 287-314.

Yang, X. W. (1999). Determination of combustion energies of thirteen amino acids. *Thermochimica Acta*, 109-115.

C. Environmental Impact

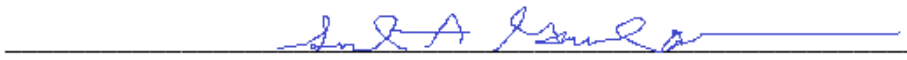
I claim categorical exclusion under 25.32 of this chapter.

D. Economic Impact

Economic impact information will be submitted upon request of the commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



_____(Signature)

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