TECHNICAL BULLETIN

SolvPro®

SolvPro® – Protein Quality Regulatory Primer

The scientific and regulatory details associated with protein quality and labeling implications in both food and supplements are very complex and need to well researched before making any new product claims.

Here is a summary of the current labeling rules for protein according to 21 CFR 101.9:

Macronutrient	Daily Value (DV)	Good Source	Excellent Source	Comments
Protein	50 grams	10-19% DV; 5.0-9.5 grams per serving, PDCAAS adjusted	>20% DV; >10 grams per serving PDCAAS adjusted	The %DV is optional and only required on the Nutrition facts panel when a qualified protein claim is made. Must be a PDCAAS of 1.0 protein to qualify for full credit in the Nutrition Facts Panel and %DV figures. There are different amino acid scoring patterns (reference standards) for determining PDCAAS, but if making any type of protein claim for food

- If your goal is regulatory compliance for U.S. Labeling, use the FDA/PDCAAS path and cite 21 CFR 101.9 and FDA guidance.
  - If you are making any qualified or regulated claims (i.e. “good” or “excellent” source, or “complete”), the FDA-recognized amino acid scoring pattern is based on the 1985/1991 FAO/WHO pattern for 2-5 year olds (except infants).

Amino Acid (g/100 g)	2007 Reference Standard Infants (birth-6 months)	2007 Reference Standard Infants (6-12 months)	2007 Reference Standard (1-2 yr olds)	1985/1991 Reference Standard (2-5 yr olds)**	1991 Reference Standard (3-10 yr olds)	1991 Reference Standard (10-18 yr olds)	2007 Reference Standard Adults (>18 Years)	2013 DIAAS Reference Standard
Histidine*	29.00	26.00	19.00	19.00	18.00	18.00	15.00	16.00
Isoleucine*	55.00	44.00	32.00	28.00	28.00	28.00	30.00	30.00
Leucine*	94.00	88.00	66.00	66.00	66.00	63.00	59.00	61.00
Lysine*	64.00	64.00	58.00	58.00	58.00	56.00	45.00	48.00
Methionine* +Cystine (SAA)	28.00	25.00	25.00	25.00	25.00	25.00	22.00	23.00
Phenylalanine* +Tyrosine (AAA)	63.00	62.00	63.00	63.00	63.00	63.00	38.00	41.00
Threonine*	34.00	32.00	34.00	34.00	34.00	34.00	23.00	25.00
Tryptophan*	11.00	11.00	11.00	11.00	11.00	11.00	6.00	6.60
Valine*	46.00	43.00	35.00	35.00	35.00	34.00	39.00	40.00
* 9 Essential Amino Acids								

  - The FDA recommends the use of amino acids residues less the molecular weight of water and in-vivo rat PDCAAS studies for digestibility.

- If your goal is scientific accuracy or an international product formulation, then use the 2007 WHO/FAO/UNU for human requirements and 2013 FAO (DIAAS) if you are applying digestibility-adjusted protein quality scoring.

The information herein is, to the best of our knowledge correct. The data outlined and statements made are intended only as a source of information. No warranties, expressed or implied are made. On the basis of this information, it is suggested that you evaluate the products on a laboratory scale prior to uses in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

SolvPro® – Protein Quality Regulatory Primer (cont'd)

- In 2007, WHO/FAO/UNU reissued adjusted guidance with new scientifically validated human adult amino acid reference standards for various age groups, but the FDA still has not changed their mandated scoring pattern.

In 2013, FAO again revisited protein quality claims and proposed a new and more accurate methodology called DIASS, with new scoring patterns and a superior way to estimate digestibility (ileal versus fecal with PDCAAS), but the FDA and Industry never moved to this new improved scientific protein quality assessment approach either.

These recommendations are based upon our protein experience and are meant to be general guidelines. Always confirm final requirements for your specific product with the regulatory authority of the target market and document your calculations.

The SolvPro® protein technical service team is available to help you identify solutions for the best utilization of our protein systems in your products. Please contact Dennis Reid at dennisr@osagefood.com or on his cell at 314-497-0920 for more information.

The information herein is, to the best of our knowledge correct. The data outlined and statements made are intended only as a source of information. No warranties, expressed or implied are made. On the basis of this information, it is suggested that you evaluate the products on a laboratory scale prior to uses in a finished product. The information contained herein should not be construed as permission for violation of patent rights.