Global Protein Regulation – A Question of Quality?

5th May 2015

Sukh Gill, Director of Global Regulatory Services

2015 Protein Trends & Technologies, Chicago USA

Introduction - Sukh Gill LIb (Hons) DTS MTSI

Business Law Graduate

Statutorily Qualified Trading Standards Professional

Over 25 years in Regulation and Compliance in Government and Industry:

- **8 years as a Trading Standards Officer/ experienced prosecutor**
- **8 years as a Trading Standards Manager for Safeway/ Wm Morrison**
- **8 years as Chief Counsel (Food & Consumer Law) - Müller Group**
- **2.5 years as Head/Director of Global Regulatory Services – Leatherhead Food Research**
- **Representative on Governmental, NGO & Trade expert working groups**
- **Council Member of the European Food Law Association EFLA(UK)**
- **Member of the BRDO's Business Reference Panel**
- **Author of professional distance learning materials on food standards for the Trading Standards Institute (TSI) Academy and University courses**
- **Part-time, pro-bono, Consumer Protection Degree Lecturer**
- **TSI - Private Sector Food Lead Support**
- **Chair of BRDO Business expert Group on Food Standards & Labelling**

Leatherhead Global Regulatory Services

Leatherhead Food Research

www.leatherheadfood.com

Comprehensive advice on global Food Law

Team of 36 multi-lingual specialist Advisors and 2 support staff, delivering:

- Member enquiries (>7,000 / year)
- Legal Highlights (weekly email alert)
- Publications including online Guides
- Regulatory training (15+ courses / year)
- Advertising and Marketing Claims support
- Confidential projects, for example:
  - Multi-lingual label checks and translations
  - Tailored training (at client's site)
  - Bespoke Consultancy projects on <u>any</u> food law issue (e.g. additive database)
- Backed-up by Leatherhead's other expert technical teams in **Food Safety, Nutrition, Innovation, and Consumer & Market insight**

Global Regulatory Expertise

Leatherhead Food Research

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- Nutrition and Health Claims
- Food and Nutrition Labelling
- Novel Foods
- Food Additives
- Flavourings
- Enzymes and Processing Aids
- Food Supplements
- Foods for Special Groups
- Pesticides
- Contaminants
- Food Contact Materials
- Food Safety and Hygiene
- Advertising Codes and Ad Clearance
- Enforcement, Litigation support, Incident management and risk assessment

The 2011 FAO Expert Consultation on Protein Quality

Primary task of Consultation was to provide FAO with tools for addressing practical questions on matters such as:

- the adequacy of food supplies,
- targets for food and nutrition policy and
- the norms to be applied in labelling and regulation of protein quality for normal populations,
- as well as providing a perspective on the potential role for protein with respect to health, well-being and clinical conditions at various stages of the life course.

Why is Protein Quality an issue ?

- ***"The match between dietary supply and human protein needs is vital to support the health and well-being of human populations."* – 2011 FAO Report**
- **Regulatory provisions around the globe take inconsistent approaches to defining the amount and quality of protein supplied by dietary sources of protein**
- **Where over-simplified regulatory approaches have been taken to food information and claims criteria, these may:**
  - not support informed choice at a basic level to meet nutritional needs
  - Be a threat to a level playing field for making marketing claims based on Protein
- **As resources become scarce, policies will need to prioritise the dietary sources of protein that best deliver against population needs**

The “static” European approach

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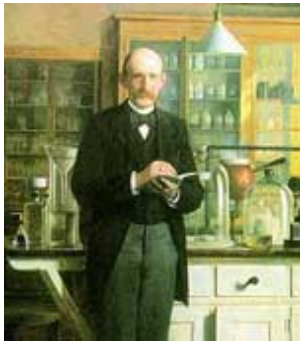

The “static” European approach

Nitrogen and protein content in foodstuffs – the nitrogen conversion factor

Proposed conversion factors for different proteins accounting for variations in the nitrogen content of different proteins/amino acids		
Dietary Source	Jones, 1941; Leung et al., 1968; Pellett and Young, 1980	Conversion factors based on the amino acid composition of a protein have been proposed to define more accurately the true protein content of different foodstuffs (AFSSA, 2007; SCF, 2003)
milk and milk products	**6.38**	**5.85**
Fish and Eggs		**5.6**
other animal products	**6.25**	
wheat	**5.83**	
legumes		**5.4**
soy protein	**5.71**	
default conversion factor		**5.6**

Over-simplification ?

Dietary proteins
supplying the body with

nitrogen (N) **amino acids**

used to synthesise and maintain

25,000 proteins encoded within the human genome

other non-protein metabolically active nitrogenous substances:
e.g. peptide hormones, neurotransmitters, nucleic acids, glutathione or creatine

deamination

and their carbon skeleton is used

in different metabolic pathways **or** **as an energy substrate**

Over-simplification ?

- non-protein fraction of the total nitrogen content of a food will influence the calculated crude protein content.
- The choice of conversion factors depends on the objective:
  - e.g. a product's capacity to supply nitrogen where a single coefficient is enough

  versus,

  - a product's potential to supply amino acids, where the use of specific coefficients based on amino acid-derived nitrogen content is more relevant.

Over-simplification ?

Indispensable amino acid composition and digestibility are key

"The **nutritional value of dietary proteins** is related to their ability to satisfy nitrogen **and** amino acid requirements for tissue growth and maintenance. According to current knowledge this ability mainly **depends on the digestibility of protein and amino acids, and the dispensable and indispensable amino acid composition** of the proteins."

SOURCE EFSA P.10, Para 2.3. Scientific Opinion on Dietary Reference Values for protein, EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) European Food Safety Authority (EFSA), Parma, Italy, published on 05 February 2015, replaces the earlier version published on 09 February 2012 **(my emphasis in bold**)

Over-simplification?

Twenty of the naturally occurring amino acids are so-called proteinogenic amino acids which build proteins in living organisms			
Indispensable* (in humans)		Dispensable****	
Strictly Indispensable**	Indispensable*	Conditionally Indispensable***	Dispensable****
lysine, threonine	histidine, isoleucine, leucine, methionine, phenylalanine, , tryptophan, and valine	arginine, cysteine, glutamine, glycine, proline, tyrosine, aspartic acid	alanine, asparagine, glutamic acid, and serine
(*cannot be synthesised in the human body from naturally occurring precursors at a rate to meet the metabolic requirement; ** they are not transaminated and their deamination is irreversible; *** limiting under special physiological or pathological conditions; ****can be synthesised)			

Over-simplification ? Digestibility

The Protein efficiency ratio (PER)

- From 1919 until 1993 (in the US) the Protein efficiency ratio (PER) had been used as a method for evaluating the quality of protein in food.
- PER is based on the weight gain of a test subject divided by its intake of a particular food protein during the test period.
- PER = Gain in body mass(g)/ Protein intake (g)
- Limitations: no direct cognisance of Amino acid composition of the foodstuff
- In 1993, a more sophisticated PDCAAS rating was adopted by the US FDA

Over-simplification ? Digestibility

Protein Digestibility Corrected Amino Acid Score (PDCAAS)

- Measure of protein quality based on, both:
  - the amino acid requirements of humans; and
  - their ability to digest it.
- The PDCAAS rating was adopted by the US FDA and the FAO/WHO in 1993, for Regulatory purposes, but **not to date, by the EU**.
- PDCAAS % = [mg of limiting amino acid in 1 g of test protein / mg of same amino acid in 1 g of reference protein] x faecal true digestibility percentage
- A PDCAAS value of 1 is the highest, and 0 the lowest.
- The maximum score is truncated to 1, even if its higher
- Whilst an improvement on Nitrogen factors, alone even PDCASS has some significant limitations

Over-simplification?

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Example of values for Protein Digestibility-Corrected Amino Acid Score (PD-CAAS) values of different foods for adults		
DIETARY SOURCE	PD-CAAS (%)	Limiting amino acid(s)
Animal sources		
Egg	>1.0	-
Milk, cheese	>1.0	-
Meat, fish	>1.0	-
Vegetable sources		
Soy	~0.95	Met+Cys
Beans	~0.7- 0.75	Met+Cys
Rice	~0.65	Lys
Wheat	~0.5	Lys
Maize	~0.5	Lys

(Source EFSA, adapted from: AFSSA, 2007; Michaelsen et al., 2009; WHO/FAO/UNU, 2007))

PDCAAS, still over-simplification ?

- Combinations of Foods with low (even 0) PDCAAS components could nevertheless have a positive PDCAAS
- Should we then consider from a whole diet rather than a single food perspective?
- For nutrition labelling whole diet approach makes sense
- From a marketing perspective, claims are made on single foods
- Questions remained on:
  - whether the true ileal digestibility is preferable to the feacal measure
  - the validity of truncating the PDCAAS values given that the current measure allows proteins with different amino acid profiles to all score 1.0
- limits its usefulness as a comparative tool.
- Different compositions = different performance = different scores ?
- Could current claims in the market be misleading ?

EU vs US – Nutrition labelling

EU	US
'protein' means the protein content calculated using the formula: protein = total Kjeldahl nitrogen × 6.25; **No explicit regulation regarding Quality**	Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content …… **except when the official procedure for a specific food requires another factor.** **QUALITY MATTERS:** Allows for correction for specific nitrogen factors and digestibility. Also protein quality value thresholds apply to: protein digestibility-corrected amino acid or Protein Efficiency Ratio (PER) scores triggering the statement: **"not a significant source of protein"** if not met

EU vs US – Protein Claims

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Claim	US Requirements	EU Requirements
"High," "Rich In," or "Excellent Source Of"	Contains 20% or more of the DV per RACC. May be used on meals or main dishes to indicate that the product contains a food that meets the definition, but may not be used to describe the meal. 21 CFR 101.54(b)	A claim that a food is high in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20 % of the energy value of the food is provided by protein.
"Good Source," "Contains," or "Provides"	10%-19% of the DV per RACC. These terms may be used on meals or main dishes to indicate that the product contains a food that meets the definition but may not be used to describe the meal. 21 CFR 101.54(e)	A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 12 % of the energy value of the food is provided by protein.
"More," "Fortified," "Enriched," "Added," "Extra," or "Plus"	10% or more of the DV per RACC than an appropriate reference food. May only be used for vitamins, minerals, protein, dietary fiber, and potassium. 21 CFR 101.54(e)	Depends on whether the semantics used categorise the claim as “High” or “Source” of

FAO recommendations for the future (1)

- In dietary protein quality evaluation treat dietary amino acids as individual nutrients
- (wherever possible) data for digestible or bioavailable amino acids should be given in food tables on an individual amino acid basis.
- A new protein quality measure (digestible indispensable amino acid score) - DIAAS is recommended to replace PDCAAS.
- DIAAS is defined as:
- DIAAS % = 100 x [(mg of digestible dietary indispensable amino acid in 1 g of the dietary protein) / (mg of the same dietary indispensable amino acid in 1g of the reference protein)].
- Concluded that on balance ileal protein or amino acid digestibility, i.e. determined at the terminal ileum at the end of the small intestine, is considered to better reflect the amounts of amino acids absorbed and should be used in calculating DIAAS.
- Digestibility should be based on the true ileal digestibility of each amino acid preferably determined in humans

FAO recommendations for the future (2)

- It is recommended that for foods susceptible to damage from processing, ‘reactive’ rather than ‘total’ lysine contents and the true ileal digestibility of reactive lysine (lysine availability) rather than of total lysine, be determined and used in the calculation of DIAAS.
- Recommended amino acid scoring patterns (i.e. amino acid pattern of the reference protein) to be used for calculating DIAAS are as follows:
- Infants (birth to 6 months), pattern of breast milk (as noted in Tables 4 and 5 of the 2011 report).
- Young children (6 months to 3 y), pattern for the 0.5 y old infant (as noted in Table 5 of the 2011 report).
- Older children, adolescents and adults, pattern for the 3 to 10 y old child (as noted in Table 5 of the 2011 report.

FAO recommendations for the future (3)

For regulatory purposes:

- two scoring patterns are recommended:
  - the amino acid composition of human milk for infant formulas, and
  - for all other foods and population groups the pattern for young children (6 months to 3 y) as noted in Table 5 of the 2011 report.
- In calculating DIAAS the ratio should be calculated for each dietary indispensable amino acid and the lowest value designated as the DIAAS.
- DIAAS can have values below or in some circumstances above 100% - these should not be truncated except where calculating DIAAS for protein or amino acid intakes for mixed diets or sole source foods.
- Currently available data are insufficient to support the application in practice of true ileal amino acid digestibility in the calculation of DIAAS.

FAO recommendations for the future (4)

For regulatory purposes:

- More data on the true ileal amino acid digestibility of human foods are urgently needed, determined in humans and animal models.
- Until such time as an agreed dataset of true ileal amino acid digestibility for human foods becomes available, the protein quality of human foods and diets should be assessed using DIAAS, but values for faecal crude protein digestibility should be used.
- In the interim, digestible individual dietary amino acid values should be calculated using faecal crude protein digestibility values applied to dietary amino acid contents.
- If resources are not allocated to fulfil the latter proposed research objectives in a timely manner, then the present recommendation for the application of DIAAS in practice may need to be reviewed

The future for Protein claims ?

Table 6. Example of the use of DIAAS for protein quality assessment in the context of making claims:

Food	Amount	Protein content (g/100g)	DIAAS[1]	Judged quality	Eligible for claim based on quantity	Eligible for claim based on quantity and quality
Wheat	100 g	11	40	Low	Yes, high	No, none
Peas	100 g	21	64	Low	Yes, high	No, none
Whole milk powder	100 g	28	122	High	Yes, high	Yes, High

Footnote 1 to table: DIAAS calculated using true ileal indispensable amino acid digestibility values and reference amino acid pattern for child (6months to 3 years).

Could claims be misleading now ? (1)

Article 3 NHCR (EU) - General principles for all claims

Nutrition and health claims may be used in the labelling, presentation and advertising of foods placed on the market in the Community only if they comply with the provisions of this Regulation….the use of nutrition and health claims shall not:

(a) be false, ambiguous or misleading;

(b) give rise to doubt about the safety and/or the nutritional adequacy of other foods;

(c) encourage or condone excess consumption of a food;

(d) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general…

(e) refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations.

Could claims be misleading now ? (2)

Article 7, EU1169/2011 -Fair information practices

"1. Food information shall not be misleading, particularly:

(a) as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production;

(b) by attributing to the food effects or properties which it does not possess;

(c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients;

(d) by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient.

2. Food information shall be accurate, clear and easy to understand for the consumer…"

Could claims be misleading now ? (3)

Approved EU Health Claims for protein:

- **Protein is needed for normal growth and development of bone in children.**
- **Protein contributes to a growth in muscle mass**
- **Protein contributes to the maintenance of muscle mass**
- **Protein contributes to the maintenance of normal bones**
- **The claims may be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation (EC) No 1924/2006.**

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Thank you for your time

SUKH GILL
sgill@leatherheadfood.com
+44(0)7771547714