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Nutrigenomics, harmonisation and health claims

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The promise of the 2006 Nutrition and Health Claims Regulation (NHCR) is a high level of consumer protection in relation to claims made on food and supplements. For industry the upcoming European Union (EU) register of claims offers hitherto unparalleled marketing access across all member states. Additionally the five-year proprietary data claims will reward investment in research and innovation- although it is not clear what non-publication of industry-funded research may have more widely, particularly in the industry-academia relationship. While the European Food Safety Authority (EFSA) whittles down applications for approved Article 13 (structure/function) claims, and reviews the first applications for Article 14 (disease risk-reduction or children's health) claims, fault lines may be developing in the foundations on which the European Register of Claims is based and threaten its long-term sustainability.

Nutrigenomics is the science which looks at the effect of diet and dietary chemicals on the genome, and includes a subdiscipline, nutrigenetics, where gene variants dictate response to, and requirements from, diet. The emerging degree of inter-ethnic and inter-individual variation represents a challenge to a pan-EU register of health claims whose legitimacy is based on the premise that a healthy, balanced diet will provide a healthy person all the nutrients they need - and that there is no reason why nutritional recommendations should not apply to all EU citizens equally.

However, leading nutrition scientists have been voicing concerns for some while. In 2002 Artemis Simopoulos of the Centre for Genetics, Nutrition and Health in Washington DC said "there may be no such thing as a 'normal' population with respect to nutrient requirements, as was assumed when dietary reference values were established", and "...populations should not copy each other's dietary recommendations for the prevention of coronary artery disease, and cancer, or any other disease for that matter" (Simopoulos 2002). The nutrition community has admitted that there is not now the information needed for setting dietary recommendations with confidence at the group level (Arab 2004), and the EFSA

expert working group on food-based dietary guidelines advised in 2007 that recommendations could not be set at the European level but "at most at the national level, and even then that special population groups needed to be considered" (EFSA 2007). In the US too, the problems have been identified. In November 2006 in Washington DC at a workshop organised by the US Institute of Medicine (IOM), the IOM President Fineberg spoke about the challenge facing the public health paradigm: "It is not just possible but likely that there are nutrients that affect some population groups differently than others, and public health guidelines will have to take such differences into account...A public health paradigm of universal education is going to have to be adapted to the scientific reality and scientific knowledge as it develops and unfolds" (Yaktine and Pool 2006).

Nonetheless harmonisation work commissioned by the EU to underpin its public health and regulatory programmes continues apace, including the EuroFIR and EURRECA projects. EuroFIR (www.eurofir.net) is a partnership of 48 universities, research institutes and SMEs from 26 European countries to provide a comprehensive food information resource which will underpin all food and health research in Europe. It recently published a synthesis report on nutrition and health claims (Aisbitt 2007) which failed to make any mention of advances in nutrigenomic science and their potential impact. Parallel work on setting micronutrient recommendations across the EU is being carried out by EURRECA (www.eurreca.org). It recently set out its roadmap for developing a toolkit which will include working with the European Nutrigenomics Organisation (Nugo; www.nugo.org) to create a database of 'nutritional phenotype' characteristics which may be correlated with micronutrient status (Ashwell et al. 2008). Scientists in the US and Australia have published on variation and micronutrient intake based on the premise that optimal levels are those that minimise DNA damage and mitochondrial decay, which may vary considerably between individuals (Ames et al. 2002; Ames 2003; Fenech 2005).

For macronutrients, too, there is evidence of inter-individual and inter-ethnic variation:

* The success of low energy diets to reduce body weight may be dependent on inter-individual genetic variation: perilipin is a protein found in adipocytes and evidence suggests that those carrying the PLIN11482A variation are resistant to weight loss on a calorie-restricted diet (Corella et al. 2005).

* For women participating in the Framingham Study, a gene-diet interaction has been found between polyunsaturated fat intake and the APOA1 -75G/A variation. Carriers of the A allele had higher HDL-C (good cholesterol) with higher polyunsaturated fat (PUFA) intake (>8% energy from fat), whereas the G/G homozygotes had lower HDL-C associated with higher PUFA intake (Corella and Ordovas 2005).

Phenotype assessment tools may also vary: the classification and cut-off points for body mass index were established for people of European descent and their use as a basis for regulation would be discriminatory in terms of race/ancestry (Deurenberg et al. 2002; Razak et al. 2007).

As the NHCR applies not only to food labelling and advertising but also to health professionals (if they promote products and induce behaviour change), its full implementation may be controversial and subject to legal challenge when criminal penalties are earned. The Commission may in hindsight wish it had not objected to the European Parliament's preference for a simple notification scheme for structure/function claims. If the promise of nutrigenomics is to be realised for personal health, then a flexible system of regulation needs to be developed lest innovation is stifled.

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