



HEALTH GRAIN

Final HEALTHGRAIN conference

Health statements and claims for
cereal grain products in Europe:
success factors and perspectives

David P. Richardson

DPR Nutrition Ltd

Lund

7th May 2010



Outline

- EFSA scientific opinion on Food-Based Dietary Guidelines (FBDG)
- EFSA draft scientific opinion on risk-benefit assessment of foods (FBDG)
- European Regulation on nutrition and health claims
- Building a successful health claims dossier
- Opportunities for communicating the benefits of cereal grain products



EFSA scientific opinion on establishing Food-Based Dietary Guidelines (FBDG). *EFSA J* (2010) 8(3), 1460

STEPWISE APPROACH:

1. Identification of diet-health relationships
2. Identification of country-specific diet-related health problems
3. Identification of nutrients of public health importance
4. Identification of foods relevant for FBDG
5. Identification of food consumption patterns
6. Testing and optimising of FBDG
7. Graphical representations of FBDG



EFSA scientific opinion on FBDG, 2010

- FBDG are intended primarily for consumer information and education.
- Benefits could be expected from the improvement of food consumption patterns for wellbeing, long-term health of individuals and populations and thus for health cost savings.
- Science-based policy recommendations and guidelines
- FBDG are only related to a number of basic food groups.
- Implementation should involve all stakeholders.
- FBDG should be comprehensible, short, simple, clear and easily memorable.
- Not feasible to establish detailed and effective FBDG for use at EU level.



EFSA scientific opinions on FBDG, 2010

- **FBDG**: Identification of diet-health relationships using WHO/FAO 2003 classification of strength of evidence—**CONVINCING, PROBABLE, POSSIBLE** and **INSUFFICIENT**
- **DIETARY FIBRE**: In relation to optimal bowel function, reduction of CVD risk and sustained weight reduction in overweight subjects because of its satiating effect
- **INADEQUATE INTAKES OF DIETARY FIBRE IN EU MEMBER STATES**
Acceptable Intake is 25 g/day based on laxation—EFSA (2010)
- **CEREAL PRODUCTS**: Important sources of energy (26%), protein (21%), fat (13%), carbohydrates (41%), dietary fibre (45%) —based on Irish consumption data



Commentary on EFSA scientific opinion on establishing FBDG, 2010

- Focus on fruit and vegetables
- One mention of 'wholegrain'
- Dutch recommended amounts for all groups of basic foods resulted in provision of various micronutrients but not enough energy: the energy gap was filled from non-basic food groups.
- Very conservative and traditional messages
- Monitoring implementation by activities such as number and contents of leaflets, booklets and government advertising campaigns
- Use of labels and logos on food products received one mention.



Draft EFSA scientific opinion: guidance on human health risk-benefit assessment of foods, April 2010

Four steps for BENEFIT ASSESSMENT:

1. Positive health effect identification
2. Positive health effect characterisation (dose-response assessment)
3. Exposure assessment
4. Benefit characterisation



Draft EFSA scientific opinion: guidance on human health risk-benefit assessment of foods, April 2010

Definition of benefit: probability of a positive health effect and/or probability of a reduction of an adverse effect

Sources of evidence: currently available/state of the art, epidemiological and nutritional data; focus on RCTs

Level of evidence required: 'convincing' according to Regulation 2004/2006

Metrics: DALYs, QALYs, 'hard' validated biomarkers





HEALTH GRAIN European Regulations on Nutrition & Health Claims 1924/2006 & 353/2008

Major impacts on:

- Existing and new product claims and formulations/recipes
- All commercial communications, e.g. labelling, advertising, websites, point-of-sale literature
- Marketing and R & D strategies
- Academic research
- Codex & international regulatory developments/USA/ASEAN/China/Japan



EFSA NDA Panel assessments (STEP 1)

Consider the extent to which:

- The food/constituent is defined and characterised
- The claimed effect is defined and has a beneficial nutritional or physiological effect ('beneficial to human health')
- A cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use)

Reference: Technical Report of EFSA: *EFSA Journal* (2009) 7 (11): 1386



EFSA NDA Panel assessments (STEP 2)

If a cause and effect relationship is considered to be established, whether:

- The quantity of food/pattern of consumption required to obtain the claimed effect can reasonably be consumed within a balanced diet.
- The proposed wording reflects the scientific evidence.
- The proposed wording complies with the criteria for the use of claims specified in the Regulation.
- The proposed conditions/restrictions of use are appropriate.





HEALTH GRAIN
Briefing document for MS and EC on the evaluation of Article
13.1 health claims (*EFSA Journal* (2009) 7 (11): 1386, published
19/11/2009)

The outcome of each assessment has one of 3 possible conclusions:

- A cause and effect relationship has been established between the consumption of the food/constituent and the claimed effect (i.e. claim is substantiated by generally accepted scientific evidence).



- The evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect (i.e. the evidence is not conclusive—emerging evidence, conflicting evidence: the claim is not substantiated by generally accepted scientific evidence).



- A cause and effect relationship is not established between the consumption of the food/constituent and the claimed effect (i.e. at most, limited scientific evidence).



Reasons for rejection by EFSA

- ◆ The foods/food constituents were not sufficiently characterised.
- ◆ Effects of food matrix, processing & stability information, bioavailability & content variability not sufficiently characterised
- ◆ A cause and effect relationship was not established between the food/food constituent & the claimed effect.
- ◆ Lack of systematic literature review and no specific inclusion/exclusion criteria
- ◆ Criticism of study designs, absence of power calculations, insufficient information on background diet & lifestyle, failure to describe target group, intervention trials lacking, no lowered risk factor/no measurable effect
- ◆ Patient (clinical studies) not used as evidence for health effects in general population





Examples of well established nutrient function claims:

Vitamin A Normal function of immune system; maintenance of normal vision

Vits B₁, (thiamin), B₁₂, niacin, pantothenic acid
Normal energy-yielding metabolism

Vitamin C Protection of DNA, proteins and lipids from oxidative damage

Calcium & vitamin D
Needed for maintenance of normal bones at all ages

Folate Normal blood function; normal maternal tissue growth during pregnancy

Iron Normal formation of red blood cells and haemoglobin; oxygen transport



YES: EFSA scientific opinion on Article 13.1 health claim related to beta-glucans and maintenance of normal blood cholesterol concentrations

- Opinion applies to beta-glucans naturally present in foods and those added to foods (oat and barley beta-glucan).
- Beta-glucans are sufficiently characterised.
- Maintenance of normal blood cholesterol is beneficial to health.
- Amounts of at least 3 g/day have shown statistically significant decreases in LDL cholesterol in both normocholesterolaemic and hypercholesterolaemic subjects.
- Cause and effect has been established (2 meta-analyses with 20 and 25 studies, respectively).



Oat claims

USA

“Soluble fibre from foods such as oat bran as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease.”

UK

“The inclusion of oats[†] as part of a diet low in saturated fat and a healthy lifestyle can help reduce blood cholesterol.”

[†] includes oat bran, rolled oats and whole oat flour

Sweden

“A nutritionally balanced diet high in soluble fibres from oats (beta-glucans) can contribute to lower cholesterol levels in the blood and thereby to a reduced risk of cardiovascular disease/atherosclerosis/hardening of the arteries. Product Z is high in soluble oat fibres.”

EFSA

“Regular consumption of beta-glucans contributes to maintenance of normal blood cholesterol concentrations



YES: EFSA scientific opinion on Article 13.5 health claims related to water-soluble tomato concentrate (WSTC) and platelet aggregation

- Application from PROVEXIS NATURAL PRODUCTS LTD on Fruitflow®
- WSTC is lycopene free, fat free, low sugar; 37 constituents identified to show inhibition of platelet aggregation. WSTC is sufficiently characterised.
- Maintenance of normal platelet aggregation is beneficial to health.
- Achievement of claimed effect, 3 g WSTC I or 150 mg WSTC II in up to 250 ml of fruit juices, flavoured water or yogurt drinks
- Cause and effect has been established based on 3 published studies (all RCTs) and 5 unpublished human studies (including 3 RCTs).





HEALTH GRAIN

Provexis Natural Products Ltd –Fruitflow®

Article 13.5 health claim: on the beneficial effect of water-soluble tomato concentrate (WSTC)

- **Applicant's proposed wording**

“Helps to maintain a healthy blood flow and benefits circulation”.

- **EFSA comments** (*EFSA Journal* (2009) 1101, 1-15)

The following wording reflects the scientific evidence: “Helps maintain normal platelet aggregation”. “Blood flow” and “healthy circulation” do not reflect the scientific evidence.

- **European Commission Decision, 17th December 09**

WSTC helps maintain normal platelet aggregation, which contributes to healthy blood flow.



Building a successful health claims dossier

- Read and understand the EU legislation 1924/2006, 353/2000 and 116/2010.
- Make use of available guidance documents:
 - Scientific and Technical Guidance for the preparation and presentation of the application for authorisation of a health claim. *EFSA Journal* (2007) 530, 1-44.
 - EFSA Frequently Asked Questions (FAQs), June 2009
 - EFSA Technical Report. *EFSA Journal* (2009) 7 (11), 1386
- Analyse EFSA opinions for Articles 13.1, 13.5 and 14.
- Critically review all the available data and your own data.
- Understand the process and roles of the national competent authorities, EFSA, European Commission.
- Marketing research to communicate benefits that are scientifically justifiable



Challenges to researchers

- ➡ Ample nutrition science is available but not necessarily designed to fit the purpose of substantiating health claims, leaving gaps & uncertainties in the final assessments.
- ➡ Need for development of methodologies for dietary interventions and heightened scrutiny of human studies & clinical trial designs, execution & interpretation
- ➡ Greater onus on peer review system for published literature with appropriate standard of rigour applied
- ➡ Development of a scientific and management framework for weighing the evidence



PR/Media

New Nutrition Business (Dec 2009/Jan 2010) 15 (3): **TEN KEY TRENDS IN FOOD, NUTRITION AND HEALTH—2010 AND BEYOND**

- Digestive health: dietary fibre, prebiotics
- Intrinsic health benefit: naturally healthy foods
- Feel the benefit: gut health, bloating, transit time
- Energy: energy is good, calories are bad!
- Superfoods: fruit → whole grain
- Antioxidants: all negative opinions
- Weight management: fibre, satiety
- Healthy snacking: convenient, no change in eating habits
- Innovative packaging: single serve
- Bones and movement: calcium fortification



HEALTH GRAIN: Key questions

- What would be the net health impact of a specified change in the diet, e.g. a public health intervention, innovative products or a change in consumer preference?
- Should there be a specific European-wide guideline for consumption of whole grain?
- Should there be greater communication that cereal grains are the foundation of a healthy diet?
- Should the definition of whole grain be expanded to provide product identifiers and logos?
- How to gain support of government agencies/member states/academics/health organisations/media/industry for FBDG to promote cereal grains?



David P. Richardson

DPR Nutrition Limited

Website www.dprnutrition.com

E-mail info@dprnutrition.com

Tel/fax: +44 (0)20 8654 3097