Marketing Opportunities for Functional Meat within the European Regulatory Framework - Case study: Enrichment of meat with Sel-Plex®

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Abstract - **In December 2006 EU decision makers adopted a Regulation on the use of nutrition and health claims for foods which lays down harmonised EU-wide rules. This study examines the process of scientifically substantiating various types of nutrition and health claims and describes the market opportunities that exist for nutritionally improved meat. The case study presented describes how meat when enriched with Sel-Plex® via animal feed can carry claims relating to immunity, antioxidant activity and thyroid function. While the process of scientifically substantiating claims on food can use up numerous resources in individual companies there are opportunities for the meat industry to differentiate by using non-holder specific claims. In the case of Sel-Plex®, when it is added to animal feed the benefits are two-fold in terms of both animal performance and food quality. In an environment where many claims are being rejected due to lack of scientific evidence, this study clarifies the requirements of the nutrition and health claims legislation in Europe and describes the opportunities that exist for the meat industry.**

Keywords – **Selenium, Value-added, Regulation**

1.INTRODUCTION

In April 2011, the first WHO Global status report [1] on non-communicable diseases (NCDs) revealed that the leading international causes of death are NCDs, such as cardiovascular disease, cancer, respiratory diseases and diabetes. Compounding the challenges associated with NCDs is the shift in the population profile towards one with an increasing proportion of older adults [2]. Such demographics and socio-economic changes have created a large market of people who want to stay healthier for longer. Indeed, 'health' continues to be a mega global food trend [3]. This opens up opportunities for the food industry to add value to their products and enter the market with new health propositions, such as functional foods. Functional foods command premium prices, as demonstrated by the difference in cost per litre of conventional yogurt (€1/L) and yogurt with added 'functionality' (~€4.50/L) [4]. In the US, functional foods accounts for more than $27 billion in annual sales and have a significantly higher predicted future growth range (8.5 to 20 %/year) than the industry as a whole (1 to 4%/year) [5]. By 2006, the European market was estimated to be ~ 15 billion US$ [6].

2. REGULATIVE ENVIRONMENT

In order to harmonise EU-wide rules, protect consumers from misleading claims on food, and ensure a level playing field for all actors in industry, the European Commission adopted Regulation (EC) No 1924/2006 [7] on the use of nutrition and health claims for foods (termed 'The Regulation' hereafter). The Regulation aims to ensure claims made on food products in the EU are clear, understandable to consumers and scientifically substantiated. In accordance with the Regulation claims must not:

- Be false or misleading
- Give rise to doubts about adequacy of other foods
- Encourage excessive consumption of foods
- Suggest or imply that a balanced diet would not provide adequate quantities of food
- Give rise or exploit fear in consumers about changes in bodily functions
- Suggest a food can prevent, cure or treat a disease.

A nutrition claim states or suggests that a food has particular beneficial nutritional properties (*e.g.* "low fat", "source of fibre"). In contrast, a health claim is "any message or representation that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health" [8] (see table 1 for the different types of health claim).

After the Regulation was introduced a list of 44,000 claims was supplied by the Member States to the European Food Safety Authority (EFSA). This list was consolidated to a list of 4,637 claims. To date 2,189 claims have been assessed in four batches, approximately 15% of which have received positive opinions from EFSA (table 2).

Table 1 Types of health claims as categorised in accordance with EU Regulation 1924/2006

Claim category	Claim type
Article 13.1 (a)	Importance of a nutrient or other substance for growth, development and functions of the body
Article 13.1 (b)	Psychological or behavioural functions
Article 13.1 (c)	Slimming or weight control or a reduction in hunger, increase in satiety or reduction in intake of energy due to consumption of the food
Article 13.5	Based on newly developed scientific evidence
Article 14	Children's development and health Reduction of disease risk

Source: Lalor *et al.* (2009)[9]

Table 2 Approval of claims submitted to EFSA to date

Date	Claims assessed	Favourable approval (%)
Oct 2009	523	174 (33%)
Feb 2010	416	9 (<1%)
Oct 2010	808	75 (9%)
April 2011	442	21(5%)

In order to achieve a positive opinion, from the Dietetic Products, Nutrition and Allergies panel (NDA), on a health claim a number of steps are involved. Most importantly, a food must show a beneficial cause and effect relationship between consumption and the claimed effect and to do this, the active ingredient must be well characterised. Following this, the biological relevance of the claimed effect on human health must be assessed (*e.g.* opinion on "reduction in cholesterol levels" was positive, whereas "increases serenity" was negative as it was deemed insufficiently defined) [8]. Next, only full versions of studies that the NDA deems pertinent to the claim are assessed for scientific rigor. Human intervention studies are required, and animal studies can be used as supporting evidence in order to clarify mechanisms involved [10]. Within the human studies, the study group must represent the intended target group for the product. EFSA also require strict monitoring of any changes made to lifestyle and nutrition over the course of any intervention study. The dosage required must be in line with patterns of consumption (*i.e.* a quantity reasonably expected to be consumed). In terms of 'biological relevance', validity and analytical suitability of the markers used to assess beneficial outcome must be defined (*e.g.* the validity of the following markers was questioned: "premature skin ageing", "mental energy" and "women's health"). Studies must be scientifically rigorous; randomised and controlled where possible. Sample sizes greater than 100 are encouraged, particularly when applying a claim to the general population [8]. High drop-out rates; the absence of power calculations; inappropriate stratification of data and failure to account for multiple effects, have all influenced the rejection of claims [11]. In essence, EFSA has declared that there is no pre-agreed formula for how best to approach the process and all applications are examined on a 'case-by-case' basis. The level of rejection of health claims has significant implications for the market place, with the few positively approved claims achieving considerable media attention and increased consumer confidence [12].

3. CASE STUDY: ENRICHMENT OF MEAT WITH SEL-PLEX®

A. The importance of selenium in the diet

Selenium is of fundamental importance to human health [12]. It is integral to the glutathione peroxidises (GPx1, GPx2, GPx3, GPx4), and to other antioxidant compounds and systems (thioredoxin reductases, selenoprotein P, prostrate epithelia selenoprotein, DNA-bound spermatid selenoprotein), which protect cells by removing hydrogen peroxide and other harmful compounds. In addition, it has a role in thyroid function, being involved in production and regulation of T3 and T4 [12]. High levels of selenium have also been found in immune tissues, such as the liver, spleen and lymph nodes [13].

Overt selenium deficiency has been linked to Keshan's disease (congestive cardiomyopathy) [14] and Kashin-Beck disease (deforming arthritis) [12]. However, less overt selenium deficiency can also

negatively influence disease susceptibility and optimal health levels. Furthermore, a significant weight of scientific evidence now links oxidative damage and low antioxidants levels to age-related and neurodegenerative diseases [15,16,17].

Although selenium is sourced mainly from stable contributors to the diet, (*e.g.* breads, cereals, fish, poultry and meat) [18] low levels of selenium in soil negatively impact the amount available from food. This is particularly an issue in Northern Europe where soil levels are poor [16]. This is further compounded by the increasing prevalence of calorie rich, nutrient poor diets in Europe, as issue though to contribute to the increasing levels of mineral and vitamin deficiencies in the US [17]. Indeed, a growing body of evidence points to a decrease in selenium intake in many European countries over recent years [12]. For example in the UK, levels dropped from 60 µg/day in 1978 to 43 µg/day in 1997 [19].

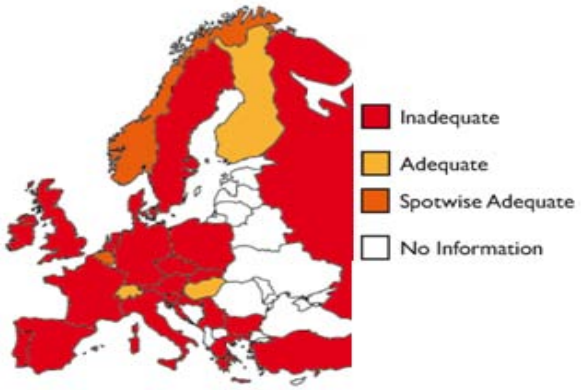

Fig. 1 *European Recorded Selenium Intakes Source[50,51, 16, 14]*

Levels below the European RDA of 55µg/day have also been reported in Belgium (30µg/day), Turkey (32µg/day), Sweden (38µg/day), France and Germany (47µg/day) and Italy (49µg/day) [16] (see figure 1). The low intake is reflected in low serum and whole blood selenium concentrations [16]. Part of this trend can be attributed to the switch from selenium rich US grain to lower selenium European grain following changes in EU policy [20]. This is further exacerbated by the increased use of sulphur in fertilisers, which competes with selenium absorption in plants.

The decrease in selenium intake across Europe calls for innovative practice to boost the average daily intake. This presents an opportunity for companies to develop a broad range of naturally selenium-enriched food and beverage products. It is now well established that organic selenium (*e.g.* Sel-Plex® from Alltech) is more efficiently absorbed and incorporated into tissues by animals than inorganic selenium (NaSe) [21,22,23]. This is due to the higher bioavailabilty of organic selenium.

B. Selenium supplementation of food

Meat, milk and eggs enriched with organic selenium were assessed by EFSA [24]. Following this, selenium is one of the few compounds which has been positively assessed for antioxidant activity, and remains the only antioxidant in which claims can be derived from its supplementation in feed. Furthermore, organic selenium fortification of the animal diet was approved for claims relating to "normal function of the immune system, normal thyroid function and normal spermatogenesis" [25,26]. To make such claims, the selenium must be from an approved source of organic yeast such as Sel-Plex® and it must be present at 15% of the recommended daily allowance (RDA) (which equates to 8.25 micrograms of selenium per 100g or 100ml of product) [25]. Therefore, claims relating to antioxidant activity, immune function and thyroid function can be made accessible to food processors by adding Sel-Plex® to the animal's diet, resulting in the production of enriched food products.

Claims such as "required/essential for normal hair and nails" can also be made on product containing 15% of the RDA of selenium [27].

The selenium content of food and feed ingredients is highly variable, due to the varying level of selenium in soils. A reduction of this variability can be achieved through supplementation of the diet of animals with organic selenium. The stability of selenium in Sel-Plex® has been established for greater than 1126 days [16] and its inclusion in the rations of cattle has been shown to more than double selenium level in beef from 0.107µg/g to 0.223µg/g [28]. Similar, if not greater, increases in selenium content of chicken and pork have also been noted following dietary inclusion of Sel-Plex® [29,30]. Within the EU, increased levels of minerals and vitamins in unprocessed foodstuffs

(such as meat, poultry and fish) must be achieved through supplementation of animal feed, as the addition of such substances during manufacturing is banned under Regulation (EC) No 1925/2006(Art. 4) [31]. Therefore, the inclusion of Sel-plex® in the diet of cattle, pigs and poultry provides a viable approach to addressing the low levels of selenium intake across Europe.

C. Meat as a functional product

The idea of using food for health purposes rather than for nutrition opens the possibility for the meat industry to move from commodity products to value-added products, which can command premium prices [32]. When reviewing the potential of meat as a functional food, Jimenez-Colmenero [33] highlighted the importance of establishing optimal levels and ensuring the bio-availability of the active functional compounds. Meat which has been enriched via feed is characterised as a highly bioavailable source of selenium [34].

Lalor and colleagues [9] found that health claims are better received by consumers when associated with 'healthier' foods. A number of studies have found meat to score reasonably well in terms of 'healthiness' [35,36,37], with poultry meat in particular perceived as a healthy option due to its low fat content [38]. Although associations with cholesterol have had a negative impact on the perception of meat as healthy, it is now accepted that dietary intake of cholesterol has minimal bearing on plasma cholesterol levels [39]. Furthermore, the important contribution of meat to protein, vitamins (A, B12, folic acid) and minerals (Fe, Se) intakes is well. Consumer perceptions regarding the 'healthiness' of meat should contribute to the success of novel meat products with added 'functionality'.

The paramount importance of the 'taste' of functional foods has been demonstrated by numerous studies, with poor aftertastes blamed for the failure of a number of products [4,41,42]. Bou and colleagues [30] found no difference in consumer acceptability of selenium supplemented poultry when compared to controls, and sensory attributes were not found to be impaired when meat contained higher levels of selenium. There are a broad range of naturally Se-enriched food, examples of successful selenium-enriched eggs (product ranges can be found in over 25 countries *e.g.* Columbus eggs) [43] and meat.

D. Business opportunity

As discussed earlier, shifting demographic trends and increasing NCD concerns are creating a large market for "healthy" products. Furthermore, the growing functional food market provides the opportunity to develop value-added product offerings, which can command premium prices [4]. Specific to antioxidant claims, the Leatherhead Food Research (2009) [43] reported that the global antioxidant market had grown 3% annually since 2004, with 2010 alone expected to be reach $470 million. Presumably the same trend exists for immune and thyroid function claims. Small and medium sized companies are often at a disadvantage in terms of functional food development due to the conflict between resource constraints and the cost of developing a new food product[41]. However, the process of enriching foods products with selenium, via animal feed, results in opportunities for product differentiation which can increase company competitiveness, while offering larger profit margins than commodity products [32] and does so at little or no extra cost because supplementation of the diet of animals has shown improvements in animal performance, sperm quality and egg production [45,46,47,48,49].

4. CONCLUSION

In an environment where many claims are being rejected due to lack of scientific evidence, this study clarifies the requirements of the nutrition and health claims legislation in Europe and describes the opportunities that exist for the meat industry.

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