

FIRST REPORT

Qualified Health Claims and Functional Foods: Emerging Evidence

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Qualified health claims (QHC) have received close scrutiny since their implementation by the Food and Drug Administration (FDA) in 2003. It has been argued that they will have a significant impact on the market for foods with additional health benefits (functional foods) as well as dietary supplements (Hooker and Teratanavat). Supporters of the Pearson v. Shalala ruling which led to the QHC policy lauded that it would permit "the delivery of a mass quantity of nutrient-disease information heretofore denied consumers" (Emord, p. 139). Taking a contrary position, Vladeck believed that the mandated disclaimers would confuse consumers suggesting "a marketplace that will be rife with unproven and unreliable health claims" (p. 132). Regardless of your position in this argument, it is of interest to determine if there has been a significant change in the functional food market following the approval of a limited range of QHC. This report starts to document the level of activity by firms in petitioning FDA for QHC and creates a list of all functional food products that currently use language permitted by the policy.



Record of Petition Attempts

The first step documents how many QHC petition attempts have been submitted and processed by FDA. A comprehensive list was compiled using the FDA website <http://www.cfsan.fda.gov/~dms/lab-qhc.html>. A database was created with the following information for each petition attempt.

- ◆ Claim statements that petition attempt sought rights to from FDA
- ◆ List of eligible foods by petition attempt
- ◆ Factors (required language and format of claim)
- ◆ Total processing time by FDA
- ◆ Firms involved (lawyer, client)
- ◆ Copy of FDA discretion letter sent to petitioning firm(s)

Sixteen functional food petition attempts have been submitted to FDA. The histograms below show the processing time achieved by the FDA for each category of petition attempts. To date 6 QHC have been approved for use by the FDA with a mean processing time of 483 days and standard deviation of 51 days.

Approved Qualified Health Claims

Level of Scientific Evidence	Permitted Qualifiers
Good to moderate level of scientific agreement	Nuts & Heart Disease "Scientific evidence suggests but does not prove..." Walnuts & Heart Disease "Supportive but not conclusive research shows..." Omega-3 fatty acids & Coronary Heart Disease "Supportive but not conclusive research shows..."
Low level of scientific agreement	Monounsaturated fatty acids from olive oil and foods with olive oil & Coronary Heart Disease "Limited and not conclusive scientific evidence suggests..."
Very low level of scientific agreement	Green tea & Cancer "Two studies do not show...but one weaker, more limited study... FDA concludes that it is highly unlikely..." (breast cancer) and "One weak and limited study does not show...another weak and limited study... FDA concludes that it is unlikely" (prostate cancer) Tomatoes and/or Tomato Sauce & Cancers "Very limited and preliminary scientific research suggests...FDA concludes that there is little scientific evidence..." (prostate cancer), "One study suggests...while this same study...FDA concludes that it is highly uncertain..." (ovarian cancer), "Four studies did not show...but three studies suggest... FDA concludes that it is unlikely..." (gastric cancer), and "One study suggests...but one weaker, more limited study... FDA concludes that it is highly unlikely..." (pancreatic cancer)

Exploring the use of Product Claims

In order to locate all functional food products using QHC language a syndicated food label database was used. The Global New Products Database (GNPD/Mintel) monitors worldwide product innovation in the consumer packaged goods markets, offering coverage of new product activity for competitor monitoring, category awareness and new product idea generation. GNPD

How Mintel Collects its Data

Collection of GNPD's new product launch information is primarily facilitated by a network of field associates (or "Shoppers"). All key retail distribution channels are monitored by GNPD's shopper network, including supermarkets, drug stores/chemists, natural food stores/health shops, gas stations/petrol forecourts, convenience stores, and other independent outlets.

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covers: Food, beverage, healthcare, household, personal care, cosmetics, fragrance and other non-food sectors within 30 categories and 122 sub-categories across all key global markets. Using GNPD's database searches were completed to capture all products that could meet the criteria in the various FDA functional food QHC letters of approval.

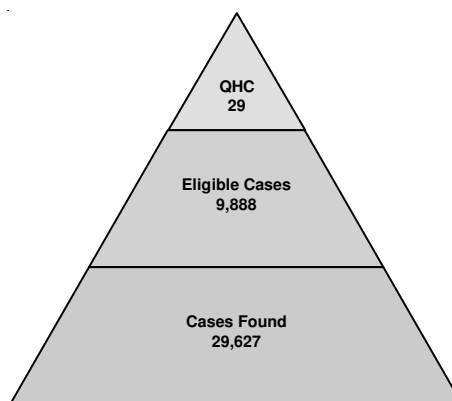
Data Analysis

For each QHC, products were selected according to the appropriate timeframe, presence in the US market and in the appropriate categories. The *ingredient* and *product description* fields were individually searched for key words. This ensured that all possible products for each QHC were captured. These records were entered into the database sheet and color coded. Separate sheets were created for each claim. The following information is recorded for each product:

Product ID	Price in Euros	New Product Count
Product	Positioning Claims	Product Description
Brand	Flavors	Launch Type
Company	Storage	Parent Company
Country	Package Size	Country/State
Date Published	Package Units	Private Label
Category	Package Type	Currency
Sub-Category	Package Material	Price in Local Currency
Price in US Dollars	Ingredients	Bar Code
Price in Euros	Nutrition	Production Code
Company Address	New Product Count	Distribution (US records only)
Patent Number	Store Department	New Product Count

The product database is broken down into three categories: *total cases found*, *eligible cases*, and *eligible cases using claim*. For a product to be *eligible* analysis was conducted to verify that it contained the appropriate amounts of required ingredients. Following this, the product description field was searched to find any use of QHC language.

Cases Found	29,627
Eligible Cases	9,888
Eligible Cases Using Claim	29



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Further Reading

Emord, Jonathan W. 2000. *Pearson v. Shalala: The Beginning of the End for FDA Speech Suppression*. *Journal of Public Policy and Marketing*, 19 (1): 139-143.

Hooker, Neal H. and Ratapol Teratanavat. 2003. *Qualified Health Claims: Marketing Implications for Functional Foods*. *First Report AEDE-FR-0012*. Available online: <http://aede.osu.edu/resources/>

Vladeck, David C. 2000. *Truth and Consequences: The Perils of Half-Truths and Unsubstantiated Health Claims for Dietary Supplements*. *Journal of Public Policy and Marketing*, 19 (1): 132-138.