

A Study on the Newly-enacted Health Claims Regulations in Korea*

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Abstract: This study was conducted to suggest recommendations for the newly-enacted Health Claims Regulation on processed food in Korea to be more consumer-friendly and effective. It analyzed the data about preference and evaluation of both consumers and experts. The following suggestions were made. First, it should include all three kinds of claims: the nutrient function claims, other function claims, and reduction of disease risk claims. And, at the beginning of enforcement, the government should require pre-review of all food products, and watch over advertisements in addition to labels. Secondly, the functional content as well as the warning should be mandated to be written in noticeable area of package to provide information at the point of purchase. Thirdly, the regulation of this new policy should be integrated with that of current system to prevent confusion. Finally, public broadcasting programs should be utilized to educate consumers on health claims easily and repeatedly.

Introduction

Health is regarded as the first priority in everyday life, and specially in food consumption, emphasizing the health is always not enough. Diet-health link has generated high awareness and has been increasing (Trijp 2007). Consumers begin to associate functional foods with a healthy life style, with safe and high quality food, therefore the demand for functional food

is constantly growing (Biacs 2007). But accurate and scientific health information of food isn't enough to consumers in the market. Consumers get health information through fancy packages, advertisements and TV programs with famous food experts. But, commercial health claims are usually emotional, not scientific, and even sometimes quite misleading. They always interrupt consumers to make appropriate and reasonable choices. However, there is no scientific consensus reached on how to substantiate health claims on food (Grossklaus 2007). It interrupts consumers to make informed and reasonable choices.

Health claims are supposed to provide truthful and non-misleading information to help consumers in choosing healthful food. Introducing health claims system to processed food should be considered to satisfy customers' high expectation for qualified health information on food and to assist them to choose food more properly.

There are examples that scientific health claims could enhance consumer knowledge and health status. Ippolito and Mathios (1996) provided substantial evidences that fat, saturated fat, and cholesterol consumption fell significantly between 1977 and 1990, as health claims spread to consumers. It indicated that improvements in

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dietary characteristics had occurred more rapidly and more consistently across food choices after 1985, when health claims became more explicit and more frequent in advertising and labeling (Ippolito and Mathios 1996). In addition, in 1989, they examined changes in the ready to eat cereal market. And they found consumer knowledge and behavior improved significantly once producer's claim helped spread the information that fiber cereals might reduce colon cancer risks (Ippolito and Mathios 1989).

In Korea, functional food differs from general food in law. Only in labeling and advertisement of functional food, all types of health claims including reduction of disease risk claims had been usable. But, with the recent change in legislation, it is now permitted to use health claims in processed food, but food industries are confused and hesitate to use them, still. Though claims on disease reduction are banned, small sized businesses still use all types of health claims accidentally or purposely. By doing so, it is making serious consumer fraud.

That is why the accurate and scientific health claims system that is applied to processed food is urgently needed. This study aims to make some suggestions to help consumers to make right choices, protect their right to know, and reduce information asymmetry. To do so, this study was conducted to suggest recommendations for the newly-enacted Health Claims Regulation on processed food in Korea to be more consumer-friendly and effective. It analyzed the

data about preference and evaluation of both consumers and experts.

Definition

A. Health claims

Health claims means any presentation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health (Codex definitions: Joint FAO/WHO 2006). Health claims include three types: 'the nutrient function claims,' 'other function claims,' and 'reduction of disease risk claims.' According to Codex Alimentarius commission, the nutrient function claims are the claim that describes the physiological role of the nutrient in growth, development and normal functions of the body. Other function claims concern specific beneficial effects of the consumption of foods and their constituents in the context of the total diet on normal functions of biological activities of the body. Reduction of disease risk claims are related to the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition. Codex committee emphasized the presentation of risk reduction claims must ensure that consumers do not interpret them as prevention claims (Codex Alimentarius Commission, Rev. 1-2004). Nutrition and health claims are important tools in attracting the interest of health-conscious consumers. It is an important task to improve information in functional foods by using correct nutrition and health claims (Biacs, 2007).

B. Processed Food and Functional Food

Processed food means just the generally produced and ordinary food, which you can find in the supermarket. Sometimes, it tries to claim it enhances the health, including health claims such as cereals with high fiber, etc. On the contrary, functional food means food manufactured or processed in a form of tablet, capsule, powder, granule, liquid or pill, etc. with ingredients or components, that possess the functionality useful for human body in Korea (Functional Food Act, amended in 2007).

Global Trend

Health claims system depends on each government's situation, and the forms of system are various. According to WHO report (2004), 35 governments have no specific regulations for health claims, 30 governments legislate against reduction of disease risk claims. 7 governments permit specific reduction of disease risk claims, and 22 governments permit the nutrient function claims and other function claims.

Currently, in Europe, the discussion and research about health claims are the most active in the world. Regulation of the European Parliament and of the Council on nutrition and health claims made on foods was adopted by co-decision in October 2006. European Food Safety Authority (EFSA) provides scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety including nutrition. EFSA has high

level of scientific excellence, independence and transparency. EFSA panel on dietetic products, nutrition and allergies (NDA) has 19 members composed of expertise in human nutrition, children nutrition, food chemistry and so on (Iglesias 2007). Reduction of disease risk claims and claims referring to children's development and health are usable based on Article 14. In those cases, rigid authorization is required. Article 13 requirements that health claims should refer to the role of a nutrient or other substance in growth, development and the functions of the body, psychological and behavioral functions, slimming, weight control, a reduction in sense of hunger. And it said health claims should be based on generally accepted scientific evidence, well understood by the average consumer.

In Korea, Food Sanitation Act has permitted to use health claims for processed food since 2007. So far in labeling and advertisements of processed food, expressions aimed to enhance body functions, nutrient claims are permitted. However, expressions regarding prevention and treatment of diseases are banned (Enforcement Rule of the Food Sanitation Act, Article 6, paragraph 2, 2006). Stock farm products, such as milk and yogurt, are the very same as processed food (Processing of Livestock Products Act, Article 32, paragraph 14, 2004). Compared to them, in those of functional food, reduction of disease risk claims are permitted including the nutrient function claims, other function claims. But the examples of reduction of disease risk claims is rare because it is very difficult to satisfy the scientific

evidence level provided by Functional Food Act.

The U.S. government introduced health claims system based on Nutrition Labeling and Education Act (NLEA) in 1990. It was the first case in the world. In the U.S., health claims are authorized by an FDA regulation. There are three ways by which the FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food or a dietary supplement : 1) the 1990 Nutrition Labeling and Education Act (NLEA) provides of FDA to issue regulations authorizing health claims for foods and dietary supplements after FDA's careful review of the scientific evidence submitted in health claim petitions; 2) the 1997 Food and Drug Administration Modernization Act (FDAMA) provides for health claims based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences; such claims may be used after submission of a health claim notification the FDA; 3) the 2003 FDA *Consumer Health Information for Better Nutrition Initiative* provides for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation (FDA 2003).

Research Questions & Methodology

The research questions of this study were the following: (1) the analysis of consumer evaluation and preference for health claims on processed food, (2) the analysis of experts' opinions on the health claims that apply to processed food, (3)

devising a way of making the consumer-friendly health claims that apply to processed food. This study focused on processed food with some health claims, because the Food Sanitation Act authorizing food labeling for processed food label is the most accurate in Korea.

Both a survey on consumers and a Delphi survey on food policy experts were carried out. The survey of consumers involved 1000 male and female adults nationwide in Korea aged between 20 and 50 on the Net from June 20, 2007 till June 29, 2007. In the survey questionnaire, respondents stated their evaluation and preference for all types of proposed health claims for 5 processed foods: milk, green tea, bean curd, processed almonds, and cereal. In the case of milk, for example, the proposed health claims are: 1) Calcium in milk helps to make healthy bones and teeth(nutrient function claim), 2)Vitamin B2 and B12 in milk help to develop muscles and skeleton(other function claims), 3) Enough calcium can help to avoid osteoporosis and arthritis for old people(reduction of disease risk claim).

Consumer evaluation is composed of the frequency of use, degree of trust, usefulness, and knowledge on health claims. In addition, it included expectation of better quality for food with health claims and acceptance of price increases caused by the application of the health claims. Consumer preferences were surveyed with respect to consideration claims' type, content, format and means of consumer education and public relations.

The Delphi survey involved a total of 16 people including 4 workers in the food industry, 3 officers and researchers in the agency in charge of food claims, 5 officers from consumer groups and the consumer protection agency, and 4 scholars specialized in food and nutrition, and consumer studies. In the Delphi survey, snow-ball sampling is used. The Delphi survey was conducted twice from June 22, 2007 till 10 July, 2007. In the second Delphi survey, the result of the previous consumer survey was reflected and a respondent refused to answer because he didn't agree with health claims system at all. The experts were both "for" and "against". The experts also stated the vary effect of introducing a

health claims system. In addition they proposed the most efficient and reasonable policies to introduce a health claims system such as claims' content/format, authorizing process/agency, a plan for integrating into the current food labeling system, and consumer education.

Results

A. Consumer Evaluation for Health Claims

It was found that consumers would often use and trust health claims if the health claims to processed food is introduced. And consumers told that health claims are useful in choosing products. Comparing to the evaluation of current health claims on functional food, the evaluation

Table 1. Evaluation of Usage, Degree of Trust, Usefulness

Items	Proposed health claims		Current health claims				
	Mean	S.D.	Functional food		Processed food		
			Mean	S.D.	Mean	S.D.	
Frequency of usage	3.96	0.72	3.94	1.03	3.72	0.97	
Degree of trust	3.80	0.77	3.25	0.78	3.45	0.76	
Usefulness	useful to choose product	3.84	0.75	3.83	0.89	3.73	0.85
	enhancing ability to choose	3.78	0.79				

- Each question was scored on a scale from 1 to 5.

- S.D. = standard deviation.

Table 2. Differences in evaluation of usage, degree of trust, usefulness

Items	Details	Frequency of usage		Degree of trust		Usefulness			
		Mean	t	Mean	t	useful to choose product		enhancing ability to choose	
						Mean	t	Mean	t
Interest in health	high	4.06	4.72***	3.90	4.45***	3.96	6.11***	3.89	4.94***
	low	3.85		3.68		3.68			
Already knows the health claims	yes	4.04	3.71***	3.91	4.83***	3.91	3.12**	3.83	2.24*
	no	3.87		3.68		3.76			
Total		3.96		3.84		3.78		3.80	

* $p < .05$, ** $p < .01$, *** $p < .001$

- 'Interest in health' was measured to put together the frequency of smoking and medical checkup, and to research eating habits.

- 'Already knows the health claims' was measured to ask if respondents knew the facts of proposed health claims.

- Independent samples t-test was used.

- Only items which have significant differences are shown.

of proposed health claims is better, especially in the category of trust.

In addition, it was shown that the application of the health claims would raise consumers' level of knowledge on food. After seeing the proposed

health claims, respondents answered more correctly about the health information of product and they felt they were provided a lot of health information.

Table 3. The rise in consumers' level of knowledge

Items	Mean	Standard deviation	Pearson correlation	t
The knowledge scores before seeing proposed health claims	19.8	5.64	0.67***	-3.09**
The knowledge scores after seeing proposed health claims	20.3	5.66		

** p < .01, *** p < .001

- The knowledge scores were measured to let respondents solve the same questions of proposed health claims before and after seeing the correct claims.

- Each question was scored on a scale from 1 to 5.

- Paired samples t-test was used

Table 4. Evaluation of consumers' level of knowledge

Items	Mean	Standard deviation
Providing a lot of health information	3.87	0.74
Raising the existing level of knowledge	3.49	0.88

- Each question was scored on a scale from 1 to 5.

Table 5. Differences in evaluation of consumers' level of knowledge

Items	Details	Providing a lot of health information		Raising the existing level of knowledge	
		Mean	t	Mean	t
Interest in health	high	3.96	4.33***	3.62	5.12***
	low	3.76		3.33	
Already knows the contents of health claims	yes	3.94	3.39***	3.48	-0.32
	no	3.79		3.50	
Total		3.87		3.49	

** p < .01, *** p < .001

- Each question was scored on a scale from 1 to 5.

Besides, consumers expected that food with health claims would have better quality than other food products. Thus, they said, they would

willingly accept price increases because of the health claims. 46% of respondents said 5% price increases were acceptable.

Table 6. Expectation on better quality and acceptance on price increases due to the application of health claims

Items	Mean	Standard deviation
Deciding to purchase due to better quality	3.71	0.82
Deciding to substitute food for medicine due to better quality	3.4	0.9
Accepting price increases	3.44	0.91

-Each question was scored on a scale from 1 to 5.

Table 7. Acceptable percentage of price increase caused by the application of health claims

Rank	Acceptable percentage of price increase (%)	Frequency (%)	Cumulative Frequency (%)
1	5	409 (46.5)	409 (46.5)
2	20	200 (22.8)	609 (69.3)
3	50	79 (9.0)	688 (78.3)
4	30	52 (5.9)	740 (84.2)
5	15	29 (3.3)	769 (87.5)
Total		879 (100)	

-Only respondents who accepted price increases are selected.

In every area, however, consumers who lacked health information and weren't less interested in health were rarely expected to share the benefits generated by the introduction of the health claims. Their evaluation and expectation of health claims were more negative than those of consumers who had a lot of health information and were very interested in health. Consumer evaluation did not display any significant difference with regard to demographic variables. (See table 2 and table 5)

B. Consumer preference for health claims

The type of health claims on processed food preferred the most by consumers was the nutrient function claims (41%), followed by reduction of disease risk claims (22%). Reduction of disease risk claims are prohibited under the current label system. As for the content of the claims, they preferred food function content (66.1%) the

most and displayed little preference for warning such as an attention claim (8.9%) or daily intake claim (5.3%). As for the format of health claims, consumers preferred the front of the package and 12-point font and larger (53.7%). Table 10 and Table 11 show the specific results compared to experts' opinions (See page 17). In addition, the means of consumer education and public relation preferred most by consumers was the surface of packages (23.2%), followed by radio and TV broadcasting programs (22.5%), and the government's advertisements in mass media (19.3%).

C. Expert opinions on the health claims

Experts stated, the health claims that apply to processed food should be introduced after the scientific and strict criteria for review is created and practiced.

Table 8. Discussion about introduction of health claims

	Approval	Approval only after the system is fully completed	Opposition
The 1st interview	7 (43.8)	3 (18.8)	6 (37.5)
The 2nd interview	5 (33.3)	8 (53.3)	2 (13.3)

They made a particularly cautious approach towards the introduction of other function claims and reduction of disease risk claims, though they

acknowledged the actual usefulness of reduction of disease risk claims.

Table 9. Discussion about introduction of health claims with respect to 3 types

Frequency(%) Reasons	Approval		Opposition	
	The nutrient function claim	The 1st	16 (100)	0 (0)
The 2nd		-	-	
<ul style="list-style-type: none"> ▶It is the most fundamental claim. ▶Currently school education about it is good, and it will be very useful for future consumers. 		-		
Other function claim	The 1st	13 (81.3)	3 (18.7)	
	The 2nd	8 (53.3)	6 (40.0)	Not decided: 1 (6.7)
	<ul style="list-style-type: none"> ▶It provides new ingredient information, and the release of it is the most effective. 		<ul style="list-style-type: none"> ▶It may mislead consumers because consumers are not familiar with new ingredients. 	
Reduction of disease risk claim	The 1st	10 (62.5)	6 (37.5)	
	The 2nd	8 (53.3)	6 (40.0)	Not decided: 1 (6.7)
	<ul style="list-style-type: none"> ▶It is difficult to mislead consumers because of rigid rules. ▶It helps chronic disease control. ▶It is the most helpful for health. 		<ul style="list-style-type: none"> ▶It may cause consumers to misunderstand functional food as medicine. ▶It may cause consumers to misunderstand reduction of disease risk as cure. ▶Operation of rigid rules is very difficult or impossible in Korea. 	

Like consumers, experts also preferred function content most with regard to the content of health claims. However, unlike consumers, they

emphasized the importance of warning such as attention claim and daily intake claim for the safety of consumers.

Table 10. Preference for content of health claims

Items	Percentage (%)	
	Experts	Consumers
Functional content	36.9	55.7
Daily intake claim	26.2	11.9
Attention claim	19	16.1
Ingredient content	17.9	16.1
Others	0	0.2
Total	100	100

As for the form of health claims, they preferred the front of package and 12-point font and larger most just like consumers. However, they displayed the same preference for 7-point font and

larger. This was because they took into account the size of existing surface of food products in which health claims are written.

Table 11. Preference for format of health claims

The location of label	Percentage (%)		The size of font	Percentage (%)	
	Experts	Consumers		Experts	Consumers
Front of package	73.3	66.1	Minimum 12-point font and larger	46.7	53.7
Back of package	20.0	25.8	Minimum 7-point font and larger	46.7	44.9
Others (up or down of package)	6.7	8.1	Minimum 6-point font and larger	6.7	1.4
Total	100	100	Total	100	100

As for the effective means of consumer education and public relations, experts separated the role of companies from that of the government. They suggested that companies take charge of consumer education and the government supervise the companies. As for the integration management with current function claims system that applies to functional food, a majority of experts (60%, in the 2nd interview) agreed to it on the grounds that both functional food and processed food enhance people's health, and that such management can be consistent and efficient.

As for the way of reviewing health claims, experts tend to agree to conduct both pre-mandatory and non-mandatory reviews case by case. The underlying reasoning is that those methods are more efficient to be authorized and it is helpful for both consumer protection and industry development simultaneously. They suggested that the standards and specifications of food and type of health claims should decide whether a health claim subjects to mandatory or non-mandatory review. The standards and specifications of food can be mandated with two kinds of type. One is to announce publicly by the commissioner

of the KFDA. The other is to review through an laboratory examination after having data provided by each industry on the standards and specifications, the safety, the functionality, etc. of such food.

Experts stated the food with announced standards and specifications or other function claims was okay to be reviewed non-compulsorily. Because announced ingredients is so common that consumers weren't confused easily, and businesses is encouraged to develop good quality products by using other function claims non-compulsorily. On contrast, experts stated the food with recognized standards and specifications or the nutrient function claims, reduction of disease risk claims should be reviewed compulsorily because recognized ingredients were new and uncommon that consumers didn't have lots of information, and so far businesses have misled consumers with the nutrient function claims, reduction of disease risk claims many times.

Table 12 Discussion about the way of reviewing health claims

Frequency (%)	Pre-compulsory reviews	Both pre-compulsory and non-compulsory reviews side by side		Non-compulsory reviews
		By the standards and specifications of food	By type of health claims	
The 1st	7 (43.8)	3 (18.8)	2 (12.5)	4 (25.0)
The 2nd	4 (26.7)	4 (26.7)	4 (26.7)	3 (20.0)

In addition, lots of experts (60%, in the 2nd interview) argue that government agency like the Korean Food and Drug Administration should review and supervise health claims to make reviews conducted fairly and consistently.

Conclusion

Based on these results, this study made the following suggestions for the introduction of the consumer-friendly health claims that apply to processed food, and consumer education on health claims.

First of all, the health claims which will be applied to processed food should include all of three claims: the nutrient function claims, other function claims, and reduction of disease risk claims. And, particularly, at the beginning of the enforcement, the survey suggests it needs the government agency should require pre-review of all food products, and watch over advertisements as well as health claims. It is very important to have openness, transparency and consultation and health claims' authorization process should be rigorous and independent (Davies 2006). That's why the public agency such as KFDA should be in charge of the authorization of health claims for processed food. In order to prevent consumer misunderstanding, the functional content

should be written accurately and briefly, and cautious content should be compulsory. Because consumers have difficulty in understanding complex information and they are confused by detail and scientific wording (Trijp 2007). In addition, if any food product is proved ineffective in improving people's health through the analysis of food ingredients, the product is prohibited from having a health claim regardless of whether or not it has any functional ingredient. In order to enhance consumer understanding, health claims should be placed in an easily noticeable area of food product. As for the size of the font for health claims, 7-point font and larger seem to be appropriate.

Consumers who lack health information and weren't less interested in health can hardly share the benefits of the introduction of the system, even when they are provided with information and education. In spite of their lack of health information, they still failed to recognize the necessity of health claims. Thus some measures should be taken for them. In order to allow them to share the health enhancing effects of the system, the minimum criteria for health claims should be set to enable them to select good quality food products though they fail to understand health claims. Besides, the management of the

health claims should be integrated with that of the current functional claims to prevent confusion. Furthermore, the criteria of food should be applied consistently to review health claims on the basis of the function of food.

Secondly, thorough & efficient consumer education and public relations are very important for consumers to gain benefits from the health claims that apply to processed food. In order to raise the effects of consumer education, information should be provided at the point of purchase. In addition, health claims should be placed in a noticeable spot of the food package. Furthermore under the direction of the government, the public broadcasting programs should be utilized to allow consumers to acquire information easily and repeatedly. Moreover, the government needs to support companies and mass media, and pre-review broadcasting programs that have significant influences on consumers. Consumers displayed little difference in the evaluations of the degree of use, trust and usefulness with regard to demographic variables. Therefore, consumer education and public relations need to access all of consumers at the beginning of the introduction of the health system that applies to processed food.

The health claims that apply to processed food need to be introduced, because they enhance consumer rights by providing useful information after scientific and strict review. Health claims are good, but only if they tell the truth and are recognized by social control. There has to be

relation to social environment and health claims have to be supported by the society (Oltersdorf 2007). If they are not properly applied, false and exaggerative claims can cause physical and financial losses to consumers. Therefore, systematic devices should be made to protect consumers' rights to know and enhance consumer knowledge and health.

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