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Commentary

The need for consumer science and regulatory science research on functional foods with health claims - What should we do to harmonize science and technology with society?

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ABSTRACT

Background: According to the Codex Alimentarius of the foods with health claims (FHCs), two major factors play a significant role in the ability for consumers to select functional foods and utilize them appropriately for health maintenance (Codex Alimentarius, 1997). These are: 1) food labeling based on scientific evidence that consumers are able to understand; and 2) standardized criteria for obtaining scientific evidence.

Scope and approach: We discuss the regulatory system for foods with health claims in the world and the need for consumer science and regulatory science research through reviewing the history and recent topics about the regulation on FHCs in Japan.

Key findings and conclusions: There are some differences in regulations on FHCs among countries participating in the Codex, which have been said sometimes to cause some troubles. These are: 1) despite of the lack of renewal system, Japan experienced the first revocation event regarding the approved Foods for Specified Health Uses category of FHCs in 2016; and 2) global export barriers. Therefore, the introduction of mutual recognition rules among countries has been desired in Japan for further international harmonization. However, its feasibility seems to be low because of the complexity caused by such differences on regulations among countries. When it happens, we expect that the global regulatory climates on FHCs may be better regulated by involving neutral academic researchers and the trained experts in the field of consumer and regulatory science of functional foods. As Japan is the first country to establish the FHCs regulatory system in the world, it should lead to discuss the introduction of mutual recognition rules with other countries immediately.

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We discuss the regulatory system for foods with health claims in the world and the need for consumer science and regulatory science research through reviewing the history and recent changes in the system.

Food serves three main functions: the primary function is nutrition, followed by preference and the prevention of lifestyle-related diseases (Shimizu, 2015). These functions were defined for the first time in 1984 in the Deployment and Systematic Analysis of Functional Food research project established by the Ministry of Education, Culture, Sports, Science and Technology, Japan

(FY1984-FY1986) (Yano, 1987). The third function, now defined in terms of foods with health claims (FHCs), was first described in Japan (Yano, 1987), one of the first countries to use FHCs (Swinbanks & O'Brien, 2003) and establish regulations for developing FHCs for health purposes (Fig. 1).

According to the Codex Alimentarius of the FHCs, two major factors play a significant role in the ability for consumers to select functional foods and utilize them appropriately for health maintenance (Codex Alimentarius, 1997). These are: 1) food labeling based on scientific evidence that consumers are able to understand; and 2) standardized criteria for obtaining scientific evidence.

Regarding point 1), foods categorized under the third function is able to be classified as FHCs, whereas other foods cannot; therefore, their value depends on this classification. Since attainment of this classification is based on scientific evidence, information about the

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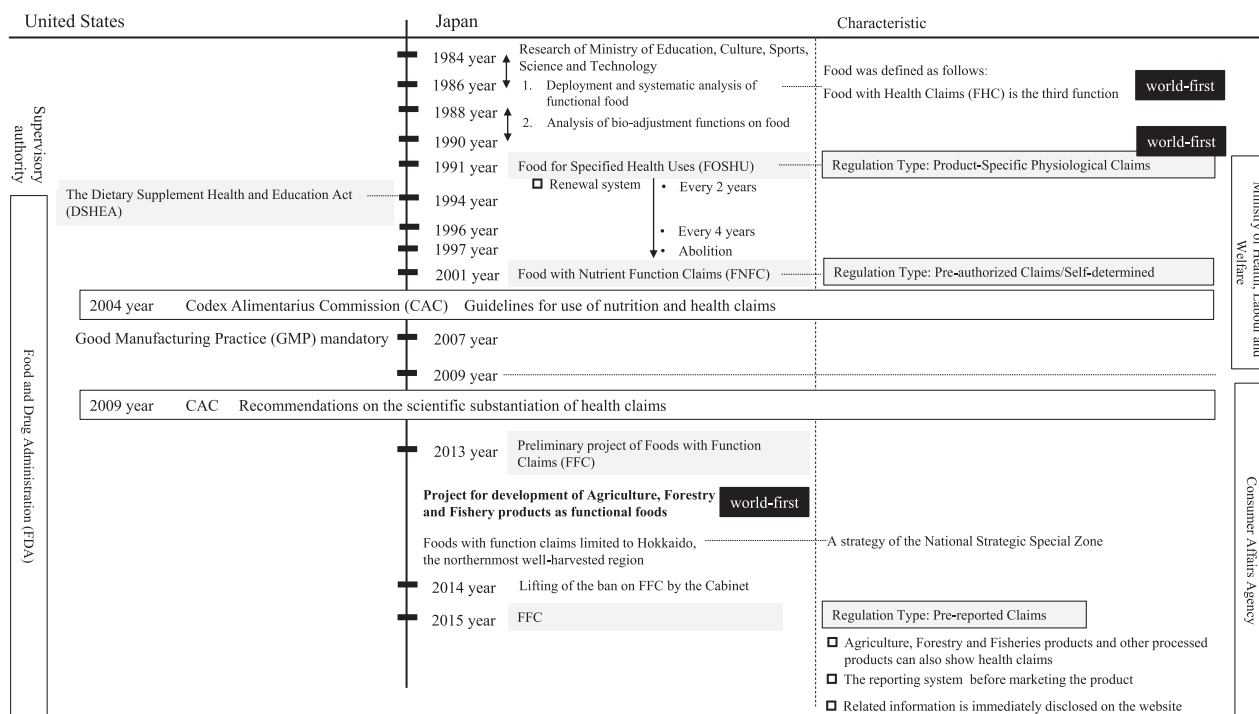


Fig. 1. History of the rules on food with health claims in Japan.

health benefits of the food should be reliable (Fig. 2). In fact, most people do not check a food's FHC specifications even if they have a particular aim for using it (The Consumer Commission, 2016). Furthermore, although Japan generates excellent research and a regulatory framework on functional foods, it currently lacks the consumer science research required to determine the effectiveness of these specifications on consumers. In contrast, a systematic review by Campos et al., in 2010 showed that consumers in other countries perceived nutrition labels as a credible source of information about food products but that there is some divide between label information and consumer understanding (Campos, Doxey, & Hammond, 2011). Although there have been no such researches into this issue in Japan, Shimizu also reported that a large amount of research conducted from 2003 to 2010 regarding the degree of comprehension and utilization of nutrition labels on food products, as determined by consumers in the United States or Europe compared with Japan (Shimizu, 2011). Such consumer behavior research is useful for health promotion and policy planning. We suggest that similar research is required to improve the current

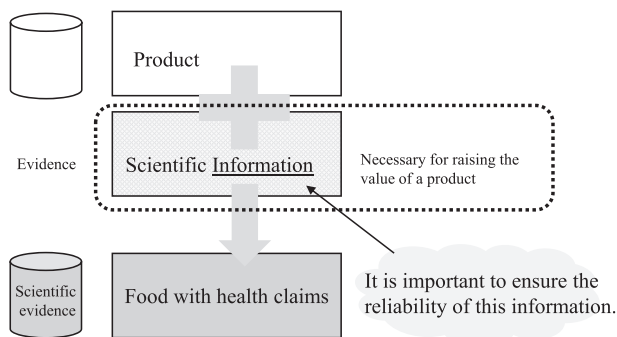


Fig. 2. Scientific evidence adds value to products.

situation in Japan.

Regarding point 2), the process of developing FHCs is still undergoing substantial yearly revisions to improve the existing system in Japan (Fig. 1). Compared to the pharmaceuticals field, it is difficult to ensure sufficient convincing scientific evidence of FHCs because of not only the lack of adequate guidelines for evaluating the efficacy and safety but also complexity of function on FHCs (Consumer Agency, 2014). It may be possible to overcome these difficulties of FHCs by combining the knowledge accumulated by individual companies. This strategy has previously been implemented by the Ministry of Health, Labor and Welfare to develop pharmaceutical guidelines, such as those for regenerative medicine (Kobayashi, 2013). We propose that a similar effort should be made in regulatory science research to develop guidelines that clarify the regulatory standards on FHCs.

When consistent and valid standards for scientific evaluation on the efficacy and safety of FHCs and relevant consumer science research are lacking, it may result in reduced transparency for consumers. This is a typical example of disconnect that often occurs between science/technology and society. We propose that incorporating consumer and regulatory science into food safety fields are able to help to reduce this gap (Fig. 3). Rather than imposing strict rules onto society and the food community, these approaches are able to introduce new, scientifically sound ways to resolve the lack of transparency arising from inadequate regulations for evaluation (Uchiyama, 1987). However, the importance of research into consumer and regulatory science has been ill-recognized by the food safety field in Japan. Despite Japan being the first country in the world to use and establish rules for developing FHCs, and the early advocacy for regulatory science by Uchida, a Japanese forerunner in the field, in 1987 (Uchiyama, 1987, 1995), there remain few Japanese experts who are actively performing consumer and regulatory research (Council of Japan. Agriculture Committee, Food Science Committee, Health and Life Sciences Committee, 2011, Nutrition component indication committee, 2011). Such research

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