

May 17, 2017

IADSA Annual General Meeting in Seoul

Current Status of Japan's Foods with Function Claims System

Atsuko Nishikawa

Japan Health and Nutrition Food Association

About JHNFA

History

- 1985 Established as an incorporated foundation: Japan Health Food Association
- 1992 Renamed as **Japan Health and Nutrition Food Association (JHNFA)**
- 2011 Authorized as a public interest incorporated foundation

Director General : Tomohisa Shimoda, M.D.

Number of member companies (As of May 10, 2017)

Regular members: 696


Supporting Members: 12

Major Activities:

- Develop specifications and standards for health foods and operate their certification system, “JHFA mark”
- Develop and operate third-party certification programs such as GMP or in-house safety assessment of health foods
- Provide technical advice on notification of Foods with Function Claims (FFC)
- Provide technical advice on application of Foods for Specified Health Uses (FOSHU)



Overview of Japan's Health Claim System

		Foods				
		Foods with Health Claims				
Pharmaceuticals		FOSHU (1991) Foods for Specified Health Uses  Individual approval from CAA Function Claims Reduction of Disease Risk Claims	FNFC (2001) Foods with Nutrient Function Claims Standardized regulation Nutrient Function Claims	FFC (2015) Foods with Function Claims Pre-market notification to CAA Function Claims	Foods in General	Health claim is NOT allowed

BACKGROUND:

- To obtain FOSHU approval, clinical trial is essential to substantiate product efficacy and safety
 - Takes a lot of time and money - bottleneck for SMEs
- FNFC doesn't require any approval/notification, but nutrient function claims are limited to 20 nutrients (13 vitamins, 6 minerals and 1 fatty acid) in 26 fixed sentences.



Foods with Function Claims (FFC) was introduced

to realize:

- ✓ Consumers' more informed choices
- ✓ Revitalization of industry – especially for SMEs

Foods with Function Claims

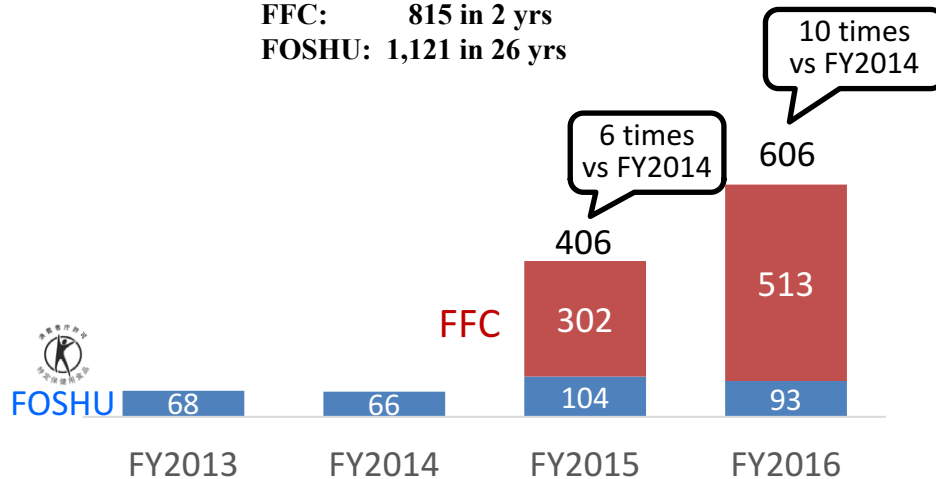
Characteristics of FFC

- By pre-market notification to the Consumer Affairs Agency(CAA), food products including fresh produce are allowed to bear function claims under the food business operator(FBO)'s responsibility.
- Unlike FOSHU, costly clinical trial is NOT essential.
- Once notification was completed, FFC Product can be sold anytime after 60days from the notification date.
- Most of the information submitted to CAA will be disclosed on the CAA website.

Number of Products

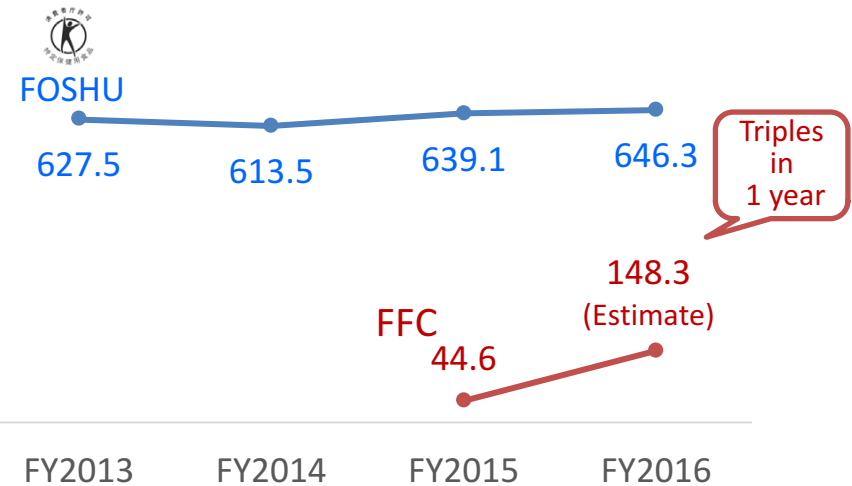
(As of March 31, 2017)

FFC: 815 in 2 yrs
FOSHU: 1,121 in 26 yrs



Market Size

(in billion JPY)



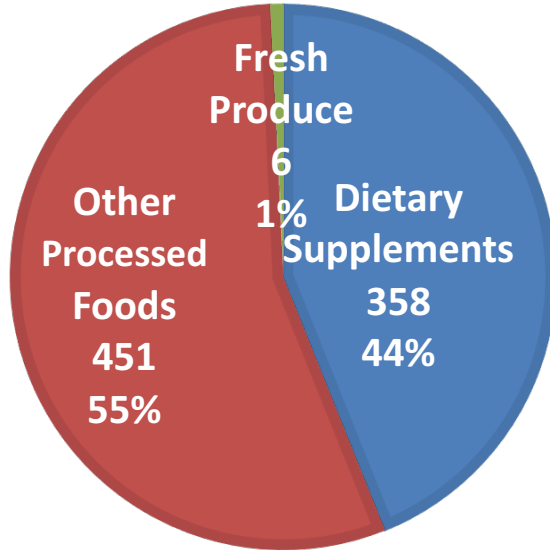
Data source: FOSHU: Japan Health & Nutrition Food Association
 FFC: Yano Research Institute Ltd.

Current Status of FFC Notification

(as of March 31, 2017)

Number of FFC Products by Product Type

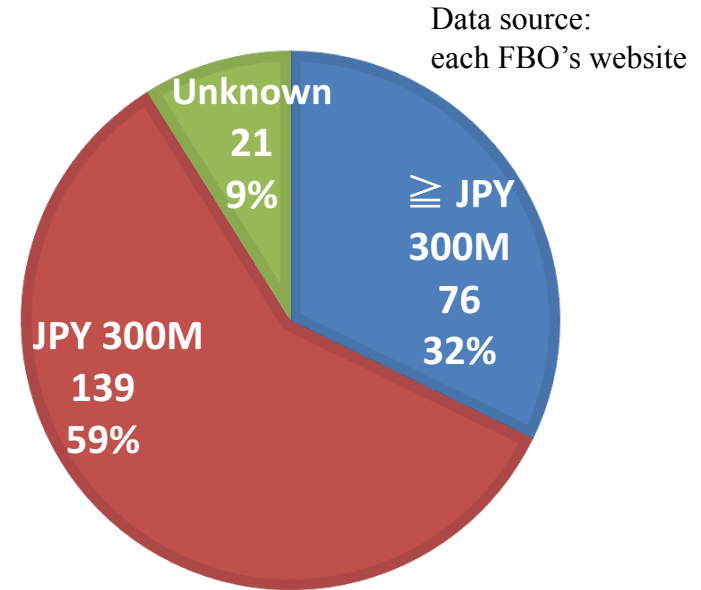
Only 6 fresh produce products.



Total: 815 FFC products

Number of FBOs with FFC Products by Capital Size

Many SMEs enter into the FFC market.



Total: 236 FBOs

Current Status of FFC Notification

(as of March 31, 2017)

Top 5 Functional Substances

	# of products
Indigestible dextrin	114 (12.1%)
GABA	86 (9.1%)
DHA	78 (8.3%)
EPA	70 (7.4%)
Sodium hyaluronate	51 (5.4%)

The rest includes : bifidobacterium, L-theanine, lutein, glucosamine, acetic acid, soy isoflavone, etc. (83 substances in total)

Top 5 Targets of Function Claims

	# of products
Triglyceride	161 (16.8%)
Blood glucose	103 (10.7%)
Bowel	102 (10.6%)
Visceral fat	93 (9.7%)
Skin	79 (8.2%)

The rest includes: blood pressure, eye, mental stress, cognitive function, sleep, bone, physical fatigue, etc.

Number of FFC by Method Substantiating Function Claims

SLR on functional substance accounts for more than 90%.

(A) Clinical trial of finished product	(B) Scientific Literature Review(SLR) on finished product	(C) SLR on functional substance	(D) Combination of (A) & (C)
44 (5%)	1 (0%)	766 (94%)	4 (1%)

Upcoming Revision of FFC

Revision is expected in FY2018

CAA held expert panel meetings and reached the following conclusions in December 2016:

- Part of carbohydrates, sugars and botanical extracts will be eligible for FFC.
- Vitamins and minerals should NOT be eligible for FFC. They should be handled in FNFC system.
- Analysis method of qualitative and quantitative identification of functional substance will be also disclosed.



CAA is to revise “Guidelines on Notification of Foods with Function Claims” and on-line notification database.

Revision is expected to be effective in FY2018, but details are not known yet.

Further revision may take place

CAA will start consideration of further revision to FFC system in FY2018 in accordance with the provisions of Food Labeling Act.

Thank you