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Availability and Utility of Crop Composition Data

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ABSTRACT: The safety assessment of genetically modified (GM) crops is mandatory in many countries. Although the most important factor to take into account in these safety assessments is the primary effects of artificially introduced transgene-derived traits, possible unintended effects attributed to the insertion of transgenes must be carefully examined in parallel. However, foods are complex mixtures of compounds characterized by wide variations in composition and nutritional values. Food components are significantly affected by various factors such as cultivars and the cultivation environment including storage conditions after harvest, and it can thus be very difficult to detect potential adverse effects caused by the introduction of a transgene. A comparative approach focusing on the identification of differences between GM foods and their conventional counterparts has been performed to reveal potential safety issues and is considered the most appropriate strategy for the safety assessment of GM foods. This concept is widely shared by authorities in many countries. For the efficient safety assessment of GM crops, an easily accessible and wide-ranging compilation of crop composition data is required for use by researchers and regulatory agencies. Thus, we developed an Internet-accessible food composition database comprising key nutrients, antinutrients, endogenous toxicants, and physiologically active substances of staple crops such as rice and soybeans. The International Life Sciences Institute has also been addressing the same matter and has provided the public a crop composition database of soybeans, maize, and cotton.

KEYWORDS: *genetically modified (GM), safety assessment, composition data*

INTRODUCTION

The cultivation of genetically modified (GM) crops has expanded in many parts of the world, and large amounts of GM crops and their products are being consumed worldwide. In fact, the global cultivation area of GM crops reached 170 million hectares across 28 countries in 2012 and is expected to spread further.[1] As of February 2013, 217 GM crops are approved and considered marketable in Japan.[2]

Safety assessment of GM crops is mandatory in many countries. The Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), and the Codex Alimentarius Commission (CAC) have played significant roles in the formulation of internationally harmonized strategies for evaluating the safety of foods and food additives produced by recombinant DNA techniques.[3−8] In the early 1980s when recombinant DNA technology was introduced for industrial use, the OECD began a vigorous discussion of safety assessment strategies. In the second-round OECD discussion resumed in 1988, the safety assessment of GM food was confirmed as an important issue.

Because of the very nature of foods as complex mixtures of many components, the application of traditional toxicological testing was not necessarily considered to be appropriate for GM foods. Calls for a new risk-assessment approach for the evaluation of the safety of GM foods resulted in the development of the concept of substantial equivalence for evaluations of food safety and nutritional quality in GM foods.[5] The concept of substantial equivalence embodies the idea that existing non-GM organisms used as food, or as a source of food, can be used as the basis for comparison in the assessment of the safety of a food or food component that has been modified or newly introduced. Once a new food or food component derived from a GM crop is found to be substantially equivalent to that from non-GM crops, it can be treated in the same manner as its conventional counterpart with respect to safety. When any significant intended or unintended differences in the quantity or quality of components between GM and non-GM crops are found, these differences become the focus of the food safety assessment, and further investigations can be performed with respect to their toxicological, analytical, and nutritional impact on human health.

Along with the global expansion of the commercialization of GM crops, greater attention has been paid internationally to the safety of GM crops as food. After deliberations in the Joint FAO/WHO Expert Meeting, the Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology of the CAC launched the formulation of international guidelines, including “Principles for the risk analysis of foods derived from modern biotechnology”[7] and “Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants”.[8] On the basis of these guidelines and the other above-mentioned documents prepared by international organizations such as the OECD, FAO, and WHO, derivative guidelines and standards were developed and have been used for safety assessments in individual countries. Nowadays, there is general consistency among various countries’ approaches to evaluating the safety of GM crops as food.

In Japan, in fact, on the basis of the CAC guidelines and other precedent documents, the “Standards for the Safety Assessment

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of Genetically Modified Foods (Seed Plants)"[9] was formulated along with two other standards and three policies, and safety assessments of GM crops have been conducted by the Expert Committee of Genetically Modified Foods of the Food Safety Commission, the Cabinet Office, Japan, in compliance with the guidelines.

Although the most important factor taken into account in safety assessments of GM foods is the primary effects of new proteins derived from transgenes, possible unintended effects attributed to the insertion of transgenes must be carefully examined in parallel. Indeed, the standards for the safety assessments described above clearly define the importance of a comparative approach focusing on the determination of differences between GM foods and their conventional counterparts, especially in terms of nutritional components, toxins, and antinutrients. Therefore, for the safety assessments of GM crops, it is imperative to obtain detailed knowledge of the compositions of conventional crops and to establish an easily accessible database for this knowledge.

NATURAL VARIABILITY OF CROP COMPOSITION

For the safety assessment of a GM crop, a comparative safety assessment process is performed; this process includes quantitative evaluations of crop compositional levels of key nutrients, antinutrients, and toxins that are relevant to human and animal health. Many studies have been conducted to evaluate the compositions of various crops.

A broad range of factors has been shown to affect crop compositions, such as the crop's genetic background, environmental factors such as temperature, geographic location, and planting year, and agronomic practices such as fertilizer use.[10−18] These studies clearly demonstrate that the levels of analytes are not static and that significant changes in analyte levels may occur due to endogenous and exogenous factors. Because the compositional properties of a GM crop must be compared to those of the GM crop's conventional counterpart with a long history of safe use, in terms of "substantial equivalence" or more strictly saying "comparative risk assessment", the concept of natural variability of crop composition should be kept in mind. Although it is difficult to define the range of natural variability that may be determined by numerous analytical data, analytes that fall outside the confines of natural variability may be subject to further consideration for the safety assessment of GM crops.

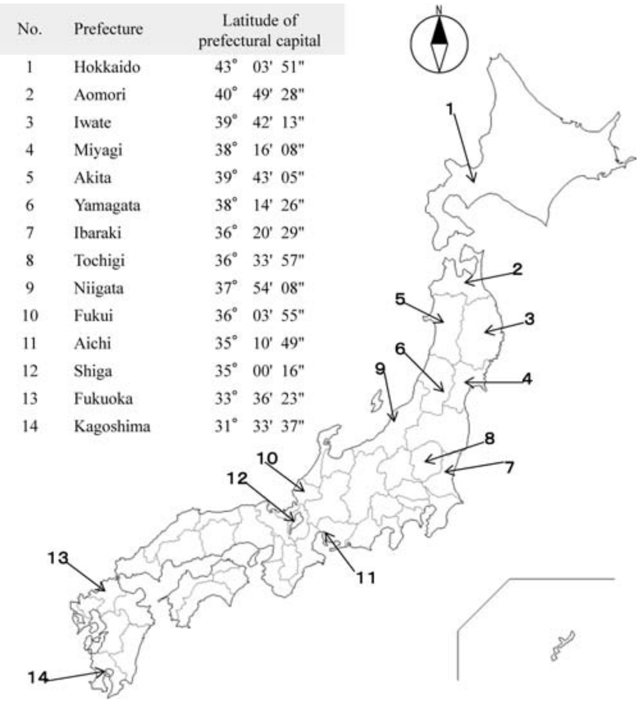
Food composition data are an essential part of the safety assessment of GM crops. Although many compositional data of various crops have been published, to our knowledge, few documents addressing compositional data in terms of food safety assessment or compilations of such data are available. The OECD published a series of Consensus Documents addressing compositional considerations for new GM crops, such as soybeans[19] and rice,[20] by identifying the key nutrients, antinutrients, and toxins of each crop. In addition to a general description of these components, the existing composition data are provided. Although these OECD documents are an excellent resource, they cannot be easily updated to reflect current data, even though many new varieties and cultivars of crops have been developed. In fact, among the series of OECD Consensus Documents, only two revised versions have so far been published for rapeseed[21] and soybeans.[22] The need for up-to-date information on the natural variability in the composition of crops for the assessment of food safety has led to the proposal for an easily accessible and updatable compilation of crop composition data.

ILSI CROP COMPOSITION DATABASE (ILSI-CCDB)

Releasing Crop Composition Database. Understanding the natural variability in composition as an essential factor for safety assessments of GM crops, the International Life Sciences Institute (ILSI) began assembling an electronic, easily accessible compilation of crop composition data for use by research and regulatory scientists worldwide. In 2003, the ILSI released version 1.0 of the Crop Composition Database (http://www.cropcomposition.org), which provides information on the natural variability in the composition of conventionally bred crops.[23] For the development of the database, a number of agricultural biotechnology companies, whose representatives comprise the ILSI International Food Biotechnology Committee's Task Force, agreed to share their crop composition data.

Version 1.0 of the database was a compilation of data on the nutrients, antinutrients, and secondary metabolites for maize and soybeans and contained more than 53000 data points. The samples provided for the ILSI database were collected from multiple locations including North America, South America, and the European Union over a 6 year period, and the samples were grown in controlled field trials under the direction of a production plan. The collected samples were treated with care. For example, the grain samples were analyzed within 12 months, and all of the ground samples were always stored frozen, whereas raw grain may have been stored at ambient temperature for several months.

Because the importance of analytical methods for obtaining reliable data has been recognized, the analyses have been conducted using validated methods in either accredited/certified laboratories or laboratories experienced with specific analytical methodology. To conduct the compilation process promptly and correctly, the format for data submission was standardized, and the data obtained were submitted in the form of either comma-delimited (.csv) or tab-delimited (.xtx) files.



No.	Prefecture	Latitude of prefectural capital
1	Hokkaido	43° 03' 51"
2	Aomori	40° 49' 28"
3	Iwate	39° 42' 13"
4	Miyagi	38° 16' 08"
5	Akita	39° 43' 05"
6	Yamagata	38° 14' 26"
7	Ibaraki	36° 20' 29"
8	Tochigi	36° 33' 57"
9	Niigata	37° 54' 08"
10	Fukui	36° 03' 55"
11	Aichi	35° 10' 49"
12	Shiga	35° 00' 16"
13	Fukuoka	33° 36' 23"
14	Kagoshima	31° 33' 37"

Figure 1. Production areas of rice samples stretched along the Japanese archipelago.

Table 1. Rice Varieties and Production Areas (2005−2009)

Year	2005	2006	2007	2008	2009
Variety and production area	Hoshinoyume ①	Hoshinoyume ①	Hoshinoyume ①	Hoshinoyume ①	Hoshinoyume ①
	Kirara397 ①	Kirara397 ①	Kirara397 ①	Kirara397 ①	Kirara397 ①
				Masshigura ②	Masshigura ②
		Tsugaruroman ②	Tsugaruroman ②	Tsugaruroman ②	Tsugaruroman ②
	Yumeakari ②	Yumeakari ②			
	Hitomebore ③	Hitomebore ③	Hitomebore ③	Hitomebore ③	Hitomebore ③
	Hitomebore ④	Hitomebore ④	Hitomebore ④	Hitomebore ④	Hitomebore ④
	Akitakomachi ⑤	Akitakomachi ⑤	Akitakomachi ⑤	Akitakomachi ⑤	Akitakomachi ⑤
	Haenuki ⑥	Haenuki ⑥	Haenuki ⑥	Haenuki ⑥	Haenuki ⑥
	Koshihikari ⑦	Koshihikari ⑦	Koshihikari ⑦	Koshihikari ⑦	Koshihikari ⑦
	Koshihikari ⑧	Koshihikari ⑧	Koshihikari ⑧	Koshihikari ⑧	Koshihikari ⑧
	Koshihikari ⑨	Koshihikari ⑨	Koshihikari ⑨	Koshihikari ⑨	Koshihikari ⑨
	Hanaechizen ⑩	Hanaechizen ⑩	Hanaechizen ⑩	Hanaechizen ⑩	Hanaechizen ⑩
	Aichinokaori ⑪	Aichinokaori ⑪	Aichinokaori ⑪	Aichinokaori ⑪	Aichinokaori ⑪
	Kinuhikari ⑫	Kinuhikari ⑫	Kinuhikari ⑫	Kinuhikari ⑫	Kinuhikari ⑫
	Hinohikari ⑬	Hinohikari ⑬	Hinohikari ⑬	Hinohikari ⑬	Hinohikari ⑬
	Hinohikari ⑭	Hinohikari ⑭	Hinohikari ⑭	Hinohikari ⑭	Hinohikari ⑭

Production areas are indicated with circled numbers as follows; ①Hokkaido, ②Aomori, ③Iwate, ④Miyagi, ⑤Akita, ⑥Yamagata, ⑦Ibaraki, ⑧Tochigi, ⑨Niigata, ⑩Fukui, ⑪Aichi, ⑫Shiga, ⑬Fukuoka, and ⑭Kagoshima. These numbers correspond to the production areas appeared in Figure 1.

For the electronic retrieval of information, the database interface prepares a search query from which the user can select the attributes and analytes of interest.

Improving Crop Composition Database. Since the release of version 1.0 of the database, there have been several version updates to improve its data and function, and as of April 2013, the most recent version is version 4.2, released in June 2011.[24] When the database was upgraded to version 3.0, additional composition data of conventional corn, cotton, and soybeans were added. Although no additional data were incorporated with the version 4.0 upgrade, the database was restructured for increased speed and efficiency.

The database has been improved especially in terms of performance, security, availability, and scalability. One of the additional features is unit conversion: the new version presents analyte data in multiple units of measure, such as % FW, % DW, % total, and mg/g. The ILSI envisions improved future versions of the database, in particular that the database will include other publicly available data that meet the acceptability criteria of ILSI and are submitted from a variety of public and private organizations.

CONSTRUCTION OF THE JAPANESE COMPOSITION DATABASE

As mentioned above, in Japan, safety assessments of GM crops have been conducted in accordance with the "Standards for the Safety Assessment of Genetically Modified Foods" and other standards that clearly specify the importance of a comparative approach focusing on the determination of differences between a GM crop and its conventional counterpart. Thus, an easily accessible and updatable compilation of composition data for crops that have new GM crops has been demanded. In an endeavor similar to the ILSI's, we have also launched a crop composition database to offer composition data of soybeans and rice for the safety assessment of GM crops.[25]

Samples. Major varieties of nonglutinous rice cultivated and distributed in Japan were collected over a 9 year period: a 4- year period from 1999 to 2002 and a 5 year period from 2005 to 2009. Whereas the samples analyzed for the ILSI composition database were grown in controlled field trials, our database is characterized by samples purchased from the market. Because some compositional alterations may occur during food distribution from farm to market, the data in our database reflect more the composition of crops that we actually eat. A total of 15 or 16 samples consisting of 10−12 varieties were obtained every year. The production areas are located on the islands of Japan stretching from the far north to south of the country (Figure 1). As an example, the varieties and production areas of rice samples grown from 2005 to 2009 are shown in Table 1. We tried to continuously obtain the same varieties from the same production areas; however, we could not always obtain the same varieties in these five consecutive years because we purchased popular varieties from the market. The authenticity of varieties and cultivars of crops was confirmed by analyses conducted by the Japan Grain Inspection Association (Tokyo, Japan).

Ten samples consisting of eight major varieties of soybeans grown in Japan were collected over a 4 year period from 1999 to 2002. Because the supply of soybeans for the Japanese market has been heavily dependent on imported soybeans, one

Table 2. Analyte Categories and Analytes for Rice Composition Database ($n = 3$)

analyte category	analyte	unit of measure	analyte category	analyte	unit of measure
energy	energy	kcal/100 g	amino acid	isoleucine	mg/100 g
	energy	kJ/100 g		leucine	mg/100 g
				lysine	mg/100 g
proximate component	moisture	g/100 g		methionine	mg/100 g
	protein	g/100 g		cystine	mg/100 g
	lipid	g/100 g		phenylalanine	mg/100 g
	carbohydrate (by calculation)	g/100 g		tyrosine	mg/100 g
	sugar (by calculation)	g/100 g		threonine	mg/100 g
	ash	g/100 g		tryptophan	mg/100 g
				valine	mg/100 g
dietary fiber	water-soluble dietary fiber	g/100 g		arginine	mg/100 g
	water-insoluble dietary fiber	g/100 g		histidine	mg/100 g
	total dietary fiber	g/100 g		alanine	mg/100 g
				aspartic acid	mg/100 g
vitamin	vitamin B1	mg/100 g		glutamic acid	mg/100 g
	vitamin B2	mg/100 g		glycine	mg/100 g
	niacin	mg/100 g		proline	mg/100 g
	vitamin B6	mg/100 g		serine	mg/100 g
	α-tocopherol	mg/100 g			
	β-tocopherol	mg/100 g	bioactive	phytic acid	g/kg
	γ-tocopherol	mg/100 g			
	δ-tocopherol	mg/100 g			
	vitamin E activity (by calculation)	mg/100 g			
fatty acid[a]	14:0 myristic	% total FA			
	15:0 pentadecanoic	% total FA			
	16:0 palmitic	% total FA			
	16:1 palmitoleic	% total FA			
	17:0 heptadecanoic	% total FA			
	18:0 stearic	% total FA			
	18:1 oleic	% total FA			
	18:2 linoleic	% total FA			
	18:3 linolenic (n-3)	% total FA			
	20:0 arachidic	% total FA			
	20:1 eicosenoic	% total FA			
	22:0 behenic	% total FA			
	22:1	% total FA			
	24:0	% total FA			
	24:1	% total FA			

[a] $n = 2$.

Brazilian-, one Chinese-, and three American-grown samples were also collected.

Analytical Data. To obtain reliable data, the analyses were conducted using verified methods in either designated/registered laboratories or laboratories experienced with specific analytical methodology. Analyte categories and analytes that were analyzed for rice samples are enumerated along with the unit of measure in Table 2. Amino acid composition data obtained with rice samples in 2009 are shown in Table 3 as an example. The values appearing in the OECD consensus document are also presented, along with the maximum and minimum values. With regard to soybean samples, in addition to the analytes for rice samples, other analytes were also chosen and analyzed, such as 6 kinds of phosphor lipids, 2 kinds of oligosaccharides, 13 kinds of isoflavones, and so on. Isoflavone data of the soybean samples collected in 2001 are presented with the minimum, median, maximum, and mean values (Table 4). Isoflavones in particular exhibited rather large variability, possibly due to varieties and production areas.[26]

For other analytes, analytical data with a wide range of variability have been acquired (data not shown). These results suggested that the levels of components of a crop can fluctuate, with a range of variability due to factors such as cultivars and the cultivation environment. Therefore, it will be crucial for the safety assessments of GM crops to measure and compile the composition data of crops grown under various conditions with standardized analytical methods.

Construction of Food Composition Database. To make the compilation of composition data accessible to the public, the Food Composition Database for Safety Assessment of Genetically Modified Crops as Foods and Feeds (http://afdb.dc.affrc.go.jp/afdb/index.asp) was constructed and has been in operation since 2008. Briefly, the database allows designated analytical laboratories to directly input composition data via the Internet, to facilitate the accurate and prompt release of the data to the public. At the same time, to prevent the release of erroneous data, a checking system is run before the data are made publicly available.

Table 3. Amino Acid Composition (Percent Protein) of Brown Rice ($n = 3$)

variety	prefecture	year	isoleucine	leucine	lysine	methionine	cystine	phenylalanine	tyrosine	threonine	tryptophan	valine	histidine	arginine	alanine	aspartic acid	glutamic acid	glycine	proline	serine
Hoshinoyume	Hokkaido	2009	3.91	8.38	3.89	2.85	2.39	5.26	4.23	3.73	1.03	5.91	2.55	8.11	5.98	9.53	17.5	4.92	4.44	5.38
Kirara397	Hokkaido	2009	3.85	8.26	3.70	2.89	2.38	5.21	3.58	3.60	1.53	5.74	2.44	7.70	5.79	9.30	17.4	4.71	4.32	5.25
Masshigura	Aomori	2009	3.32	7.34	3.21	2.76	2.35	4.59	3.37	3.24	1.62	5.09	1.97	6.84	5.16	8.25	15.4	4.22	3.87	4.69
Tsugaruroman	Aomori	2009	3.87	8.18	3.90	2.82	2.33	5.15	4.15	3.62	1.11	5.85	2.39	7.82	5.89	9.43	16.7	4.85	4.26	5.15
Hitomebore	Iwate	2009	3.82	8.05	3.74	2.83	2.29	5.12	4.09	3.52	1.14	5.80	2.42	8.03	5.80	9.26	16.9	4.78	4.22	5.15
Hitomebore	Miyagi	2009	3.74	7.96	3.93	3.16	2.44	5.04	3.54	3.65	1.49	5.79	2.49	7.79	5.93	9.30	16.6	4.91	4.47	5.23
Akitakomachi	Akita	2009	3.96	8.36	3.91	3.22	2.79	5.27	3.73	3.63	1.45	5.97	2.51	7.91	5.96	9.63	17.1	4.88	4.16	5.24
Haenuki	Yamagata	2009	3.78	7.94	3.83	3.03	2.54	5.03	3.73	3.56	1.13	5.81	2.29	7.73	5.78	9.05	16.3	4.79	4.27	5.03
Koshihikari	Ibaraki	2009	3.78	7.83	3.88	3.00	2.61	5.06	4.11	3.47	1.55	5.78	2.50	8.16	5.70	8.95	16.1	4.80	4.31	4.91
Koshihikari	Tochigi	2009	3.83	7.97	4.02	2.97	2.61	5.08	4.07	3.58	1.20	5.83	2.51	8.08	5.85	9.22	16.4	4.86	4.46	5.05
Koshihikari	Niigata	2009	3.78	7.85	3.83	3.30	2.70	4.98	4.07	3.50	1.77	5.75	2.48	7.90	5.68	9.07	16.1	4.75	4.53	4.98
Hanaechizen	Fukui	2009	3.89	8.28	3.75	2.80	2.54	5.40	3.95	3.57	1.10	5.94	2.56	8.37	5.88	9.40	17.6	4.81	4.35	5.31
Aichinokaori	Aichi	2009	3.88	8.16	3.86	2.64	2.36	5.19	3.59	3.56	0.97	5.97	2.52	7.91	5.86	9.31	16.8	4.91	4.33	5.06
Kinuhikari	Shiga	2009	3.72	7.88	3.97	2.52	2.24	5.09	3.49	3.52	1.10	5.70	2.54	8.09	5.84	9.25	16.4	4.90	4.43	5.10
Hinohikari	Fukuoka	2009	3.65	7.94	3.74	2.76	2.39	5.03	3.71	3.52	1.38	5.62	2.47	7.88	5.86	9.12	16.7	4.82	4.32	5.14
Hinohikari	Kagoshima	2009	3.69	7.78	3.92	3.12	2.51	4.97	3.81	3.59	1.02	5.73	2.44	7.86	5.75	9.24	16.4	4.88	4.20	5.12
maximum		2009	3.96	8.38	4.02	3.30	2.79	5.40	4.23	3.73	1.77	5.97	2.56	8.37	5.98	9.63	17.6	4.92	4.53	5.38
minimum		2009	3.32	7.34	3.21	2.52	2.24	4.59	3.37	3.24	0.97	5.09	1.97	6.84	5.16	8.25	15.4	4.22	3.87	4.69
OECD data			3.6−4.6	8.3−8.9	3.9; 4.3	2.3; 2.5	2.2−2.4[a]	5.0; 5.3	3.8−4.6	3.9−4.0	1.3−1.5	5.0−6.6	2.4; 2.6	8.5−10.5	5.8	9.0; 9.5	16.9; 17.6	4.7; 4.8	4.8; 5.1	4.8−5.8

[a] Cystein.

Table 4. Isoflavone Values (μg/g) of Soybean Samples (2001; $n = 3$)

variety	production area	daidzin	glycitin	genistin	daidzein	glycitein	genistein	acetyl daidzin	acetyl glycitin	acetyl genistin	equol	coumestrol	formononetin	biochanin A
Suzumaru	Hokkaido	493	80.4	507	41.1	3.56	43.4	126	31.9	110	nd[a]	nd	nd	nd
Toyokomachi	Hokkaido	475	55.4	642	38.3	1.82	59.8	60.6	37.5	140	nd	nd	nd	nd
Toyomusume	Hokkaido	505	54.6	654	40.6	1.80	63.9	71.5	40.8	140	nd	nd	nd	nd
Tachinagaha	Miyagi	774	149	756	64.5	5.47	66.5	110	45.8	173	nd	nd	nd	nd
Ryuho	Akita	389	107	570	23.4	3.46	35.7	55.3	31.0	107	nd	nd	nd	nd
Tachinagaha	Tochigi	585	129	658	41.3	4.85	48.5	69.2	38.9	156	nd	nd	nd	nd
Enrei	Toyama	320	121	416	24.3	5.63	33.3	52.7	26.6	119	nd	nd	nd	nd
Fukuyutaka	Mie	396	37.7	635	21.1	1.79	37.4	47.5	36.4	129	nd	nd	nd	nd
Fukuyutaka	Fukuoka	317	35.5	557	21.2	2.37	35.6	42.6	30.6	93.4	nd	nd	nd	nd
Murayutaka	Saga	369	43.9	629	17.7	2.12	27.7	39.2	33.6	104	nd	nd	nd	nd
NK-1990	USA	717	98.4	653	59.5	4.86	57.3	57.3	33.1	127	nd	nd	nd	nd
Vinton	USA	558	57.1	562	33.2	2.35	40.8	45.4	31.5	117	nd	nd	nd	nd
unknown	USA	623	103	566	47.1	4.26	50.7	60.5	38.1	114	nd	nd	nd	nd
unknown	Brazil	138	119	231	13.9	6.91	25.1	25.2	8.90	55.5	nd	nd	nd	nd
unknown	China	439	82.9	461	33.5	4.37	42.3	43.0	30.0	105	nd	nd	nd	nd
mimimum		138	35.5	231	13.9	1.79	25.1	25.2	26.6	55.5				
median		475	82.9	570	33.5	3.91	42.3	56.3	35	117				
maximum		774	149	756	64.5	6.91	66.5	126	45.8	173				
mean		473	84.9	566	34.7	3.84	44.5	61.6	35.4	119				

[a]nd, <1.

Because the database lists various varieties and cultivars, multiple production areas, and multiple analytes for one crop, the data have been made accessible by ‘crop’, ‘variety’, ‘production area (country, or region)’, and ‘analyte (analytical category and analyte)’ as retrieval items (Figure 2). Analytical methods and their references are also listed. In addition, the database was constructed to allow users to download the retrieval data in .csv format. A security system was also implemented to prevent fraudulent falsification from the outside.

An example of data retrieval using the database is shown in Figure 2. The analytical data of phytic acid found in 16 samples of rice in 2009 were easy to obtain from the database, and the data were downloadable. In addition, to make the database available to a much wider range of users, an English version of the database was developed and has been accessible since 2009 (http://afdb.dc.affrc.go.jp/afdb/index_e.asp). The access numbers entered in the database since the formal release are summarized in Table 5.

■ ROLE OF COMPOSITION DATA IN THE SAFETY ASSESSMENT PROCESS

Using as an example a DP-305423-1 event, which imparts a high-oleic-acid trait in soybeans, the methods by which differences from its traditional counterpart are evaluated will be explained here. The following description was taken from the safety assessment document prepared by the Food Safety Commission of Japan after the safety assessment of the DP-305423-1 event.[27] According to the data submitted by the applicant, the major components, fatty acid composition, amino acid composition, inorganics, vitamins, antinutrients, and secondary metabolites were compared between the DP-305423-1 event and its non-recombinant control soybeans grown in six locations in the United States. The measurements of the major components such as protein, total lipid, fibers, ash, and carbohydrate showed no statistically significant differences between the DP-305423-1 and its non-GM counterpart, or if there were statistically significant differences, the level of analytes in question fell into the range of natural variability defined by the literature. Eighteen amino acids, nine inorganics, eight vitamins, antinutrients, and secondary metabolites also gave similar results.

Among the 25 fatty acids analyzed in the soybean samples, oleic acid, heptadecanoic acid, and heptadecenoic acid levels were significantly increased and that of linoleic acid was significantly decreased in the DP-305423-1 event. Most of the other fatty acids measured demonstrated no significant differences, or if they differed, the analyte levels fell within the boundaries of natural variability defined by the literature.

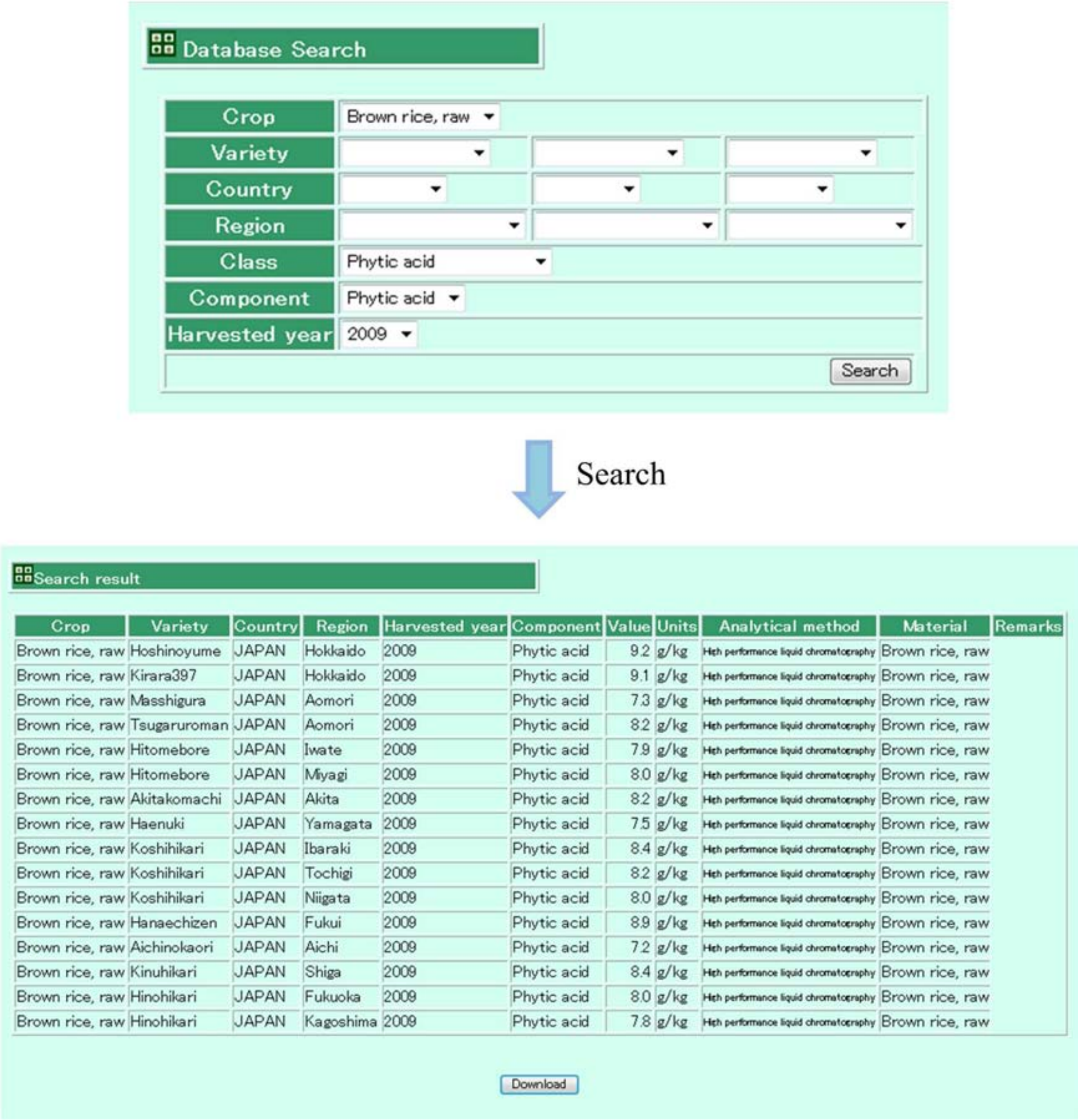
The significant differences found in the levels of oleic acid, heptadecanoic acid, heptadecenoic acid, and linoleic acid required further consideration in terms of the impact on human health. The level of oleic acid in DP-305423-1 was comparable to that found in natural oil containing high levels of oleic acid, such as olive oil. Heptadecanoic acid and heptadecenoic acid are present in various types of foods that are consumed routinely in the Japanese diet. If the non-GM soybean oil consumed by one Japanese person per day was replaced with that of DP-305423-1, the increased heptadecanoic acid and heptadecenoic acid to total lipid intake would be negligible.

Deficiencies of essential fatty acids such as linoleic acid are preventable even with limited food consumption. Again, if the non-GM soybean oil consumed by one Japanese person per day was replaced by DP-305423-1-based soybean oil, the intake of linoleic acid would be in the range of regular consumption. Therefore, the safety assessment concluded that the significant increases in oleic acid, heptadecanoic acid, and heptadecenoic acid and the decrease of linoleic acid in DP-305423-1 would not have an impact on human health.

As seen in this example, to identify the key nutrients and antinutrients that may be beyond natural variability and may be relevant to further consideration, the compilation of a wide range of composition data serves a crucial role in defining the boundaries of natural variability in each crop.

■ FUTURE PERSPECTIVE

For the comparative safety assessment process required to assess GM crops, the compilation of composition data is indispensable.



Crop: Brown rice, raw
Variety:
Country:
Region:
Class: Phytic acid
Component: Phytic acid
Harvested year: 2009

Crop	Variety	Country	Region	Harvested year	Component	Value	Units	Analytical method	Material	Remarks
Brown rice, raw	Hoshinoyume	JAPAN	Hokkaido	2009	Phytic acid	9.2	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Kirara397	JAPAN	Hokkaido	2009	Phytic acid	9.1	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Masshigura	JAPAN	Aomori	2009	Phytic acid	7.3	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Tsugaruroman	JAPAN	Aomori	2009	Phytic acid	8.2	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Hitomebore	JAPAN	Iwate	2009	Phytic acid	7.9	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Hitomebore	JAPAN	Miyagi	2009	Phytic acid	8.0	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Akitakomachi	JAPAN	Akita	2009	Phytic acid	8.2	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Haenuki	JAPAN	Yamagata	2009	Phytic acid	7.5	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Koshihikari	JAPAN	Ibaraki	2009	Phytic acid	8.4	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Koshihikari	JAPAN	Tochigi	2009	Phytic acid	8.2	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Koshihikari	JAPAN	Niigata	2009	Phytic acid	8.0	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Hanaechizen	JAPAN	Fukui	2009	Phytic acid	8.9	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Aichinokaori	JAPAN	Aichi	2009	Phytic acid	7.2	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Kinuhikari	JAPAN	Shiga	2009	Phytic acid	8.4	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Hinohikari	JAPAN	Fukuoka	2009	Phytic acid	8.0	g/kg	High performance liquid chromatography	Brown rice, raw	
Brown rice, raw	Hinohikari	JAPAN	Kagoshima	2009	Phytic acid	7.8	g/kg	High performance liquid chromatography	Brown rice, raw	

Figure 2. Example of a database search and its result.

Table 5. Access Numbers Entered in Database

	fiscal year (April−March)					
page	2008	2009	2010	2011	2012	total
home	7296	6624	4768	4574	3058	26320
database search	3583	2582	2637	2219	1618	12639
result	1063	738	1648	426	532	4407
result download	156	111	91	44	66	468
analytical methods	10583	11590	10839	6380	2224	41616
references	947	820	786	986	640	4179
renewal information	928	827	756	946	648	4105
Q&A	1326	1096	1085	1140	820	5467
copyright/ disclaimer, etc.	924	747	747	943	671	4032
links	966	980	984	1009	654	4593

Meanwhile, new methodologies that allow the detection of alterations in transcripts, proteins, and metabolites have been developed, and numerous so-called "omics" studies have been conducted. Although some omics studies were even conducted in the context of GM crop assessment, it seems still premature to adapt omics techniques for the safety assessment of GM crops.[28−30] Omics techniques have a great potential to detect numerous alterations of analytes and measure relative expression levels in crops, but such alterations in transcriptome, proteome, or metabolome can be caused by many factors, such as cultivars, growth stages, and the cultivation environment. In fact, it was reported that abiotic stresses caused altered expression of approximately 8000 genes (35% of the *Arabidopsis* genome) in both wild-type and transgenic plants.[31] To make an effective use of omics data for the safety assessment of GM crops, we still have to wait for the compilation of natural variability data of transcripts, proteins, and metabolites and internationally validated methods to interpret omics data correctly.

Because comparative compositional studies are expected to consecutively play a significant role for the safety assessment of GM crops for a while, the improvement of already existing crop composition databases, including updates and expansion to include other crops, will be required.

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Notes

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