

Results of official testing of specified feed additives (FY 2014)

Specified feed additives mean the feed additives for which the standards are set in accordance with the provision of Article 3, paragraph 1 of the Law Concerning Safety Assurance and Quality Improvement of Feeds (Law No. 35 issued April 11, 1953; hereinafter referred to as “Feed Safety Law”) and which are the antibacterial preparations specified in Article 2, item 2 of the Order for Enforcement of the Law Concerning Safety Assurance and Quality Improvement of Feeds (Order No. 198 issued July 16, 1976). Only the specified feed additives with a certificate of passing the testing which the Food and Agricultural Materials Inspection Center (hereinafter referred to as “FAMIC”) conducts in accordance with the provisions of Article 5, paragraph 1 of the Feed Safety Law may be distributed; provided, however, that those manufactured by the manufacturers of specified feed additives registered under Article 7, paragraph 1 of the Feed Safety Law (hereinafter referred to as “registered manufacturers of specified feed additives”) on which the indication referred to in Article 16 paragraph 1 of the same Law is placed and those manufactured by the foreign manufacturers of specified feed additives registered under Article 21 paragraph 1 which the indication referred to the paragraph 2 of the same Article is placed on may be distributed.

The following report is the summary of the results of official testing of the specified feed additives, which are applied for at FAMIC in FY 2014. The quantity and others of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2014 are also reported. At the present time, there is no foreign registered manufacturer of specified feed additives.

1. Names of applicants and others

Table 1 shows the names of applicants and others concerning the official testing of the specified feed additives in FY 2014.

Eight business entities (9 in the previous FY) applied the official testing of specified feed additives. The manufacturing forms and others of these business entities: four of them manufacture preparations from raw materials for manufacturing they imported, one of them manufactures preparations from raw materials for manufacturing or preparations it imported, and the other 3 imported preparation.

Eleven types of specified feed additives, corresponding to 19 brands, are applied for the testing in FY 2014 (9 types and 15 brands in the previous FY). The manufacturing of raw materials or preparations of 10 types of them except nosiheptide are dependent on foreign countries.

As for the import source countries of raw material for manufacturing or preparations: 1) China for zinc bacitracin (preparation), alkyltrimethylammonium calcium oxytetracycline (raw material for manufacturing), enramycin (raw material for manufacturing), and colistin sulfate (raw material for manufacturing), 2) the UK for avilamycin (preparation), 3) Singapore for chlortetracycline (preparation), 4) the USA for tylosin phosphate (preparation) and narasin (preparation), 5) Bulgaria for monensin sodium (raw material for manufacturing), and 6) China and Bulgaria for

salinomycin sodium (raw material for manufacturing). The number of the import source countries was 5 as in the previous fiscal year.

2. Number of the passed cases of the specified feed additives by type and others

Table 2 shows the results of the number of the passed cases by type, the passed quantity, and the quantity converted from the actual quantity into potency of the specified feed additives in FYs 2012, 2013, and 2014. Designation of sedecamycin as a feed additive has been revoked in accordance with the amendment of the Ministerial Ordinance concerning the Ingredient Standards for Feed and Feed Additives (Ordinance of Ministry of Agriculture, Forestry and Fisheries No. 35, 1976) in February 6, 2014.

In FY 2014, 180 cases (application: 180 cases) were passed, there were no cases which did not pass the testing. The passed quantity and the quantity converted from the actual quantity into potency were 909 tons and 105 tons (potency), respectively. The passed cases, the passed quantity, and the quantity converted from the actual quantity into potency were 91%, 99%, and 97%, respectively, compared with the previous fiscal year.

The percentage of the specified feed additives in the total passed quantity by type was 35%, which was the highest one, for narasin (21% in the previous FY), followed in descending order by 27% for salinomycin sodium (33% in the previous FY), 17% for colistin sulfate (24% in the previous FY), 10% for avilamycin (11% in the previous FY), and 4% for zinc bacitracin (5% in the previous FY). As for the percentage of them in the total of which the quantity converted from the actual quantity into potency, the highest was 30% for narasin (18% in the previous FY), followed in descending order by 23% for salinomycin sodium (29% in the previous FY), 17% for avilamycin (19% in the previous FY), 15% for colistin sulfate (20% in the previous FY), and 5% for tylosin phosphate (5% in the previous FY).

Compared with the previous fiscal year, the testing-passed quantity and the quantity converted from the actual quantity into potency of monensin sodium and narasin increased, while those of zinc bacitracin, colistin sulfate, chlortetracycline, tylosin phosphate, salinomycin sodium and avilamycin decreased.

Enramycin, nosiheptide and alkyltrimethylammonium calcium oxytetracycline, which were not applied for the testing in the previous fiscal year, were subjected to the testing. Flavophospholipol, which were applied for testing in the previous fiscal year, were not subjected to the testing. Semduramicin sodium, and lasalocid sodium since FY 2010, virginiamycin since FY 2008, efrotomycin since FY 2005, and bicozamycin since FY 1999 have not been subjected to the testing, all of which were not also subjected to in FY 2014.

In addition, lasalocid sodium were not subjected to the testing, but were manufactured by the registered manufacturers of specified feed additives as shown in Table 5.

3. The number of the testing-passed cases of the specified feed additives by refining grade and feed grade and others

The specified feed additives are classified as the refining grade or the feed grade according to the

difference of the post-cultivation manufacturing methods. The former is derived from the high purity raw materials for manufacturing in which the only active constituent of an antibiotic is extracted from a culture solution and then refined, while the latter is derived from the low purity raw materials for manufacturing in which a culture solution containing a medium component and a fungus compound used for manufacturing is dried.

Table 3 shows the number of the testing-passed cases, the passed quantity, and the quantity converted from the actual quantity into potency of the specified feed additives by refining grade and feed grade in FY 2014.

Compared between percentages of the refining grade and the feed grade based on the testing-passed quantity, the feed grade accounted for 79% of the total (73% in the previous FY). The feed grade also accounted for 77% of the total (73% in the previous FY) by the comparison based on the quantity converted from the actual quantity into potency.

Both the refining grade and the feed grade are set for nosiheptide, colistin sulfate, and salinomycin sodium. In FY 2014, only the refining grade of colistin sulfate and only the feed grade of nosiheptide and salinomycin sodium were subjected to the testing.

4. Changes in the testing-passed quantity and others of the specified feed additives by category

Figures 1 and 2 show the changes in the testing-passed quantity and the quantity converted from the actual quantity into potency by category of the specified feed additives over the last decade, from 2005 to 2014, respectively.

The total of the testing-passed quantity was on a declining trend with repeating increase and decrease from FY 2005 to FY 2008, significantly decreased in FY 2009 because the manufacturing of some of the specified feed additives were transferred to that by the registered manufacturers of specified feed additives, and since then has stayed about the same. The quantity converted from the actual quantity into potency also showed the same trend.

As for the testing-passed quantity of the specified feed additives by category, polyether antibiotics was highest in each fiscal year and has hovered at a rate of around 50% of the total. In FY 2014, the polyether antibiotics accounted for 63% of the total (56% in the previous FY), followed by the polypeptide antibiotics, 23% (29% in the previous FY).

The quantity converted from the actual quantity into potency was also highest for the polyether antibiotics, which changed at a rate of around 60% of the total from FY 2005 to FY 2008 and since FY 2009 has remained more than 40%. The polyether antibiotics accounted for 56% (48% in the previous FY), followed by the polypeptide antibiotics, at 19% (25% in the previous FY).

5. Number of the testing-passed cases and others of specified feed additives by the jurisdiction area

Table 4 shows the number of the testing-passed cases, the passed quantity and the quantity converted from the actual quantity into potency within the jurisdiction areas of the FAMIC headquarters and respective regional centers in FY 2014.

The number of the testing-passed cases, the passed quantity and the quantity converted from the actual quantity into potency in FY 2014 were highest within the jurisdiction area of the Kobe center, followed by the jurisdiction areas of the headquarters, and the Fukuoka center.

The number of the testing-passed cases, the passed quantity and the quantity converted from the actual quantity into potency increased within the jurisdiction areas of the Kobe, but decreased within the jurisdiction areas of the headquarters and the Fukuoka center, compared with the previous fiscal year.

In addition, within the jurisdiction areas of the Sapporo, Sendai, and Nagoya centers, there have been no reports of testing since FY 2005, FY 1995, and FY 2007, respectively. All of them also had no reports in FY 2014.

6. Quantity of the specified feed additives manufactured by the registered manufacturers of specified feed additives

As of the end of March in 2015, the 3rd plant, Kyushu Plant, Kohkin Chemical Co., Ltd. is registered as a place of business as a manufacturer of specified feed additives concerning nosiheptide (the registration for semduramicin sodium was abolished in September, 1, 2014), Tatsuno Factory, Scientific Feed Laboratory Co., Ltd., is registered as a place of business as a manufacturer of specified feed additives concerning salinomycin sodium, monensin sodium, lasalocid sodium, enramycin, colistin sulfate and nosiheptide.

Table 5 shows the manufactured quantity and the quantity converted from the actual quantity into potency of the specified feed additives by the registered manufacturers of specified feed additives in FY 2014. Moreover, lasalocid sodium which have not undergone the testing as a specified feed additive in FY 2014 were manufactured by the registered manufacturers of specified feed additives.

The quantity of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2014 was 689 tons (101% over the previous FY) and the quantity converted from the actual quantity into potency was 92 tons (potency) (100% over the previous FY).

The descending order of the manufactured quantity in FY 2014 was salinomycin sodium, monensin sodium, lasalocid sodium, enramycin, nosiheptide, and colistin sulfate.

The descending order of the quantity converted from the actual quantity into potency was monensin sodium, salinomycin sodium, lasalocid sodium, enramycin, nosiheptide, and colistin sulfate.

7. Total manufactured quantity of the specified feed additives

Table 6 shows the total manufactured quantity and others and the total quantity converted from the actual quantity into potency, which are the total of the testing-passed quantity of the specified feed additives and the quantity manufactured by the registered manufacturers of specified feed additives.

The total manufactured quantity by category in FY 2014 was highest for the polyether antibiotics,

1,136 tons (testing: 575 tons; registration: 561 tons), which accounted for 71% of the total. The descending order by type was salinomycin sodium (30%), narasin (20%), and monensin sodium (15%). The total quantity converted from the actual quantity into potency by category was also highest for the polyether antibiotics, 143 tons (testing: 59 tons; registration: 84 tons), which accounted for 72% of the total. The descending order by type was monensin sodium (25%), salinomycin sodium (25%), and narasin (16%).

Figures 3 and 4 show the changes in the total manufactured quantity and others and the total quantity converted from the actual quantity into potency of the specified feed additives by category over the last decade, from FY 2005 to FY 2014, respectively.

There have been significant changes since FY 2009, because the manufacturing of some of the specified feed additives were transferred to that by the registered manufacturers of specified feed additives since FY 2007.

The total manufactured quantity was on a declining trend with repeating increase and decrease from FY 2005 to FY 2009, increased in FY 2010, and since then has stayed about the same. The total quantity converted from the actual quantity into potency was also on a declining trend with repeating increase and decrease from FY 2005 to FY 2009, increased in FY 2010, and since then has been almost unchanged.

In FY 2014, the percentage of the manufacturing by the registered manufacturers of specified feed additives of the total was 43% for the manufactured quantity (43% in the previous FY) and 47% for the quantity converted from the actual quantity into potency (46% in the previous FY).

8. Summary

The results of the official testing of the specified feed additives and the manufacturing by the registered manufacturers of specified feed additives in FY 2014 were as follows.

- (1) Nineteen brands of 11 specified feed additives were applied for the official testing of specified feed additives by 8 business entities.
- (2) The number of the passed cases, the passed quantity, and the quantity converted from the actual quantity into potency were 180 cases (application: 180 cases), 909 tons, and 105 tons (potency), respectively. The cases, the quantity and the quantity converted from the actual quantity into potency decreased compared to the previous fiscal year. There were no rejected cases.
- (3) The testing-passed quantity of the specified feed additives by type was highest of narasin, followed by salinomycin sodium and colistin sulfate in descending order.
- (4) The quantity converted from the actual quantity into potency of the specified feed additives passed the testing by type was highest for narasin, followed by salinomycin sodium and avilamycin in descending order.
- (5) Compared between percentages of the refining grade and the feed grade on the testing-passed quantity and the quantity converted from the actual quantity into potency of the specified feed additives, the feed grade accounted for 77% of the total.
- (6) The number of the testing-passed cases, the passed quantity and the quantity converted from

the actual quantity into potency by jurisdiction area were highest for the Kobe center.

- (7) The quantity of the specified feed additives manufactured by the registered manufacturers of specified feed additives by type was highest for salinomycin sodium, followed by monensin sodium and lasalocid sodium in descending order.
- (8) The quantity converted from the actual quantity into potency of the specified feed additives manufactured by the registered manufacturers of specified feed additives by type was highest for monensin sodium, followed by salinomycin sodium and lasalocid sodium in descending order.
- (9) The total manufactured quantity and others which are the total of the testing-passed quantity of the specified feed additives and the quantity manufactured by the registered manufacturers of specified feed additives, by type was salinomycin sodium, narasin, and monensin sodium in descending order. The total quantity converted from the actual quantity into potency was monensin sodium, salinomycin sodium, and narasin in descending order.

Table 1: Names of applicants and others for the official testing of the specified feed additives (FY 2014)

Contact office of FAMIC	Name of applicant	Place of manufacturing	Type of the specified feed additives	Feed grade	Content potency (mg (potency)/g)	Remarks
Headquarters	Nichiku Yakuin Kogyo Corporation	Kanagawa	Monensin sodium		200	
			Salinomycin sodium	o	100	
	Japan Nutrition Co., Ltd.	Ibaraki	Salinomycin sodium	o	100	
			TNB Co., Ltd.	*	Chlortetracycline	o
	Rokku Chemical Products Co., Ltd.	Shizuoka	Colistin sulfate		100	
			Enramycin	o	80	
Salinomycin sodium			o	100		
Kobe	Scientific Feed Laboratory Co., Ltd.	Hyogo	Colistin sulfate		100	
			Tylosin phosphate		275	
	Eli Lilly Japan K. K.	*	Avilamycin	o	200	
			Narasin	o	100	
Fukuoka	Scientific Feed Laboratory Co., Ltd.	Miyazaki	Colistin sulfate		100	
			Alkyltrimethylammonium calcium oxytetracycline		400	
	Kohkin Chemical Co., Ltd.	Kagoshima	Noshiheptide	o	40	
			Salinomycin sodium	o	100	
	Zoetis Japan Inc.	*	Zinc bacitracin	o	100	4,200 unit/g
			o	150	6,300 unit/g	
Total	8 business entities	9 places			19 brands	

* Fallen under an importer

Table 2: Number of the testing-passed cases, passed quantity, and quantity converted into potency of specified feed additives
(Sorted by the type of the antibiotics, FYs 2012 to 2014)

Category	Type of the specified feed additives	FY 2012					FY 2013					FY 2014				
		Passed cases	Passed quantity kg	Compos ition ratio (%)	Quantity converted into potency kg(potency)	Compos ition ratio (%)	Passed cases	Passed quantity kg	Compos ition ratio (%)	Quantity converted into potency kg(potency)	Compos ition ratio (%)	Passed cases	Passed quantity kg	Compos ition ratio (%)	Quantity converted into potency kg(potency)	Compos ition ratio (%)
Polypeptide antibiotics	Zinc bacitracin	10	54,780	6	6,220	6	8	44,920	5	5,241	5	7	34,780	4	3,727	4
	Enramycin	-	-	-	-	-	-	-	-	-	-	2	2,380	0	190	0
	Colistin sulfate	60	236,200	25	23,620	22	56	220,320	24	22,032	20	41	158,120	17	15,812	15
	Virginiamycin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Nosiheptide	2	8,000	1	320	0	-	-	-	-	-	3	12,000	1	480	0
	Subtotal	72	298,980	31	30,160	28	64	265,240	29	27,273	25	53	207,280	23	20,209	19
Tetracycline antibiotics	Chlortetracycline	3	12,000	1	1,200	1	4	16,000	2	1,600	1	3	14,400	2	1,440	1
	Alkyltrimethylammonium calcium oxytetracycline	1	2,000	0	800	1	-	-	-	-	-	1	2,000	0	800	1
	Subtotal	4	14,000	1	2,000	2	4	16,000	2	1,600	1	4	16,400	2	2,240	2
Macrolide antibiotics	Tylosin phosphate	4	19,700	2	5,418	5	4	20,262	2	5,572	5	5	19,370	2	5,327	5
	Sedecamycin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Subtotal	4	19,700	2	5,418	5	4	20,262	2	5,572	5	5	19,370	2	5,327	5
Polysaccharide antibiotics	Flavophospholipol	1	1,250	0	100	0	1	2,500	0	200	0	-	-	-	-	-
	Subtotal	1	1,250	0	100	0	1	2,500	0	200	0	-	-	-	-	-
Polyether antibiotics	Monensin sodium	3	10,860	1	2,172	2	2	7,940	1	1,588	1	3	12,140	1	2,428	2
	Salinomycin sodium	58	235,178	25	23,518	22	76	308,122	33	30,812	29	61	244,875	27	24,488	23
	Lasalocid sodium	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Semduramicin sodium	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Narasin	27	296,275	31	29,628	27	18	197,625	21	19,763	18	29	317,775	35	31,778	30
	Subtotal	88	542,313	57	55,317	51	96	513,687	56	52,163	48	93	574,790	63	58,693	56
Others	Avilamycin	21	77,825	8	15,565	14	28	104,200	11	20,840	19	25	91,575	10	18,315	17
	Bicozamycin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Efrotomycin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Subtotal	21	77,825	8	15,565	14	28	104,200	11	20,840	19	25	91,575	10	18,315	17
Total		190	954,068	100	108,560	100	197	921,889	100	107,648	100	180	909,415	100	104,784	100
Ratio to the previous fiscal year (%)		88	96		97		104	97		99		91	99		97	

Note: Quantity and others of the specified feed additives manufactured by the registered manufacturers are shown separately in Table 5.

Table 3: Number of the testing-passed cases, passed quantity, and quantity converted into potency
(Sorted by the grade of the preparation, FY 2014)

Category	Type of the specified feed additives	Refining grade			Feed grade		
		Passed cases	Passed quantity	Quantity converted into potency	Passed cases	Passed quantity	Quantity converted into potency
			kg	kg(potency)		kg	kg(potency)
Polypeptide antibiotics	Zinc bacitracin	/	/	/	7	34,780	3,727
	Enramycin	/	/	/	2	2,380	190
	Nosiheptide	-	-	-	3	12,000	480
	Virginiamycin	-	-	-	/	/	/
	Colistin sulfate	41	158,120	15,812	-	-	-
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	1	2,000	800	/	/	/
	Chlortetracycline	/	/	/	3	14,400	1,440
Macrolide antibiotics	Tylosin phosphate	5	19,370	5,327	/	/	/
Polysaccharide antibiotics	Flavophospholipol	/	/	/	-	-	-
Polyether antibiotics	Salinomycin sodium	-	-	-	61	244,875	24,488
	Semduramicin sodium	-	-	-	/	/	/
	Narasin	/	/	/	29	317,775	31,778
	Monensin sodium	3	12,140	2,428	/	/	/
	Lasalocid sodium	-	-	-	/	/	/
Others	Avilamycin	/	/	/	25	91,575	18,315
	Efrotomycin	-	-	-	/	/	/
	Bicozamycin	-	-	-	/	/	/
Total		50	191,630	24,367	130	717,785	80,417
Proportion (%)		28	21	23	72	79	77

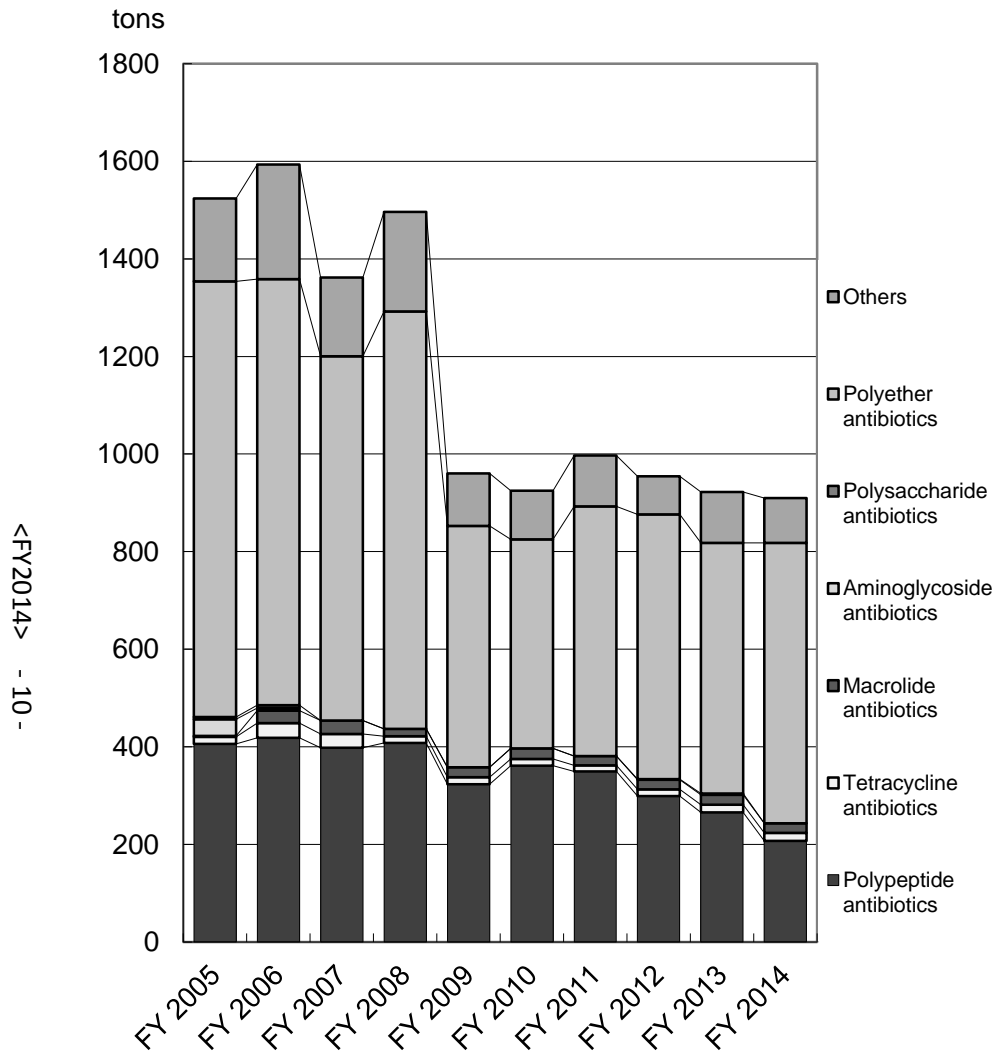


Figure 1: Changes in the testing-passed quantity of the specified feed additives (Sorted by category of antibiotics)

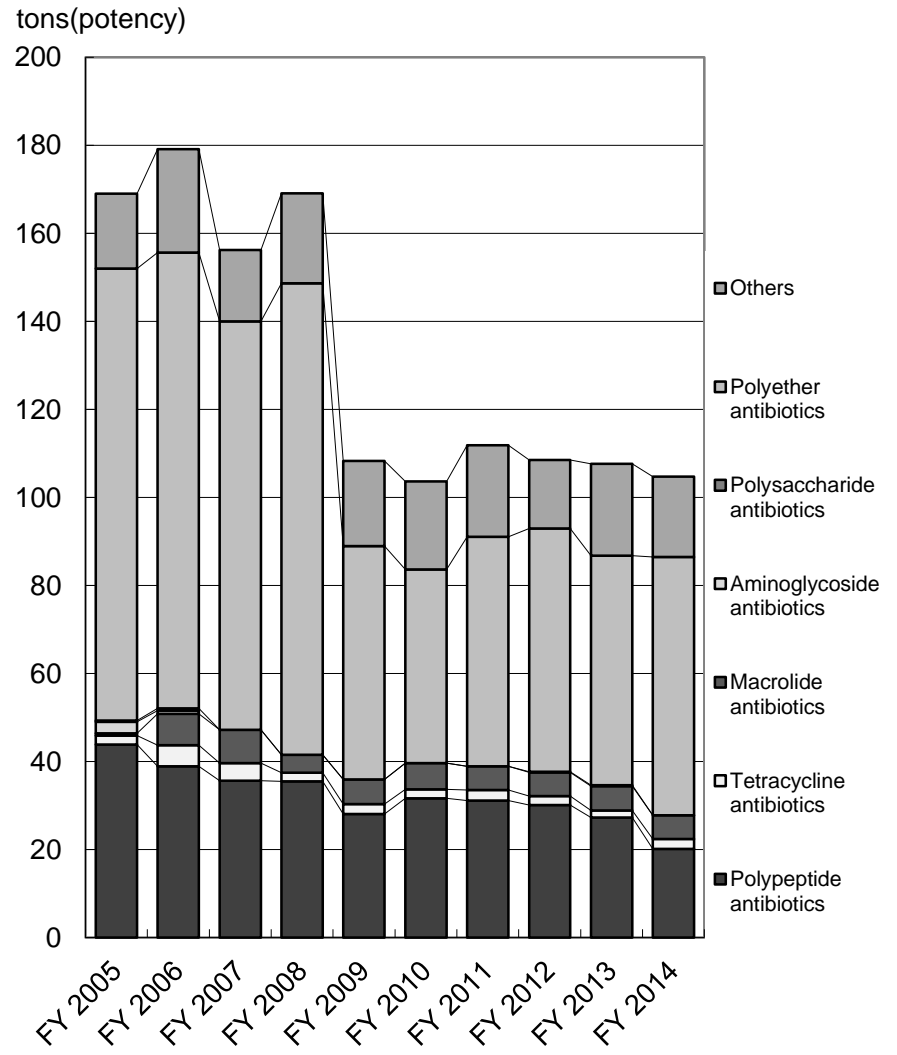


Figure 2: Changes in the testing-passed quantity of the specified feed additives converted into potency (Sorted by category of antibiotics)

Table 4: Number of the testing-passed cases, passed quantity, and quantity converted into potency
(Sorted by the contact office of FAMIC, FY 2014)

Contact office of FAMIC	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)
Headquarters	55 (53)	222,042 (209,275)	22,948 (22,094)
Sapporo	- -	- -	- -
Sendai	- -	- -	- -
Nagoya	- -	- -	- -
Kobe	79 (80)	433,867 (507,340)	57,353 (63,281)
Fukuoka	63 (47)	265,980 (192,800)	27,347 (19,409)
Total	197 (180)	921,889 (909,415)	107,648 (104,784)

Data of the previous year are in parentheses.

Table 5: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2014)

Category	Type of the specified feed additives	Manufactured quantity kg	Quantity converted into potency kg(potency)
Polypeptide antibiotics	Enramycin	68,680	5,494
	Colistin sulfate	4,020	402
	Nosiheptide	55,500	2,220
	Subtotal	128,200	8,116
Polyether antibiotics	Salinomycin sodium	240,320	24,032
	Semduramicin sodium	-	-
	Monensin sodium	233,540	46,708
	Lasalocid sodium	87,300	13,095
	Subtotal	561,160	83,835
Total		689,360	91,951
Ratio to the previous fiscal year (%)		101	100

(Hearing from each registered manufacturer of specified feed additives)

Table 6: Total manufactured quantity of the specified feed additives (FY 2014)

Category	Type of specified feed additives	Total quantity ^{*1}	Compositi on ratio	Total quantity converted into potency ^{*2}	Compositi on ratio
		(kg)	(%)	(kg(potency))	(%)
Polypeptide antibiotics	Zinc bacitracin	34,780	2	3,727	2
	Enramycin	71,060	4	5,685	3
	Colistin sulfate	162,140	10	16,214	8
	Virginiamycin	-	-	-	-
	Nosiheptide	67,500	4	2,700	1
	Subtotal	335,480	21	28,326	14
Tetracycline antibiotics	Chlortetracycline	14,400	1	1,440	1
	Alkyltrimethylammonium calcium oxytetracycline	2,000	0	800	0
	Subtotal	16,400	1	2,240	1
Macrolide antibiotics	Tylosin phosphate	19,370	1	5,327	3
	Subtotal	19,370	1	5,327	3
Polysaccharide antibiotics	Flavophospholipol	-	-	-	-
	Subtotal	-	-	-	-
Polyether antibiotics	Monensin sodium	245,680	15	49,136	25
	Salinomycin sodium	485,195	30	48,520	25
	Lasalocid sodium	87,300	5	13,095	7
	Semduramicin sodium	-	-	-	-
	Narasin	317,775	20	31,778	16
	Subtotal	1,135,950	71	142,528	72
Others	Avilamycin	91,575	6	18,315	9
	Bicozamycin	-	-	-	-
	Efrotomycin	-	-	-	-
	Subtotal	91,575	6	18,315	9
Total		1,598,775	100	196,736	100

*1 The total quantity of the specified feed additives of the testing-passed quantity and the quantity manufactured by the registered manufacturers

*2 The total quantity converted into potency of the testing-passed quantity and the quantity manufactured by the registered manufacturers

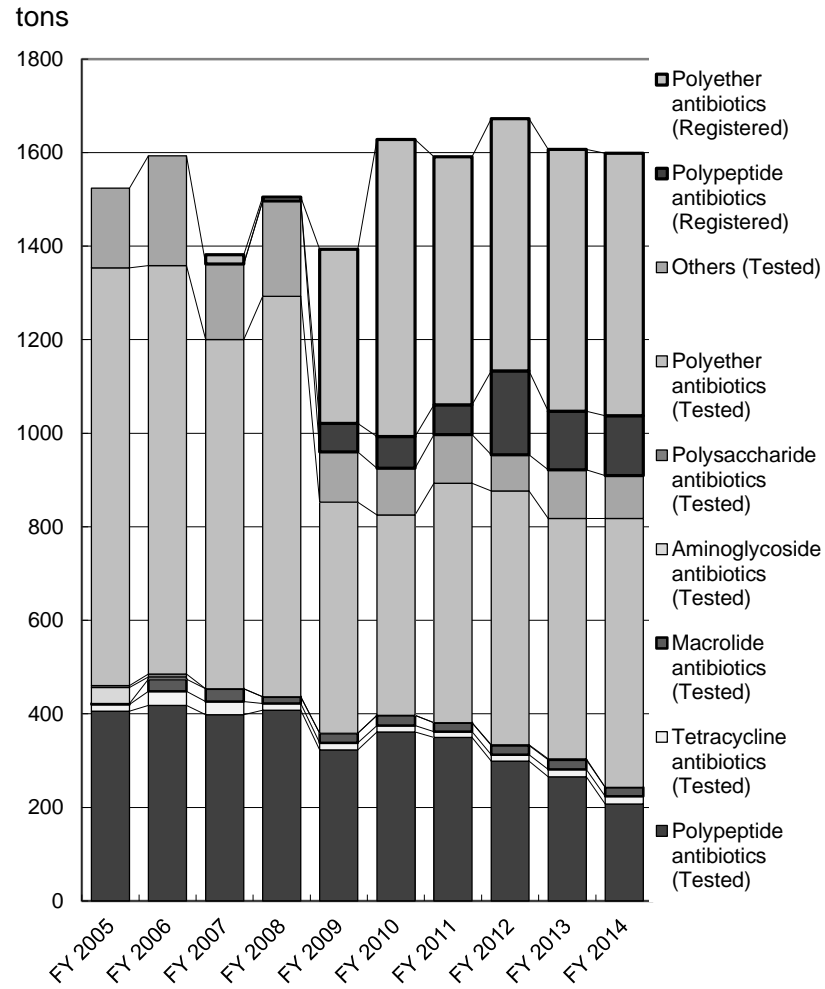


Figure 3: Changes in the testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives (Sorted by category of antibiotics)

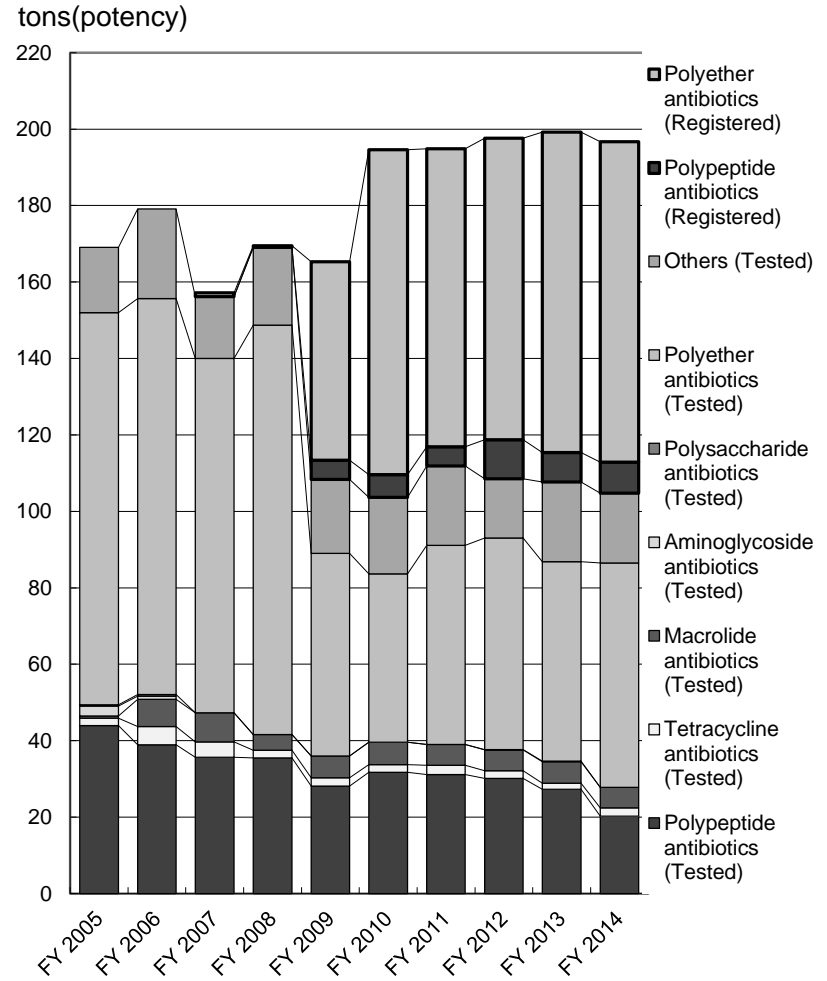


Figure 4: Changes in the testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives converted into potency (Sorted by category of antibiotics)