Results of official testing of specified feed additives (FY 2016)

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 (Act No. 35 of 1953; hereinafter referred to as "Feed Safety Law") and which are the antibacterial preparations specified in Article 2, item 2 of the Enforcement Order of the Law Concerning Safety Assurance and Quality Improvement of Feeds (Enforcement Order No. 198 of 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 the specified feed additives passed the official testing, which are applied for at FAMIC in FY 2016. The quantity and others of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2016 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 specified feed additives passed the official testing in FY 2016.

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 manufactured preparations from raw materials for manufacturing they imported, three of them imported preparations, and the other one manifactured preparations from raw materials for manufacturing they imported or imported preparations.

Eleven types of specified feed additives, corresponding to 19 brands, are applied for the testing in FY 2016 (12 types and 20 brands in the previous FY). The manufacturing of raw materials are dependent on foreign countries.

As for the import source countries of raw material for manufacturing or preparations: 1) China for alkyltrimethylammonium calcium oxytetracycline (raw material for manufacturing), enramycin (raw material for manufacturing), nosiheptide (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 narasin (preparation) and tylosin phosphate (preparation), 5) Bulgaria for flavophospholipol (preparation), 6) China and Bulgaria for salinomycin sodium (raw material for manufacturing) and monensin sodium (raw material for

manufacturing), and 7) Korea for colistin sulfate (preparation). The number of the import source countries was 6 (6 in the previous FY).

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 2014, 2015, and 2016.

In FY 2016, 192 cases were passed. The passed quantity and the quantity converted from the actual quantity into potency were 871 tons and 93 tons (potency), respectively. The passed cases, the passed quantity, and the quantity converted from the actual quantity into potency were 106.1 %, 110.7 %, and 105.2 %, respectively, compared with the previous fiscal year.

The percentage of the specified feed additives in the total passed quantity by type was 33.3 %, which was the highest one, for salinomycin sodium (36.7 % in the previous FY), followed in descending order by 24.4 % for colistin sulfate (28.5 % in the previous FY), 22.7 % for narasin (16.7 % in the previous FY), 8.4 % for avilamycin (8.0 % in the previous FY), and 6.9 % for nosiheptide (2.8 % 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 31.1 % for salinomycin sodium (32.6 % in the previous FY), followed in descending order by 22.8 % for colistin sulfate (25.3 % in the previous FY), 21.2 % for narasin (14.9 % in the previous FY), 15.7 % for avilamycin (14.2 % in the previous FY), and 2.6 % for tylosin phosphate (1.0 % 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 enramycin, nosiheptide, monensin sodium, narasin, salinomycin sodium, and avilamysin increased, while those of colistin sulfate, alkyltrimethylammonium calcium oxytetracycline, and tylosin phosphate decreased.

Zinc bacitracin, which were applied for testing in the previous fiscal year, were not subjected to the testing. Lasalocid sodium since FY 2010, virginiamycin since FY 2008, semduramicin sodium since FY 2007, 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 2016.

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 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 2016.

Compared between percentages of the refining grade and the feed grade based on the testing-passed quantity, the feed grade accounted for 66.6 % of the total (65.8 % in the previous FY). The feed grade also accounted for 70.0 % of the total (65.0 % 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 colistin sulfate, nosiheptide, and salinomycin sodium. In FY 2016, only the refining grade of colistin sulfate and nosiheptide, and only the feed grade of 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 2007 to 2016, respectively.

The total of the testing-passed quantity was 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 it was remained almost unchanged. 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 2016, the polyether antibiotics accounted for 57 % of the total (54 % in the previous FY), followed by the polypeptide antibiotics, 32 % (33 % 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 2007 to FY 2008 and since FY 2009 has remained around 50 %. The polyether antibiotics accounted for 55 % (49 % in the previous FY), followed by the polypeptide antibiotics, at 26 % (28 % in the previous FY).

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

As of the end of March in 2017, 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, Tatsuno Factory, Scientific Feed Laboratory Co., Ltd., is registered as a place of business as a manufacturer of specified feed additives concerning colistin sulfate, enramycin, lasalocid sodium, monensin sodium, nosiheptide, and salinomycin sodium.

Table 4 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 2016. Moreover, lasalocid sodium which have not undergone the testing as a specified feed additive in FY 2016 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 2016 was 843 tons (119 % over the previous FY) and the quantity converted from the actual quantity into potency was 117 tons (potency) (113 % over the previous FY).
The descending order of the manufactured quantity in FY 2016 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.

6. Total manufactured quantity of the specified feed additives

Table 5 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 2016 was highest for the polyether antibiotics, 1,229 tons (testing: 498 tons; registration: 731 tons), which accounted for 71.7 % of the total. The descending order by type was salinomycin sodium (35.2 %), monensin sodium (18.1 %), and colistin sulfate (12.9 %). The total quantity converted from the actual quantity into potency by category was also highest for the polyether antibiotics, 160 tons (testing: 51 tons; registration: 109 tons), which accounted for 76.1 % of the total. The descending order by type was monensin sodium (29.6 %), salinomycin sodium (28.7 %), and colistin sulfate (10.5 %).
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 2007 to FY 2016, 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 increased in FY2010, and remained almost unchanged until slightly increasing in FY 2016. The quantity converted from the actual quantity into potency also showed the same trend.
In FY 2016, the percentage of the manufacturing by the registered manufacturers of specified feed additives of the total was 49 % for the manufactured quantity (47 % in the previous FY) and 56 % for the quantity converted from the actual quantity into potency (54 % in the previous FY).

7. 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 2016 were as follows.
(1) Nineteen brands of 11 specified feed additives passed the official testing were applied 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 192 cases, 871 tons, and 93 tons (potency), respectively. The cases, the quantity and the quantity converted from the actual quantity into potency were slightly increased compared to the previous fiscal year.

(3) The testing-passed quantity of the specified feed additives by type was highest of salinomycin sodium, followed by colistin sulfate and narasin 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 salinomycin sodium, followed by colistin sulfate and narasin 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 67 % and 70 % of the total respectively.

(6) 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.

(7) 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.

(8) 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, monensin sodium, and colistin sulfate in descending order. The total quantity converted from the actual quantity into potency was monensin sodium, salinomycin sodium, and colistin sulfate in descending order.

Table 1: Names of applicants and others for the official testing of the specified feed additives (FY 2016)

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	Japan Nutrition Co., Ltd.	Ibaraki	Salinomycin sodium	○	100	
	Miyarisan Pharmaceutical Co., Ltd.	*	Flavophospholipol	○	80	
	Nichiku Yakuhin Kogyo Corporation	Kanagawa	Monensin sodium		200	
			Salinomycin sodium	○	100	
	Rokku Chemical Products Co., Ltd.	Shizuoka	Colistin sulfate		100	2 brands
			Enramycin	○	80	
			Salinomycin sodium	○	100	
	TNB Co., Ltd.	*	Chlortetracycline	○	100	
Kobe	Eli Lilly Japan K. K.	*	Avilamycin	○	200	
			Narasin	○	100	
			Tylosin phosphate		275	
	Scientific Feed Laboratory Co., Ltd.	Hyogo	Colistin sulfate		100	
Fukuoka	Japan Nutrition Co., Ltd.	*	Colistin sulfate		100	
	Kohkin Chemical Co., Ltd.	Kagoshima	Alkyltrimethylammonium calcium oxytetracycline		400	
			Monensin sodium		200	
			Nosiheptide		40	
			Salinomycin sodium	○	100	
	Scientific Feed Laboratory Co., Ltd.	Miyazaki	Colistin sulfate		100	
Total	8 business entities	10 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 2014 to 2016)

Category	Type of the specified feed additives	FY 2014					FY 2015					FY 2016				
		Passed cases	Passed quantity kg	Compo-sition ratio (%)	Quantity converted into potency kg(potency)	Compo-sition ratio (%)	Passed cases	Passed quantity kg	Compo-sition ratio (%)	Quantity converted into potency kg(potency)	Compo-sition ratio (%)	Passed cases	Passed quantity kg	Compo-sition ratio (%)	Quantity converted into potency kg(potency)	Compo-sition ratio (%)
Polypeptide antibiotics	Colistin sulfate	41	158,120	17.4	15,812	15.1	58	223,820	28.5	22,382	25.3	55	212,680	24.4	21,268	22.8
	Enramycin	2	2,380	0.3	190	0.2	3	3,720	0.5	298	0.3	2	4,820	0.6	386	0.4
	Nosiheptide	3	12,000	1.3	480	0.5	6	22,000	2.8	880	1.0	15	60,000	6.9	2,400	2.6
	Zinc bacitracin	7	34,780	3.8	3,727	3.6	2	9,500	1.2	950	1.1	-	-	-	-	-
	Subtotal	53	207,280	22.8	20,209	19.3	69	259,040	32.9	24,510	27.7	72	277,500	31.9	24,054	25.8
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	1	2,000	0.2	800	0.8	1	3,000	0.4	1,200	1.4	1	1,400	0.2	560	0.6
	Chlortetracycline	3	14,400	1.6	1,440	1.4	3	14,000	1.8	1,400	1.6	3	14,000	1.6	1,400	1.5
	Subtotal	4	16,400	1.8	2,240	2.1	4	17,000	2.2	2,600	2.9	4	15,400	1.8	1,960	2.1
Macrolide antibiotics	Tylosin phosphate	5	19,370	2.1	5,327	5.1	4	19,994	2.5	5,498	6.2	1	5,039	0.6	1,386	1.5
	Subtotal	5	19,370	2.1	5,327	5.1	4	19,994	2.5	5,498	6.2	1	5,039	0.6	1,386	1.5
Polysaccharide antibiotics	Flavophospholipol	-	-	-	-	-	1	1,250	0.2	100	0.1	1	1,250	0.1	100	0.1
	Subtotal	-	-	-	-	-	1	1,250	0.2	100	0.1	1	1,250	0.1	100	0.1
Polyether antibiotics	Lasalocid sodium	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Monensin sodium	3	12,140	1.3	2,428	2.3	3	6,080	0.8	1,216	1.4	4	11,500	1.3	2,300	2.5
	Narasin	29	317,775	34.9	31,778	30.3	12	131,625	16.7	13,163	14.9	18	197,500	22.7	19,750	21.2
	Salinomycin sodium	61	244,875	26.9	24,488	23.4	71	288,780	36.7	28,878	32.6	72	289,487	33.3	28,949	31.1
	Semduramicin sodium	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Subtotal	93	574,790	63.2	58,693	56.0	86	426,485	54.2	43,257	48.9	94	498,487	57.3	50,999	54.8
Others	Avilamycin	25	91,575	10.1	18,315	17.5	17	62,675	8.0	12,535	14.2	20	72,950	8.4	14,590	15.7
	Bicozamycin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Efrotomycin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Virginiamycin	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Subtotal	25	91,575	10.1	18,315	17.5	17	62,675	8.0	12,535	14.2	20	72,950	8.4	14,590	15.7
Total		180	909,415	100.0	104,784	100.0	181	786,444	100.0	88,499	100.0	192	870,626	100.0	93,088	100.0
Ratio to the previous fiscal year (%)		91	99		97		101	86		84		106	111		105	

Note: Quantity and others of the specified feed additives manufactured by the registered manufacturers are shown separetely in Table 4.

Table 3: Number of the testing-passed cases, passed quantity, and quantity converted into potency
(Sorted by the grade of the preparation, FY 2016)

Category	Type of the specified feed additives	Refining grade			Feed grade		
		Passed cases	Passed quantity kg	Quantity convreted into potency kg(potency)	Passed cases	Passed quantity kg	Quantity convreted into potency kg(potency)
Polypeptide antibiotics	Colistin sulfate	55	212,680	21,268	–	–	–
	Enramycin				2	4,820	386
	Nosiheptide	15	60,000	2,400	–	–	–
	Zinc bacitracin				–	–	–
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	1	1,400	560			
	Chlortetracycline				3	14,000	1,400
Macrolide antibiotics	Tylosin phosphate	1	5,039	1,386			
Polysaccharide antibiotics	Flavophospholipol				1	1,250	100
Polyether antibiotics	Lasalocid sodium	–	–	–			
	Monensin sodium	4	11,500	2,300			
	Narasin				18	197,500	19,750
	Salinomycin sodium	–	–	–	72	289,487	28,949
	Semduramicin sodium	–	–	–			
Others	Avilamycin				20	72,950	14,590
	Bicozamycin	–	–	–			
	Efrotomycin	–	–	–			
	Virginiamycin	–	–	–			
Total		76	290,619	27,914	116	580,007	65,174
Proportion (%)		39.6	33.4	30.0	60.4	66.6	70.0

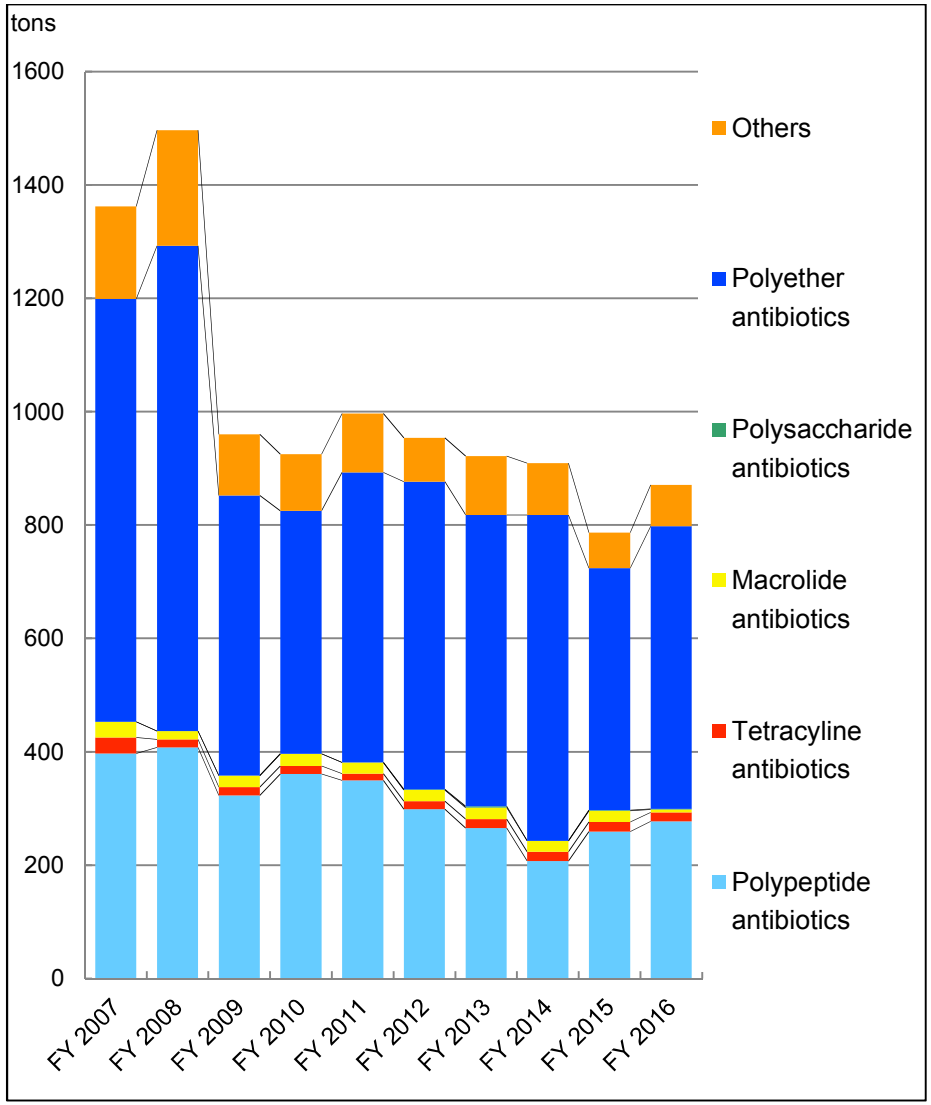

Figure 1: Changes in the testing-passed quantity of the specified feed additives (Sorted by category of antibiotics)

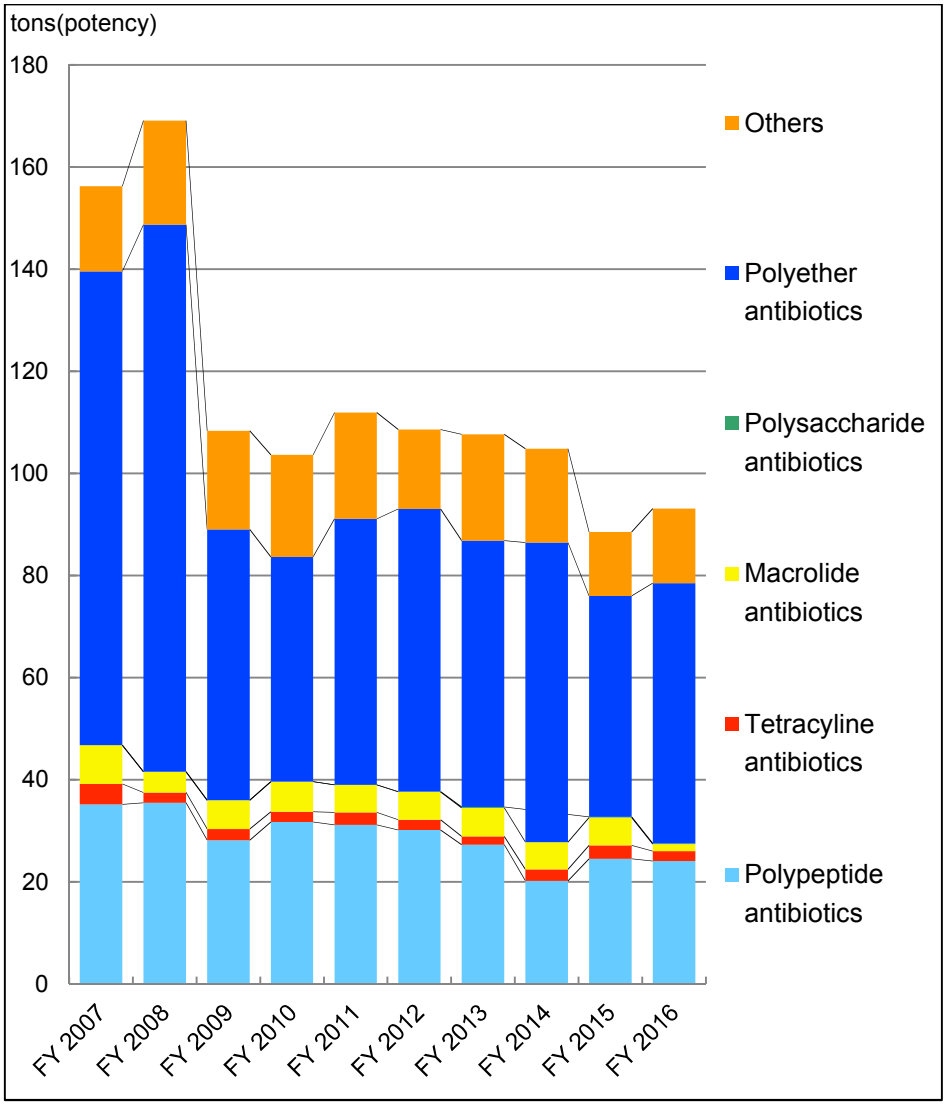

Figure 2: Changes in the testing-passed quantity of the specified feed additives converted into potency (Sorted by category of antibiotics)

Table 4: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2015 and 2016)

Category	Type of the specified feed additives	FY 2015		FY 2016	
		Manufactured quantity*	Quantity converted into potency	Manufactured quantity*	Quantity converted into potency
		kg	kg(potency)	kg	kg(potency)
Polypeptide antibiotics	Colistin sulfate	4,000	400	8,120	812
	Enramycin	34,620	2,770	76,680	6,134
	Nosiheptide	48,220	1,929	27,720	1,109
	Subtotal	86,840	5,098	112,520	8,055
Polyether antibiotics	Lasalocid sodium	116,920	17,538	117,060	17,559
	Monensin sodium	303,760	60,752	299,560	59,912
	Salinomycin sodium	201,200	20,120	314,240	31,424
	Subtotal	621,880	98,410	730,860	108,895
Total		708,720	103,508	843,380	116,950
Ratio to the previous fiscal year (%)		103	113	119	113

* Hearing from each registered manufacturer of specified feed additives.

Table 5: Total manufactured quantity of the specified feed additives (FY 2016)

Category	Type of specified feed additives	Total quantity *1 (kg)	Composition ratio (%)	Total quantity converted into potency *2 (kg(potency))	Composition ratio (%)
Polypeptide antibiotics	Colistin sulfate	220,800	12.9	22,080	10.5
	Enramycin	81,500	4.8	6,520	3.1
	Nosiheptide	87,720	5.1	3,509	1.7
	Zinc bacitracin	—	—	—	—
	Subtotal	390,020	22.8	32,109	15.3
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	1,400	0.1	560	0.3
	Chlortetracycline	14,000	0.8	1,400	0.7
	Subtotal	15,400	0.9	1,960	0.9
Macrolide antibiotics	Tylosin phosphate	5,039	0.3	1,386	0.7
	Subtotal	5,039	0.3	1,386	0.7
Polysaccharide antibiotics	Flavophospholipol	1,250	0.1	100	0.0
	Subtotal	1,250	0.1	100	0.0
Polyether antibiotics	Lasalocid sodium	117,060	6.8	17,559	8.4
	Monensin sodium	311,060	18.1	62,212	29.6
	Narasin	197,500	11.5	19,750	9.4
	Salinomycin sodium	603,727	35.2	60,373	28.7
	Semduramicin sodium	—	—	—	—
	Subtotal	1,229,347	71.7	159,894	76.1
Others	Avilamycin	72,950	4.3	14,590	6.9
	Bicozamycin	—	—	—	—
	Efrotomycin	—	—	—	—
	Virginiamycin	—	—	—	—
	Subtotal	72,950	4.3	14,590	6.9
Total		1,714,006	100.0	210,038	100.0

*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

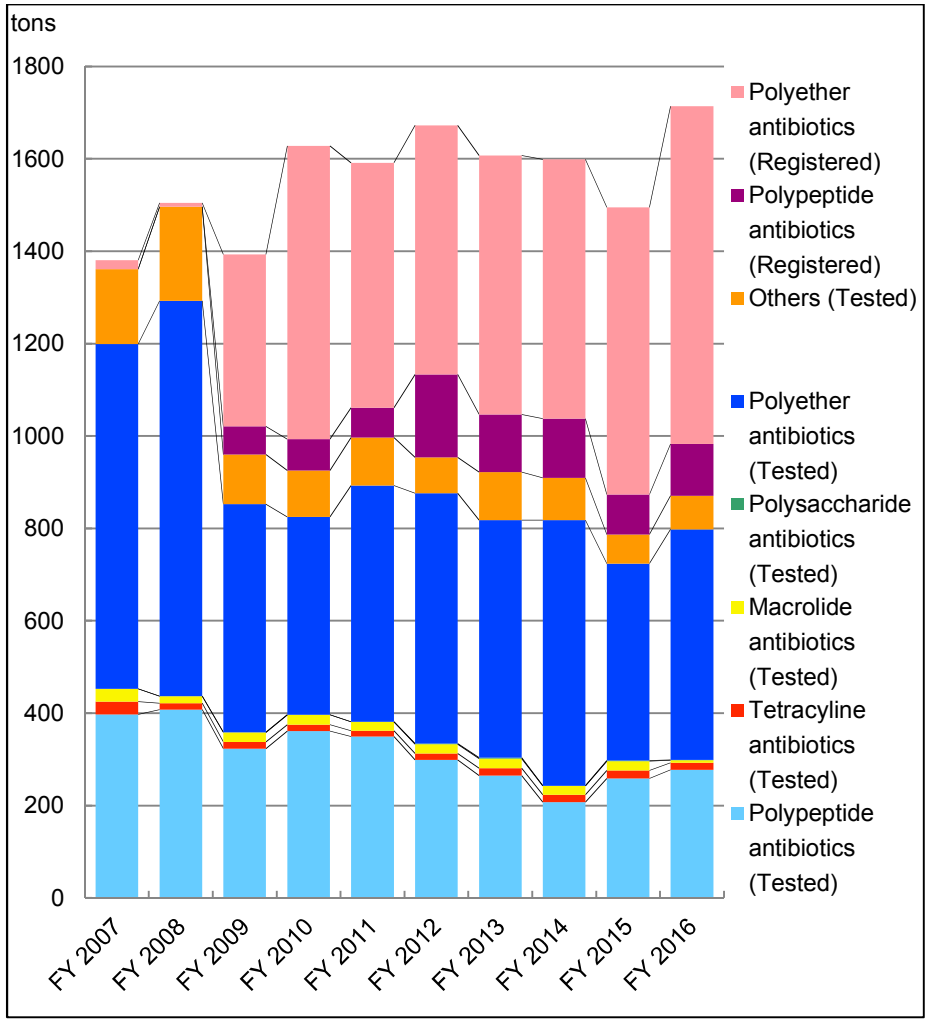

Figure 3: Changes in the testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives (Sorted by category of antibiotics)

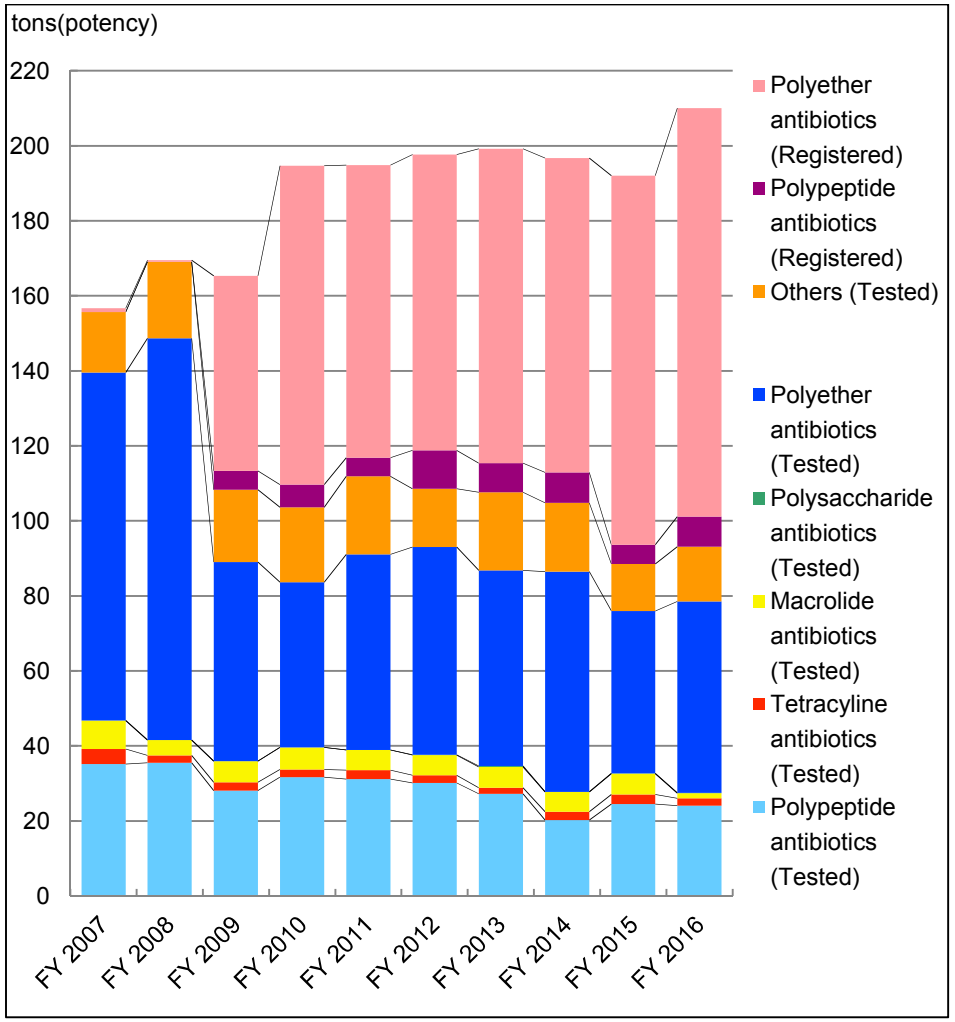

Figure 4: Changes in the testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives converted into potency (Sorted by category of antibiotics)