

Results of official testing of specified feed additives (FY 2009)

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 2009.

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 2009.

Seven business entities applied the official testing of specified feed additives. As for their manufacturing forms and others, four of the seven import raw materials for manufacturing or preparations by themselves or purchase them from other companies to manufacture preparations, and the other three import preparations and market them only. There was no business entity which manufactures from raw materials for manufacturing to preparations by itself.

Eleven antibiotic preparations (12 in the previous FY) were applied as specified feed additives for a total of 24 brands (24 in the previous FY), which means the number of the types of antibiotic preparations decreased. Of them, the types and brands of the antibiotic preparations whose raw materials for manufacturing or preparation are dependent on foreign sources was 10 (11 in the previous FY) and 22 (21 in the previous FY), respectively.

Zinc bacitracin (preparation) was imported from Norway and China, and colistin sulfate (raw material for manufacturing) from China, alkyltrimethylammonium calcium oxytetracycline (raw material for manufacturing) from China, chlortetracycline (preparation) from Singapore, tylosin phosphate (preparation) from the USA, salinomycin sodium (raw material for manufacturing) from China, Bulgaria and Brazil, narasin (preparation) from the USA, monensin sodium (raw material for manufacturing) from the USA and China, lasalocid sodium (raw material for manufacturing) from the USA, and avilamycin (preparation) from the UK. The number of the

import source countries was seven (7 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 2007, 2008, and 2009.

In FY 2009, 215 cases and 960 tons were passed, and the quantity converted from the actual quantity into potency was 108 tons (potency). All of the passed cases, the passed quantity, and the quantity converted from the actual quantity decreased compared with the previous fiscal year, 62.0%, 64.2%, and 64.1%, respectively.

The percentage of the antibiotic preparations in the total passed quantity by type was 26.6%, which was the highest one, for salinomycin sodium (24.4% in the previous FY), followed in descending order by 21.3% for colistin sulfate (13.3% in the previous FY), 20.5% for narasin (14.9% in the previous FY), 11.2% for avilamycin (13.6% in the previous FY), and 8.3% for nosiheptide (5.9% 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 23.6% for salinomycin sodiums (21.6% in the previous FY), followed in descending order by 18.9% for colistin sulfate (11.8% in the previous FY), 18.1% for narasin (13.2% in the previous FY), 17.9% for avilamycin (12.1% in the previous FY), and 5.6% for monensin sodium (19.2% in the previous FY).

Both the passed quantity and the quantity converted from the actual quantity of colistin sulfate, tylosin phosphate and alkyltrimethylammonium calcium oxytetracycline increased compared with FY 2008, while salinomycin sodium, narasin, avilamycin and nosiheptide decreased.

The following substances were not applied in FY 2009: virginiamycin, which has not been applied since FY 2008; destomycin A, flavophospholipol and semduramicin sodium, which have not been applied since FY 2007; efrotomycin and sedecamycin, which have not been applied since FY 2005; and bicozamycin, which have not been applied since FY 1999. In addition, enramycin was not applied in FY 2009, but has been manufactured by the registered manufacturers of specified feed additives referred to in Article 7, paragraph 1 of the Law Concerning Safety Assurance and Quality Improvement of Feeds.

3. The number of the testing-passed cases and others 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 2009.

Compared between percentages of the refining grade and the feed grade based on the quantity converted from the actual quantity into potency, the feed grade accounted for 66.0 % of the total (55.6 % in the previous FY).

Both the refining grade and the feed grade are set for nosiheptide, colistin sulfate, and salinomycin sodium. In FY 2009, only the refining grade of colistin sulfate, only the feed grade of nosiheptide and the both grades of salinomycin sodium were subjected to the testing.

As for salinomycin sodium, the feed grade preparations are approximately 13 times as much as the refining grade preparations when the quantities converted from the actual quantity into potency are compared.

4. Changes in the passed quantity and others of antibiotic preparations 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 2000 to 2009, respectively.

The passed quantity of antibiotic preparations by category was on a declining trend from FY 2000 to FY 2002, since then has repeated increase and decrease, and in FY 2009 was the lowest over the past decade. The quantity converted from the actual quantity into potency has also repeated increase and decrease since FY 2000, and was the lowest over the past decade in FY 2009, and the rate of decrease was the highest over the past decade (64% over the previous year). As for the quantity converted from the actual quantity into potency of antibiotic preparations by category, polyether antibiotics has changed since FY 2000 at a rate of more than half of the total, and in FY 2009 accounted for 49.0% of the total (63.3% in the previous FY), and polypeptide antibiotics accounted for 26.0% (21.0% in the previous FY).

5. Number of the 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 2009.

The number of the testing-passed cases, the passed quantity and the quantity converted from the actual quantity into potency in FY 2009 were highest within the jurisdiction area of the Kobe center, followed by the jurisdiction areas of the Fukuoka center, and the headquarters.

The number of the passed cases, the passed quantity and the quantity converted from the actual quantity into potency increased within the jurisdiction areas of the headquarters and the Fukuoka center, but decreased within the jurisdiction of the Kobe 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 2009.

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

In FY 2007, the 3rd plant, Kyushu Plant, Kohkin Chemical Co., Ltd. was registered as a place of business as a manufacturer of specified feed additives concerning semduramicin sodium, and one brand has been manufactured. In FY 2009, Tatsuno Factory, Scientific Feed Laboratory Co., Ltd was registered as a place of business as a manufacturer of specified feed additives concerning salinomycin sodium, monensin sodium, lasalocid sodium, enramycin and colistin sulfate and has manufactured them. The number of brands manufactured by these plants, the manufactured quantity and the quantity converted from the actual quantity into potency in FY 2009 are shown in Table 5.

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 2009 were as follows.

- (1) Twenty four brands of 11 specified feed additives were applied for the official testing of specified feed additives by 7 business entities.
- (2) The manufacturing of raw materials or preparations for 22 brands of 10 specified feed additives was dependent on foreign sources.
- (3) The number of the passed cases, the passed quantity, and the quantity converted from the actual quantity into potency were 215 cases, 960 tons, and 108 tons (potency), respectively. All of them decreased compared to the previous fiscal year.
- (4) The antibiotic preparations with the highest most passed quantity were salinomycin sodium (26.6%), followed by colistin sulfate, narasin, avilamycin, and nosiheptide in descending order.
- (5) The antibiotic preparation with the highest quantity converted from the actual quantity into potency was salinomycin sodium (23.6%), followed by colistin sulfate, narasin, avilamycin, and monensin sodium in descending order.
- (6) Compared between percentages of the refining grade and the feed grade on the testing-passed quantity converted from the actual quantity into potency of the specified feed additives, the feed grade accounted for 66.0 % of the total.
- (7) The changes in the quantity converted from the actual quantity into potency over the last decade show that it has repeated increase and decrease since FY 2000, and in FY 2009 it was the lowest and the rate of decrease was the highest over the last decade (64% over the previous year).
- (8) 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.
- (9) Semduramicin sodium, salinomycin sodium, monensin sodium, lasalocid sodium, enramycin and colistin sulfate were manufactured by the registered manufacturers of specified feed additives.

Table 1: Names of applicants and others for the official testing of the specified feed additives (FY 2009)

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	Kaken Pharmaceutical Co., Ltd.	*	Zinc bacitracin	0	100	4,200 unit/g	
				0	150	6,300 unit/g	
	Nichiku Yakuhin Kogyo Corporation	Kanagawa	Salinomycin sodium	0	100		
			Monensin sodium		200		
			Salinomycin sodium	0	100		
			Salinomycin sodium	0	100		
	Kobe	Fumakilla Totalsystem Ltd.	*	Chlortetracycline	0	100	
				Salinomycin sodium	0	100	
				Monensin sodium		200	
				Monensin sodium		200	
Scientific Feed Laboratory Co., Ltd.		Hyogo	Lasalocid sodium		150		
			Colistin sulfate		100		
Eli Lilly Japan K. K.		*	Tylosin phosphate		275		
			Avilamycin	0	100		
			Narasin	0	200		
			Tylosin phosphate	0	100		
Fukuoka	Scientific Feed Laboratory Co., Ltd.	Miyazaki	Colistin sulfate		100		
			Alkyltrimethylammonium calcium oxytetracycline		400		
			Salinomycin sodium	0	100		
			Nosiheptide	0	40		
Total	7 business entities	8 places			24 brands		

* Fallen under an importer

Table 2: Number of the testing-passed cases, passed quantity, and quantity converted from the actual quantity into potency
(Sorted by the type of the antibiotics, FYs 2007 to 2009)

Category	Type of the specified feed additives	2007				2008				2009			
		Passed cases	Passed quantity kg	Composition ratio (%)	Quantity converted into potency kg(potency)	Passed cases	Passed quantity kg	Composition ratio (%)	Quantity converted into potency kg(potency)	Passed cases	Passed quantity kg	Composition ratio (%)	Quantity converted into potency kg(potency)
Polypeptide antibiotics	Zinc bacitracin	14	54,600.0	4.0	6,850.0	13	56,475.0	3.8	6,921.3	11	38,325.0	4.0	4,423.8
	Enramycin	18	64,300.0	4.7	5,144.0	15	64,360.0	4.3	5,148.8	0	0.0	0.0	0.0
	Nosiheptide	18	72,000.0	5.3	2,880.0	22	87,920.0	5.9	3,516.8	20	80,000.0	8.3	3,200.0
	Virginiamycin	1	1,000.0	0.1	500.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Colistin sulfate	53	206,080.0	15.1	20,283.2	54	199,140.0	13.3	19,914.0	53	204,940.0	21.3	20,494.0
	Subtotal	104	397,980.0	29.2	35,657.2	104	407,895.0	27.3	35,500.9	84	323,265.0	33.7	28,117.8
Tetracycline antibiotics	Alkylmethylammonium calcium oxytetracycline	2	4,000.0	0.3	1,600.0	1	2,000.0	0.1	800.0	0.5	2,520.0	0.3	1,008.0
	Chlortetracycline	6	24,000.0	1.8	2,400.0	3	12,000.0	0.8	1,200.0	0.7	12,000.0	1.2	1,200.0
	Subtotal	8	28,000.0	2.1	4,000.0	4	14,000.0	0.9	2,000.0	1.2	14,520.0	1.5	2,208.0
Macrolide antibiotics	Tylosin phosphate	6	27,648.0	2.0	7,603.3	3	14,822.0	1.0	4,076.1	2.4	20,477.0	2.1	5,631.2
	Sedecamycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Subtotal	6	27,648.0	2.0	7,603.3	3	14,822.0	1.0	4,076.1	2.4	20,477.0	2.1	5,631.2
Aminoglycoside antibiotics	Destomycin A	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Subtotal	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Flavophospholipol	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Polysaccharide antibiotics	Subtotal	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Salinomycin sodium	90	359,280.0	26.4	35,928.0	91	364,840.0	24.4	36,484.0	21.6	255,400.0	26.6	25,540.0
	Semduramycin sodium	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Polyether antibiotics	Narasin	16	177,750.0	13.1	17,775.0	21	222,575.0	14.9	22,257.5	13.2	196,525.0	20.5	19,652.5
	Monsensin sodium	41	152,940.0	11.2	30,588.0	42	162,080.0	10.8	32,416.0	19.2	30,360.0	3.2	6,072.0
	Lasalocid sodium	14	56,560.0	4.2	8,484.0	27	106,300.0	7.1	15,945.0	9.4	11,780.0	1.2	1,767.0
	Subtotal	161	746,530.0	54.8	92,775.0	181	855,795.0	57.2	107,102.5	63.3	494,065.0	51.5	53,031.5
	Avilamycin	44	161,725.0	11.9	16,172.5	55	204,000.0	13.6	20,400.0	12.1	107,950.0	11.2	19,347.5
Others	Efrotomycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Bicozamycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Subtotal	44	161,725.0	11.9	16,172.5	55	204,000.0	13.6	20,400.0	12.1	107,950.0	11.2	19,347.5
	Total	323	1,361,883.0	100.0	156,208.0	347	1,496,512.0	100.0	169,079.4	100.0	960,277.0	100.0	108,335.9
Ratio to the previous fiscal year (%)		73.6	85.5		87.2	109.9		108.2		62.0	64.2		64.1

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 from the actual quantity into potency
(Sorted by the grade of the preparation, FY 2009)

Category	Type of the specified feed additives	Refining grade			Feed grade		
		Passed cases	Passed quantity kg	Quantity converted into potency kg (potency)	Passed cases	Passed quantity kg	Quantity converted into potency kg (potency)
Polypeptide antibiotics	Zinc bacitracin				11	38,325.0	4,423.8
	Enramycin				-	-	-
	Nosiheptide	-	-	-	20	80,000.0	3,200.0
	Virginiamycin	-	-	-			
	Colistin sulfate	53	204,940.0	20,494.0	-	-	-
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	2	2,520.0	1,008.0			
	Chlortetracycline				3	12,000.0	1,200.0
Macrolide antibiotics	Sedecamycin	-	-	-			
Aminoglycoside antibiotics	Tylosin phosphate	4	20,477.0	5,631.2			
	Destomycin A	-	-	-			
Polysaccharide antibiotics	Flavophospholipol				-	-	-
	Salinomycin sodium	5	18,640.0	1,864.0	59	236,760.0	23,676.0
Polyether antibiotics	Semduramicin sodium	-	-	-			
	Narasin				18	196,525.0	19,652.5
	Monensin sodium	8	30,360.0	6,072.0			
	Lasalocid sodium	3	11,780.0	1,767.0			
Others	Avilamycin				29	107,950.0	19,347.5
	Efrotomycin	-	-	-			
	Bicozamycin	-	-	-			
Total		75	288,717.0	36,836.2	140	671,560.0	71,499.8
Proportion (%)		34.9	30.1	34.0	65.1	69.9	66.0

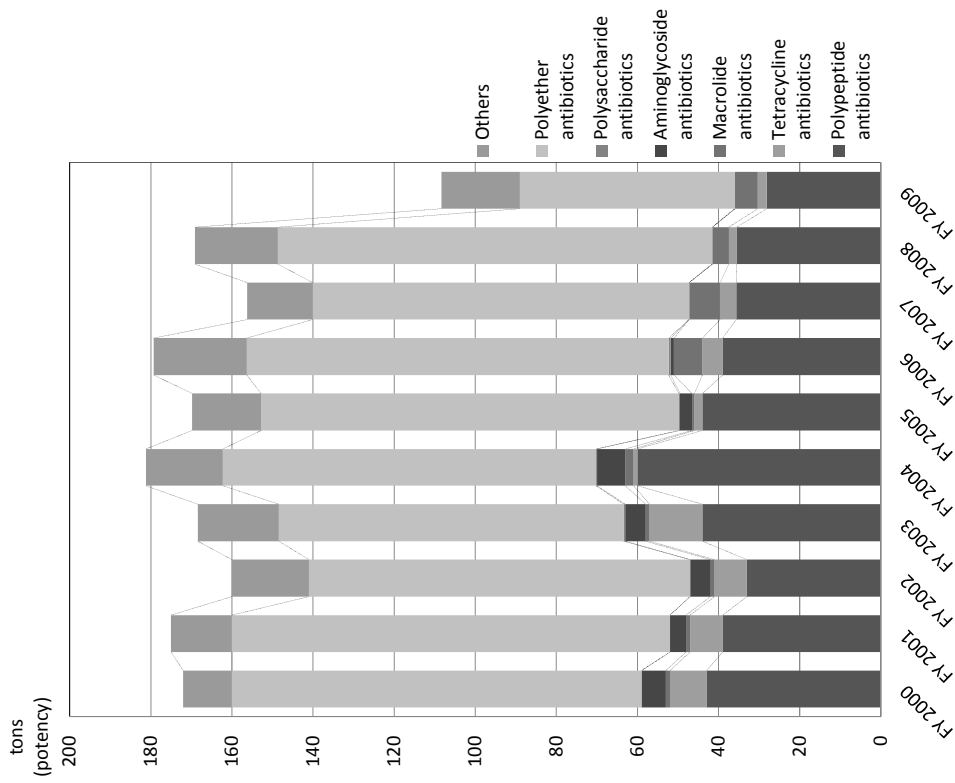


Figure 2: Changes in the testing-passed quantity of the specified feed additives converted into potency (Sorted by category of antibiotics)

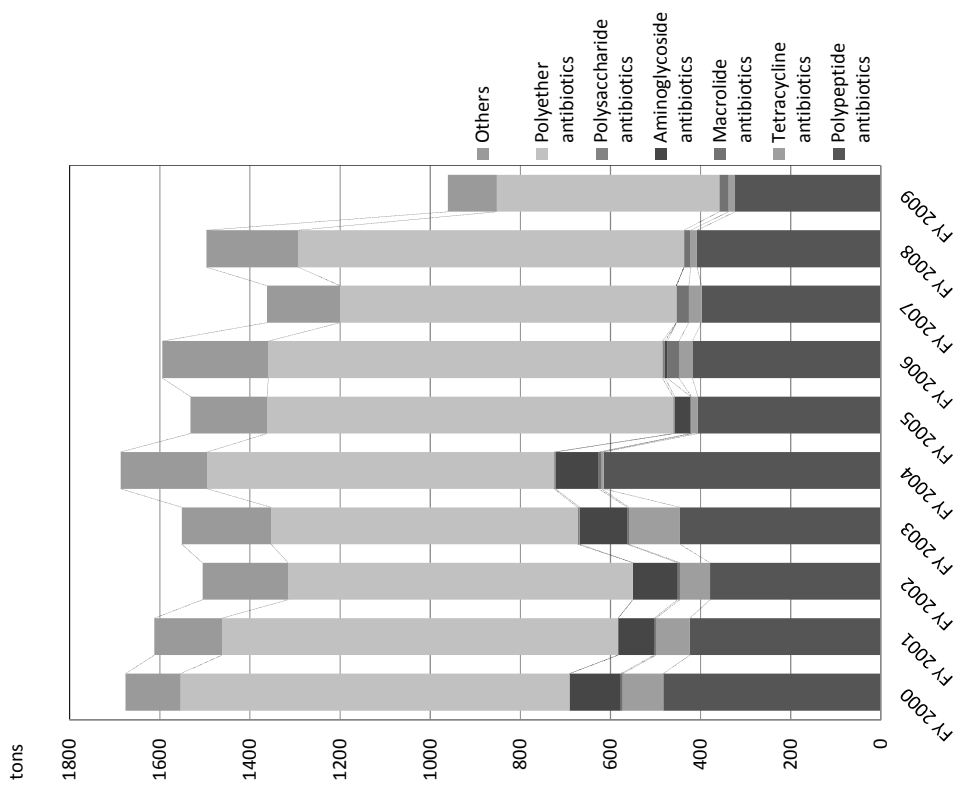


Figure 1: Changes in the testing-passed quantity of the specified feed additives (Sorted by category of antibiotics)

Table 4: Number of the testing-passed cases, passed quantity, and quantity converted into potency
 (Sorted by the jurisdiction area of FAMIC, FY 2009)

Contact office of FAMIC	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)
Headquarters	43 (30)	165,305 (123,635)	17,826 (14,353)
Sapporo	- (-)	- (-)	- (-)
Sendai	- (-)	- (-)	- (-)
Nagoya	- (-)	- (-)	- (-)
Kobe	111 (262)	556,752 (1,160,397)	70,732 (138,153)
Fukuoka	61 (55)	238,220 (212,480)	19,778 (16,573)
Total	215 (347)	960,277 (1,496,512)	108,336 (169,079)

Data of the previous year are in parentheses.

Table 5: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2009)

Category	Type of the specified feed additives	2009	
		Manufactured quantity kg	Quantity converted into potency kg(potency)
Polypeptide antibiotics	Enramycin	52,300	4,184
	Colistin sulfate (Refining grade)	8,220	822
	Subtotal	60,520	5,006
Polyether antibiotics	Salinomycin sodium (Feed grade)	156,460	15,646
	Semduramicin sodium	20,000	1,000
	Monensin sodium	122,660	24,532
	Lasalocid sodium	72,420	10,863
	Subtotal	371,540	52,041
Total		432,060	57,047
Ratio to the previous fiscal year (%)		5,401	14,262

(Hearing from each registered manufacturer of specified feed additives)

Results of official testing of specified feed additives (FY 2010)

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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 2010. The quantity and others of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2010 are also reported.

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 2010.

Seven business entities applied the official testing of specified feed additives. As for their manufacturing forms and others, four of the seven import raw materials for manufacturing or preparations by themselves or purchase them from other companies to manufacture preparations, and the other three import preparations and market them only. There was no business entity which manufactures from raw materials for manufacturing to preparations by itself.

Ten antibiotic preparations (11 in the previous FY) were applied as specified feed additives for a total of 16 brands (24 in the previous FY), which means the numbers of the types and brands of antibiotic preparations decreased. Of them, the types and brands of the antibiotic preparations whose raw materials for manufacturing or preparations are dependent on foreign sources were 9 (11 in the previous FY) and 13 (21 in the previous FY), respectively.

Zinc bacitracin (preparation), monensin sodium (raw material for manufacturing), colistin sulfate (raw material for manufacturing), and alkyltrimethylammonium calcium oxytetracycline (raw material for manufacturing) were imported from China, and salinomycin sodium (raw material for manufacturing) from China, Bulgaria and Brazil, chlortetracycline (preparation) from Singapore, tylosin phosphate (preparation) and narasin (preparation) from the USA, and avilamycin

(preparation) from the UK. The number of the import source countries was 6 (7 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 2008, 2009, and 2010.

There were no antibiotic preparations which did not pass in the testing in 2010. In FY 2010, 194 cases and 925 tons were passed, and the quantity converted from the actual quantity into potency was 104 tons (potency). All of the passed cases, the passed quantity, and the converted quantity decreased compared with the previous fiscal year, 90.2%, 96.3%, and 95.7%, respectively.

The percentage of the antibiotic preparations in the total passed quantity by type was 28.4%, which was the highest one, for narasin (20.5% in the previous FY), followed in descending order by 23.8% for colistin sulfate (21.3% in the previous FY), 16.7% for salinomycin sodium (26.6% in the previous FY), 10.8% for avilamycin (11.2% in the previous FY), and 9.6% for nosiheptide (8.3% 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 25.3% for narasin (18.1% in the previous FY), followed in descending order by 21.3% for colistin sulfate (18.9% in the previous FY), 19.3% for avilamycin (17.9% in the previous FY), 14.9% for salinomycin sodium (23.6% in the previous FY), and 5.9% for zinc bacitracin (4.1% in the previous FY).

Both the passed quantity and the converted quantity of zinc bacitracin, narasin, nosiheptide, colistin sulfate and tylosin phosphate increased compared with those in FY 2009, while both of alkyltrimethylammonium calcium oxytetracycline, salinomycin sodium and monensin sodium decreased.

Virginiamycin since FY 2008, efrotomycin and sedecamycin 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 2010.

Enramycin, semduramicin sodium and lasalocid sodium were not subjected to the testing, but were manufactured by the registered manufacturers of specified feed additives.

Destomycin A has not been applied since FY 2007 and its designation as a feed additive was revoked by the Notification No. 270 of February 4, 2010 of the Ministry of Agriculture, Forestry and Fisheries.

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

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 2010.

Compared between percentages of the refining grade and the feed grade based on the quantity converted from the actual quantity into potency, the feed grade accounted for 70.0 % of the total (66.0 % in the previous FY).

Both the refining grade and the feed grade are set for nosiheptide, colistin sulfate, and salinomycin sodium. In FY 2010, only the refining grade of colistin sulfate, only the feed grade of nosiheptide and salinomycin sodium were subjected to the testing.

4. Changes in the passed quantity and others of antibiotic preparations 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 2001 to 2010, respectively.

The passed quantity of antibiotic preparations by category was on a declining trend with repeating increase and decrease since FY 2004, which was the peak, significantly decreased from FY 2008 through FY 2009, and was the lowest in FY 2010, the lowest of the past 10 years. The quantity converted from the actual quantity into potency shows a similar trend, which significantly decreased from FY 2008 through FY 2009 (rate of decrease: 64% over the previous year), and was the lowest in FY 2010, the lowest of the past 10 years. In addition, one type and five types of specified feed additives have been manufactured by the registered manufacturers of specified feed additives since FY 2007 and FY 2009, respectively.

As for the quantity converted from the actual quantity into potency of antibiotic preparations by category, polyether antibiotics has changed since FY 2001 at a rate of more than half of the total and in FY 2010 accounted for 42.5% of the total (49.0% in the previous FY), and polypeptide antibiotics accounted for 30.6% (26.0% in the previous FY).

5. Number of the 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 2010.

The number of the testing-passed cases, the passed quantity and the quantity converted from the actual quantity into potency in FY 2010 were highest within the jurisdiction area of the Kobe center, followed by the jurisdiction areas of the Fukuoka center, and the headquarters.

The number of the passed cases, the passed quantity and the quantity converted from the actual quantity into potency decreased within the jurisdiction area of each 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 2009.

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

In accordance with the provision of Article 7, paragraph 1 of the Law Concerning Safety Assurance and Quality Improvement of Feeds, the 3rd plant, Kyushu Plant, Kohkin Chemical Co., Ltd. was registered as a place of business as a manufacturer of specified feed additives concerning semduramicin sodium in FY 2007 and Tatsuno Factory, Scientific Feed Laboratory Co., Ltd., was registered as a place of business as a manufacturer of specified feed additives concerning salinomycin sodium, monensin sodium, lasalocid sodium, enramycin and colistin sulfate in FY 2009 and they have manufactured those preparations. The number of brands manufactured by these plants, the manufactured quantity and the quantity converted from the actual quantity into potency in FY 2009 are shown in Table 5.

As for the quantity manufactured by the registered manufacturers of specified feed additives, the total manufactured quantity and the total quantity converted from the actual quantity into potency were 704 tons (163% over the previous year) and 91 tons (155% over the previous year) respectively in FY 2010, and has continued to increase since FY 2008.

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 2010 were as follows.

- (1) Sixteen brands of 10 specified feed additives were applied for the official testing of specified feed additives by 7 business entities.
- (2) The manufacturing of raw materials or preparations for 13 brands of 9 specified feed additives was dependent on foreign sources.
- (3) The number of the passed cases, the passed quantity, and the quantity converted from the actual quantity into potency were 194 cases, 925 tons, and 104 tons (potency), respectively. All of them decreased compared to the previous fiscal year.
- (4) The antibiotic preparations with the highest most passed quantity were narasin (28.4%), followed by colistin sulfate, salinomycin sodium, avilamycin, and nosiheptide in descending order.
- (5) The antibiotic preparations with the highest quantity converted from the actual quantity into potency were narasin (25.3%), followed by colistin sulfate, avilamycin, salinomycin sodium, and zinc bacitracin in descending order.
- (6) Compared between percentages of the refining grade and the feed grade on the testing-passed quantity converted from the actual quantity into potency of the specified feed additives, the feed grade accounted for 70.0 % of the total.
- (7) The changes in the quantity converted from the actual quantity into potency of the passed preparations over the last decade show that they have decreased with repeating increase and decrease since FY 2004 and in FY 2009 the rate of decrease was the highest of the past 10

years (64% over the previous year), and then the quantity further decreased to be the lowest over the past decade in FY 2010.

- (8) The number of the passed cases, the passed quantity, and the quantity converted from the actual quantity into potency by each regional center were the highest within the jurisdiction of the Kobe center.
- (9) Semduramicin sodium, salinomycin sodium, monensin sodium, lasalocid sodium, enramycin and colistin sulfate were manufactured by the registered manufacturers of specified feed additives. The total manufactured quantity and the total quantity converted from the actual quantity into potency have continued to increase since FY 2008.

Table 1: Names of applicants and others for the official testing of the specified feed additives (FY 2010)

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	Kaken Pharmaceutical Co., Ltd.	*	Zinc bacitracin	0	100	4,200 unit/g
			Salinomycin sodium Monensin sodium	0	150	6,300 unit/g
Kobe	Nichiku Yakuhin Kogyo Corporation	Kanagawa	Salinomycin sodium	0	100	
			Monensin sodium		200	
	Japan Nutrition Co., Ltd.	Ibaraki	Salinomycin sodium	0	100	
			TNB Co., Ltd.	*	Chlortetracycline	0
	Scientific Feed Laboratory Co., Ltd.	Hyogo	Nosineptide	0	40	
			Colistin sulfate		100	
			Tylosin phosphate		275	
			Avilamycin	0	200	
			Narasin	0	100	
			Tylosin phosphate		275	
Fukuoka	Scientific Feed Laboratory Co., Ltd.	Miyazaki	Colistin sulfate		100	
			Alkyltrimethylammonium calcium oxytetracycline		400	
			Kohkin Chemical Co., Ltd.	Kagoshima	Salinomycin sodium	0
Total	7 business entities	8 places	Nosineptide	0	40	
					16 brands	

* Fallen under an importer

Table 2: Number of the testing-passed cases, passed quantity, and quantity converted into potency
(Sorted by the type of the antibiotics, FYs 2008 to 2010)

Category	Type of the specified feed additives	2008			2009			2010						
		Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)	Composition ratio (%)	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)	Composition ratio (%)	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)	Composition ratio (%)	
Polypeptide antibiotics	Zinc bacitracin	13	56,475.0	6,921.3	4.1	11	38,325.0	4,423.8	4.1	10	52,260.0	6,121.0	5.9	
	Enramycin	15	64,360.0	5,148.8	3.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	
	Nosiheptide	22	87,920.0	3,516.8	2.1	20	80,000.0	3,200.0	3.0	26	88,360.0	3,534.4	3.4	
	Virginiamycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	
	Colistin sulfate	54	199,140.0	19,914.0	11.8	53	204,940.0	21.3	20,494.0	18.9	57	220,360.0	22,036.0	21.3
	Subtotal	104	407,895.0	35,500.9	27.3	84	323,265.0	33.7	28,117.8	93	360,980.0	31,691.4	30.6	
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	1	2,000.0	800.0	0.5	2	2,520.0	0.3	1,008.0	0.9	1	2,000.0	800.0	0.8
	Chlortetracycline	3	12,000.0	1,200.0	0.7	3	12,000.0	1.2	1,200.0	1.1	3	12,000.0	1,200.0	1.2
	Subtotal	4	14,000.0	2,000.0	1.2	5	14,520.0	1.5	2,208.0	2.0	4	14,000.0	1,500.0	1.9
Macrolide antibiotics	Tylosin phosphate	3	14,822.0	4,076.1	2.4	4	20,477.0	2.1	5,631.2	5.2	4	21,588.0	5,936.8	5.7
	Sedecamycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	
	Subtotal	3	14,822.0	4,076.1	2.4	4	20,477.0	2.1	5,631.2	5.2	4	21,588.0	5,936.8	5.7
Polysaccharide antibiotics	Flavophospholipol	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	
	Subtotal	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	
	Salinomycin sodium	91	364,840.0	36,484.0	21.6	64	255,400.0	26.6	25,540.0	23.6	38	154,120.0	15,412.0	14.9
Polyether antibiotics	Semduramicin sodium	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	
	Narasin	21	222,575.0	22,257.5	13.2	18	196,525.0	20.5	19,652.5	18.1	24	262,725.0	26,272.5	25.3
	Monensin sodium	42	162,080.0	32,416.0	19.2	8	30,360.0	3.2	6,072.0	5.6	4	11,600.0	2,320.0	2.2
	Lasalocid sodium	27	106,300.0	15,945.0	9.4	3	11,780.0	1.2	1,767.0	1.6	0	0.0	0.0	0.0
	Subtotal	181	855,795.0	107,102.5	63.3	93	494,065.0	51.5	53,031.5	49.0	66	428,445.0	44,004.5	42.5
Others	Avilamycin	55	204,000.0	20,400.0	12.1	29	107,950.0	11.2	19,347.5	17.9	27	100,050.0	20,010.0	19.3
	Efrotomycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	
	Biozamycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	
	Subtotal	55	204,000.0	20,400.0	12.1	29	107,950.0	11.2	19,347.5	17.9	27	100,050.0	20,010.0	19.3
	Total	347	1,496,512.0	169,079.4	100.0	215	960,277.0	100.0	108,335.9	100.0	194	925,063.0	103,642.7	100.0
	Ratio to the previous fiscal year (%)	107.4	109.9	108.2		62.0	64.2	64.1	64.1	90.2	96.3	95.7		

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 2010)

Category	Type of the specified feed additives	Refining grade			Feed grade		
		Passed cases	Passed quantity kg	Quantity converted into potency kg (potency)	Passed cases	Passed quantity kg	Quantity converted into potency kg (potency)
Polypeptide antibiotics	Zinc bacitracin				10	52,260.0	6,121.0
	Enramycin				-	-	-
	Nosiheptide	-	-	-	26	88,360.0	3,534.4
	Virginiamycin	-	-	-			
	Colistin sulfate	57	220,360.0	22,036.0	-	-	-
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	1	2,000.0	800.0			
	Chlortetracycline				3	12,000.0	1,200.0
Macrolide antibiotics	Sedecamycin	-	-	-			
Polysaccharide antibiotics	Tylosin phosphate	4	21,588.0	5,936.8			
	Flavophospholipol				-	-	-
Polyether antibiotics	Salinomycin sodium	-	-	-	38	154,120.0	15,412.0
	Semduramicin sodium	-	-	-			
	Narasin				24	262,725.0	26,272.5
	Monensin sodium	4	11,600.0	2,320.0			
Others	Lasalocid sodium	-	-	-			
	Avilamycin				27	100,050.0	20,010.0
	Efrotomycin	-	-	-			
	Bicozamycin	-	-	-			
Total		66	255,548.0	31,092.8	128	669,515.0	72,549.9
Proportion (%)		34.0	27.6	30.0	66.0	72.4	70.0

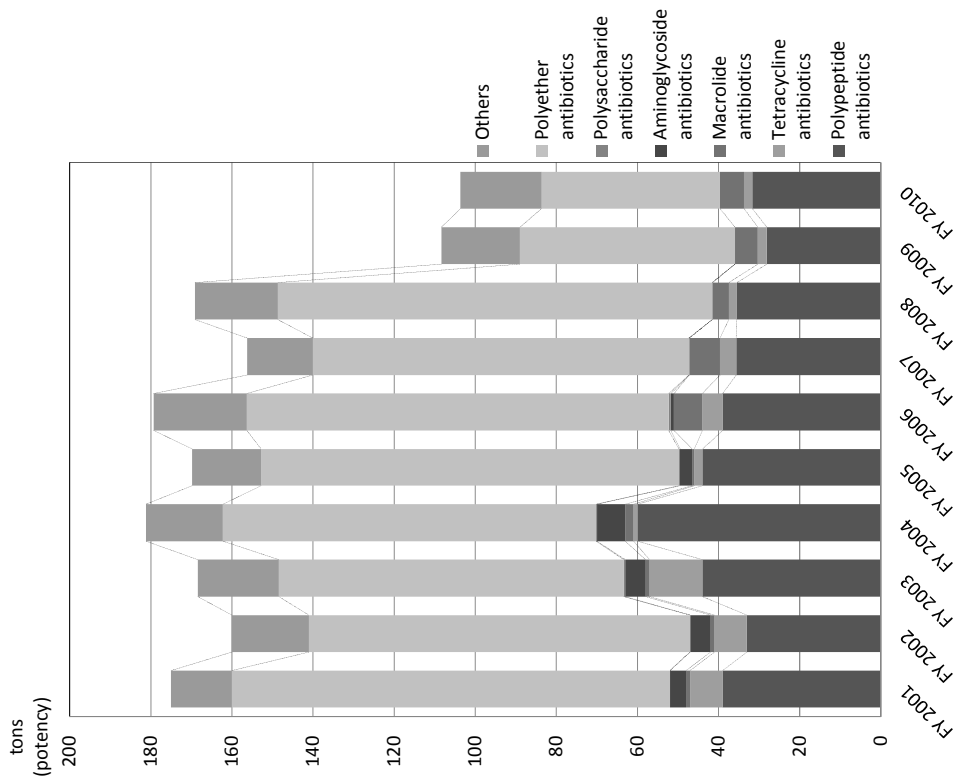


Figure 2: Changes in the testing-passed quantity of the specified feed additives converted into potency (Sorted by category of antibiotics)

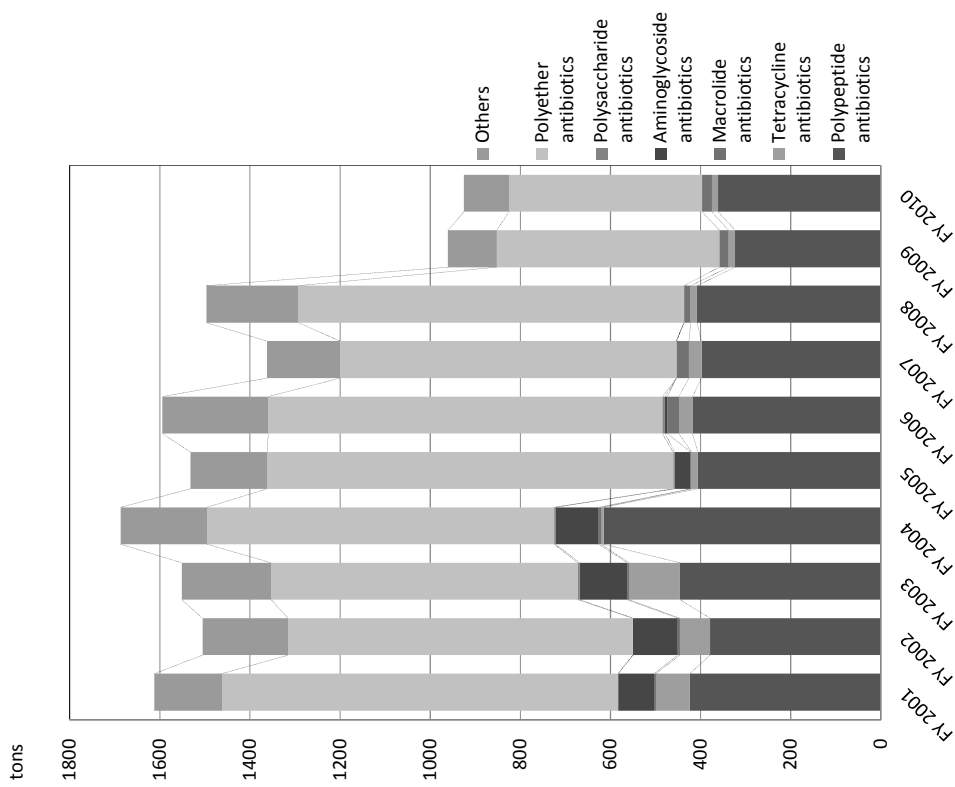


Figure 1: Changes in the testing-passed quantity of the specified feed additives (Sorted by category of antibiotics)

Table 4: Number of the testing-passed cases, passed quantity, and quantity converted from the actual quantity into potency
 (Sorted by the jurisdiction area of FAMIC, FY 2010)

Contact office of FAMIC	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)
Headquarters	41 (43)	173,980 (165,305)	19,453 (17,826)
Sapporo	- (-)	- (-)	- (-)
Sendai	- (-)	- (-)	- (-)
Nagoya	- (-)	- (-)	- (-)
Kobe	94 (111)	518,403 (556,752)	64,642 (70,732)
Fukuoka	59 (61)	232,680 (238,220)	19,548 (19,778)
Total	194 (215)	925,063 (960,277)	103,643 (108,336)

Data of the previous year are in parentheses.

Table 5: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2010)

Category	Type of the specified feed additives	2010	
		Manufactured quantity kg	Quantity converted into potency kg(potency)
Polypeptide antibiotics	Enramycin	62,780	5,022
	Colistin sulfate (Refining grade)	5,600	560
	Subtotal	68,380	5,582
Polyether antibiotics	Salinomycin sodium (Feed grade)	357,060	35,706
	Semduramicin sodium	12,000	600
	Monensin sodium	177,440	35,488
	Lasalocid sodium	88,900	13,335
	Subtotal	635,400	85,129
Total		703,780	90,711
Ratio to the previous fiscal year (%)		163	159

(Hearing from each registered manufacturer of specified feed additives)

Results of official testing of specified feed additives (FY 2011)

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 2011. The quantity and others of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2011 are also reported.

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 2011.

Seven business entities applied the official testing of specified feed additives. As for their manufacturing forms and others, four of the seven import raw materials for manufacturing or preparations by themselves or purchase them from other companies to manufacture preparations, and the other three import preparations and market them only. There was no business entity which manufactures from raw materials for manufacturing to preparations by itself.

Ten antibiotic preparations (10 in the previous FY) were applied as specified feed additives for a total of 16 brands (16 in the previous FY), which means the numbers of the types of antibiotic preparations and brands did not change from the previous fiscal year. Of them, the types and brands of the antibiotic preparations whose raw materials for manufacturing or preparation are dependent on foreign sources were 9 (9 in the previous FY) and 14 (13 in the previous FY), respectively.

As for the import source countries of preparations and raw material for manufacturing, zinc bacitracin (preparation), monensin sodium (raw material for manufacturing), colistin sulfate (raw material for manufacturing), and alkyltrimethylammonium calcium oxytetracycline (raw material for manufacturing) were imported from China, and salinomycin sodium (raw material for

manufacturing) from China and Bulgaria, chlortetracycline (preparation) from Singapore, tylosin phosphate (preparation) and narasin (preparation) from the USA, and avilamycin (preparation) from the UK. The number of the import source countries was 5 (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 2009, 2010, and 2011.

One case of salinomycin sodium was not passed because of non-compatibility in the test for property (particle size) in the testing in FY 2011. In FY 2011, 215 cases (application: 216 cases), 997 tons, were passed, and the quantity converted from the actual quantity into potency was 112 tons (potency). All of the passed cases, the passed quantity, and the converted quantity increased compared with the previous fiscal year, 110.8%, 107.8%, and 107.9%, respectively.

The percentage of the antibiotic preparations in the total passed quantity by type was 25.3%, which was the highest one, for narasin (28.4% in the previous FY), followed in descending order by 25.1% for salinomycin sodium (16.7% in the previous FY), 22.1% for colistin sulfate (23.8% in the previous FY), 10.4% for avilamycin (10.8% in the previous FY), and 8.0% for nosiheptide (9.6% 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 22.5% for narasin (25.3% in the previous FY), followed in descending order by 22.4% for salinomycin sodium (14.9% in the previous FY), 19.7% for colistin sulfate (21.3% in the previous FY), 18.6% for avilamycin (19.3% in the previous FY), and 5.3% for zinc bacitracin (5.9% in the previous FY).

Both the passed quantity and the converted quantity of salinomycin sodium, alkyltrimethylammonium calcium oxytetracycline, and avilamycin increased compared with those in FY 2010, while those of narasin, colistin sulfate, nosiheptide, zinc bacitracin, tylosin phosphate, monensin sodium, and chlortetracycline decreased.

Enramycin, semduramicin sodium, and lasalocid sodium since FY 2010, virginiamycin since FY 2008, flavophospholipol since FY 2007, efrotomycin and sedecamycin 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 2010.

Enramycin and lasalocid sodium were not subjected to the testing, but were manufactured by the registered manufacturers of specified feed additives.

3. The number of the testing-passed cases and others 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 2011.

Compared between percentages of the refining grade and the feed grade based on the quantity converted from the actual quantity into potency, the feed grade accounted for 72.4 % of the total (70.0 % in the previous FY).

Both the refining grade and the feed grade are set for nosiheptide, colistin sulfate, and salinomycin sodium. In FY 2011, only the refining grade of colistin sulfate, only the feed grade of nosiheptide and salinomycin sodium were subjected to the testing.

4. Changes in the passed quantity and others of antibiotic preparations 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 2002 to 2011, respectively.

The passed quantity of antibiotic preparations by category was on a declining trend with repeating increase and decrease since FY 2004, which was the peak, significantly decreased from FY 2008 through to FY 2009, and was the lowest in FY 2010, the lowest of the past 10 years, however it increased slightly in FY 2011 (108% over the previous year). The quantity converted from the actual quantity into potency shows a similar trend. In addition, one type and five types of specified feed additives have been manufactured by the registered manufacturers of specified feed additives since FY 2007 and FY 2009, respectively.

As for the quantity converted from the actual quantity into potency of antibiotic preparations by category, polyether antibiotics has changed at a rate of more than half of the total from FY 2002 to FY 2008 and in the 40% range since FY 2009. In FY 2011, it accounted for 46.6% of the total (42.5% in the previous FY), and polypeptide antibiotics accounted for 27.9% (30.6% in the previous FY).

5. Number of the 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 2011.

The number of the testing-passed cases, the passed quantity and the quantity converted from the actual quantity into potency in FY 2011 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 passed cases, the passed quantity and the quantity converted from the actual quantity into potency increased within the jurisdiction area of each 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 2011.

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

In accordance with the provision of Article 7, paragraph 1 of the Law Concerning Safety Assurance and Quality Improvement of Feeds, the 3rd plant, Kyushu Plant, Kohkin Chemical Co., Ltd. in FY 2007 and the Tatsuno Factory, Scientific Feed Laboratory Co., Ltd in FY 2009 were registered as a place of business as a manufacturer of specified feed additives concerning semduramicin sodium and as a place of business as a manufacturer of specified feed additives concerning salinomycin sodium, monensin sodium, lasalocid sodium, enramycin and colistin sulfate, respectively. Table 5 shows the manufactured quantity and the quantity converted from the actual quantity into potency by types of antibiotic preparations in FY 2011. Moreover, lasalocid sodium and enramycin have not been applied for the testing and only have manufactured by the registered manufacturers of specified feed additives.

As for the quantity manufactured by the registered manufacturers of specified feed additives, in FY 2011 the total manufactured quantity was 594 tons (84% over the previous year) and the total quantity converted from the actual quantity into potency was 83 tons (92% over the previous year), which accounted for 43% of the total including the quantity that passed the testing. Figures 3 and 4 show the changes in antibiotic preparations by category which passed the testing and the total manufactured quantity and the total quantity converted from the actual quantity into potency by the registered manufactures of specified feed additives over the last decade, from FY 2002 to FY 2011. The total quantity converted from the actual quantity into potency has been flat in the last two years, which was higher than that in FY 2004. The descending order of the manufactured quantities of antibiotic preparations by types was salinomycin sodium (29.6%), narasin (15.8%) and colistin sulfate (14.1%), and the descending order of the quantity converted from the actual quantity into potency was salinomycin sodium (24.1%), monensin sodium (20.6%), and narasin (12.9%).

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 2011 were as follows.

- (1) Sixteen brands of 10 specified feed additives were applied for the official testing of specified feed additives by 7 business entities.
- (2) The manufacturing of raw materials or preparations for 14 brands of 9 specified feed additives was dependent on foreign sources.
- (3) The number of the passed cases, the passed quantity, and the quantity converted from the actual quantity into potency were 215 cases (application: 216 cases), 997 tons, and 112 tons (potency), respectively. All of them increased compared to the previous fiscal year. One case was not passed because of non-compatibility in the test for property (particle size).
- (4) The antibiotic preparations with the highest most passed quantity were narasin (25.3%),

followed by salinomycin sodium, colistin sulfate, avilamycin, and nosiheptide in descending order.

- (5) The antibiotic preparations with the highest quantity converted from the actual quantity into potency were narasin (22.5%), followed by salinomycin sodium, colistin sulfate, avilamycin, and zinc bacitracin in descending order.
- (6) Compared between percentages of the refining grade and the feed grade on the testing-passed quantity converted from the actual quantity into potency of the specified feed additives, the feed grade accounted for 72.4 % of the total.
- (7) The changes in the quantity converted from the actual quantity into potency of the passed preparations over the last decade show that they have decreased with repeating increase and decrease since FY 2004, was the lowest of the past 10 years in FY 2010, and then slightly increased in FY 2011.
- (8) The number of the passed cases, the passed quantity, and the quantity converted from the actual quantity into potency by each regional center were the highest within the jurisdiction of the Kobe center.
- (9) Salinomycin sodium, monensin sodium, lasalocid sodium, enramycin, and colistin sulfate were manufactured by the registered manufacturers of specified feed additives.
- (10) When combined the pass of the testing and the manufacture by the registered manufacturers of specified feed additives, the antibiotic preparations with high manufactured quantity were salinomycin sodium (29.6%), narasin and colistin sulfate, and the antibiotic preparations with high quantity converted from the actual quantity into potency were salinomycin sodium (24.1%), monensin sodium and narasin.

Table 1: Names of applicants and others for the official testing of the specified feed additives (FY 2011)

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	Kaken Pharmaceutical Co., Ltd.	*	Zinc bacitracin	0	100	4,200 unit/g		
			Salinomycin sodium Monensin sodium	0	150	6,300 unit/g		
Kobe	Nichiku Yakuhin Kogyo Corporation	Kanagawa	Salinomycin sodium	0	100			
			Monensin sodium		200			
	Japan Nutrition Co., Ltd.	Ibaraki	Salinomycin sodium	0	100			
			TNB Co., Ltd.	*	Chlortetracycline	0	100	
	Scientific Feed Laboratory Co., Ltd.	Hyogo	Nosineptide	0	40			
			Colistin sulfate		100			
			Tylosin phosphate		275			
			Avilamycin	0	200			
			Narasin	0	100			
			Tylosin phosphate		275			
Fukuoka	Scientific Feed Laboratory Co., Ltd.	Miyazaki	Colistin sulfate		100			
			Alkyltrimethylammonium calcium oxytetracycline		400			
			Kohkin Chemical Co., Ltd.	Kagoshima	Salinomycin sodium	0	100	
			Nosineptide	0	40			
Total	7 business entities	8 places			16 brands			

* Fallen under an importer

Table 2: Number of the testing-passed cases, passed quantity, and quantity converted into potency
(Sorted by the type of the antibiotics, FYs 2009 to 2011)

Category	Type of the specified feed additives	2009			2010			2011					
		Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)	Compos ition ratio (%)	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)	Compos ition ratio (%)	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)	Compos ition ratio (%)
Polypeptide antibiotics	Zinc bacitracin	11	38,325.0	4,423.8	4.1	10	52,260.0	6,121.0	5.9	11	49,880.0	5,984.0	5.3
	Enramycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Nosiheptide	20	80,000.0	3,200.0	3.0	26	88,360.0	3,534.4	3.4	22	79,760.0	3,190.4	2.9
	Virginiamycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Colistin sulfate	53	204,940.0	20,494.0	18.9	57	220,360.0	22,036.0	21.3	55	220,000.0	22,000.0	19.7
	Subtotal	84	323,265.0	28,117.8	26.0	93	360,980.0	31,691.4	30.6	88	349,640.0	31,174.4	27.9
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	2	2,520.0	1,008.0	0.9	1	2,000.0	800.0	0.8	2	4,000.0	1,600.0	1.4
	Chlortetracycline	3	12,000.0	1,200.0	1.1	3	12,000.0	1,200.0	1.2	2	8,000.0	800.0	0.7
	Subtotal	5	14,520.0	2,208.0	2.0	4	14,000.0	2,000.0	1.9	4	12,000.0	2,400.0	2.1
Macrolide antibiotics	Tylosin phosphate	4	20,477.0	5,631.2	5.2	4	21,588.0	5,936.8	5.7	5	19,609.0	5,392.5	4.8
	Sedecamycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Subtotal	4	20,477.0	5,631.2	5.2	4	21,588.0	5,936.8	5.7	5	19,609.0	5,392.5	4.8
Polysaccharide antibiotics	Flavophospholipol	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Subtotal	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Salinomycin sodium	64	255,400.0	25,540.0	23.6	38	154,120.0	15,412.0	14.9	64	250,612.0	25,061.2	22.4
Polyether antibiotics	Semduramicin sodium	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Narasin	18	196,525.0	19,652.5	18.1	24	262,725.0	26,272.5	25.3	23	251,875.0	25,187.5	22.5
	Monensin sodium	8	30,360.0	6,072.0	5.6	4	11,600.0	2,320.0	2.2	3	9,260.0	1,852.0	1.7
	Lasalocid sodium	3	11,780.0	1,767.0	1.6	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Subtotal	93	494,065.0	53,031.5	49.0	66	428,445.0	44,004.5	42.5	90	511,747.0	52,100.7	46.6
Others	Avilamycin	29	107,950.0	19,347.5	17.9	27	100,050.0	20,010.0	19.3	28	103,975.0	20,795.0	18.6
	Efrotomycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Bicozamycin	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Subtotal	29	107,950.0	19,347.5	17.9	27	100,050.0	20,010.0	19.3	28	103,975.0	20,795.0	18.6
	Total	215	960,277.0	108,335.9	100.0	194	925,063.0	103,642.7	100.0	215	996,971.0	111,862.6	100.0
	Ratio to the previous fiscal year (%)	62.0	64.2	64.1		90.2	96.3	95.7		110.8	107.8	107.9	

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 2011)

Category	Type of the specified feed additives	Refining grade			Feed grade		
		Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)
Polypeptide antibiotics	Zinc bacitracin	—	—	—	11	49,880.0	5,984.0
	Enramycin	—	—	—	0	0.0	0.0
	Nosiheptide	0	0.0	0.0	22	79,760.0	3,190.4
	Virginiamycin	0	0.0	0.0	—	—	—
	Colistin sulfate	55	220,000.0	22,000.0	0	0.0	0.0
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	2	4,000.0	1,600.0	—	—	—
	Chlortetracycline	—	—	—	2	8,000.0	800.0
Macrolide antibiotics	Sedecamycin	0	0.0	0.0	—	—	—
	Tylosin phosphate	5	19,609.0	5,392.5	—	—	—
Polysaccharide antibiotics	Flavophospholipol	—	—	—	0	0.0	0.0
	Salinomycin sodium	0	0.0	0.0	64	250,612.0	25,061.2
Polyether antibiotics	Semduramicin sodium	0	0.0	0.0	—	—	—
	Narasin	—	—	—	23	251,875.0	25,187.5
	Monensin sodium	3	9,260.0	1,852.0	—	—	—
	Lasalocid sodium	0	0.0	0.0	—	—	—
Others	Avilamycin	—	—	—	28	103,975.0	20,795.0
	Efrotomycin	0	0.0	0.0	—	—	—
	Bicozamycin	0	0.0	0.0	—	—	—
Total		65	252,869.0	30,844.5	150	744,102.0	81,018.1
Proportion (%)		30.2	25.4	27.6	69.8	74.6	72.4

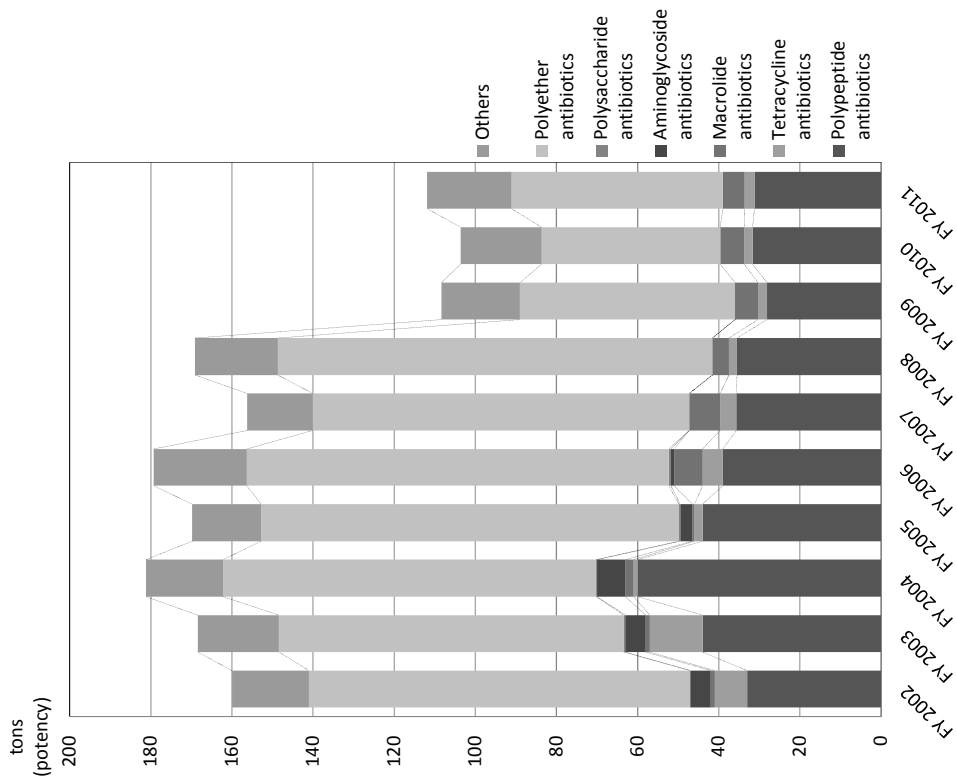


Figure 2: Changes in the testing-passed quantity of the specified feed additives converted into potency (Sorted by category of antibiotics)

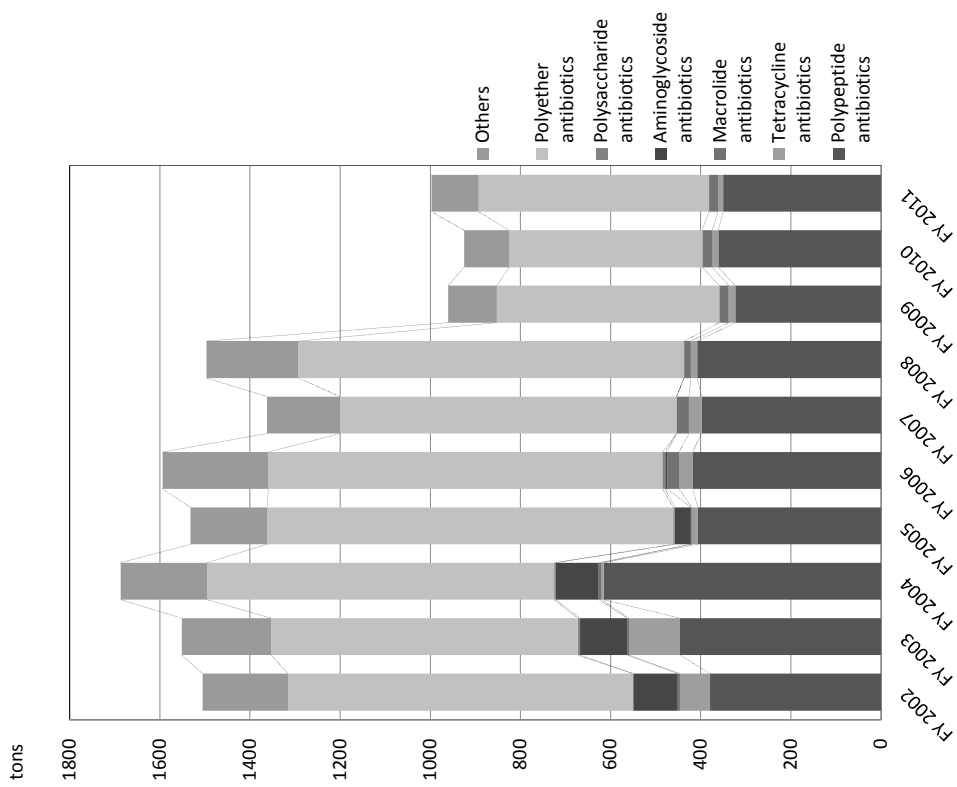


Figure 1: Changes in the testing-passed quantity of the specified feed additives (Sorted by category of antibiotics)

Table 4: Number of the testing-passed cases, passed quantity, and quantity converted into potency
 (Sorted by the jurisdiction area of FAMIC, FY 2011)

Contact office of FAMIC	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)
Headquarters	61 (41)	241,752 (173,980)	26,097 (19,453)
Sapporo	- (-)	- (-)	- (-)
Sendai	- (-)	- (-)	- (-)
Nagoya	- (-)	- (-)	- (-)
Kobe	95 (94)	531,419 (518,403)	65,065 (64,642)
Fukuoka	59 (59)	223,800 (232,680)	20,700 (19,548)
Total	215 (194)	996,971 (925,063)	111,863 (103,643)

Data of the previous year are in parentheses.

Table 5: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2011)

Category	Type of the specified feed additives	2011	
		Manufactured quantity kg	Quantity converted into potency kg(potency)
Polypeptide antibiotics	Enramycin	59,800	4,784
	Colistin sulfate (Refining grade)	3,920	392
	Subtotal	63,720	5,176
Polyether antibiotics	Salinomycin sodium (Feed grade)	219,540	21,954
	Semduramicin sodium	0	0
	Monensin sodium	191,700	38,340
	Lasalocid sodium	118,940	17,841
	Subtotal	530,180	78,135
Total		593,900	83,311
Ratio to the previous fiscal year (%)		84	92

(Hearing from each registered manufacturer of specified feed additives)

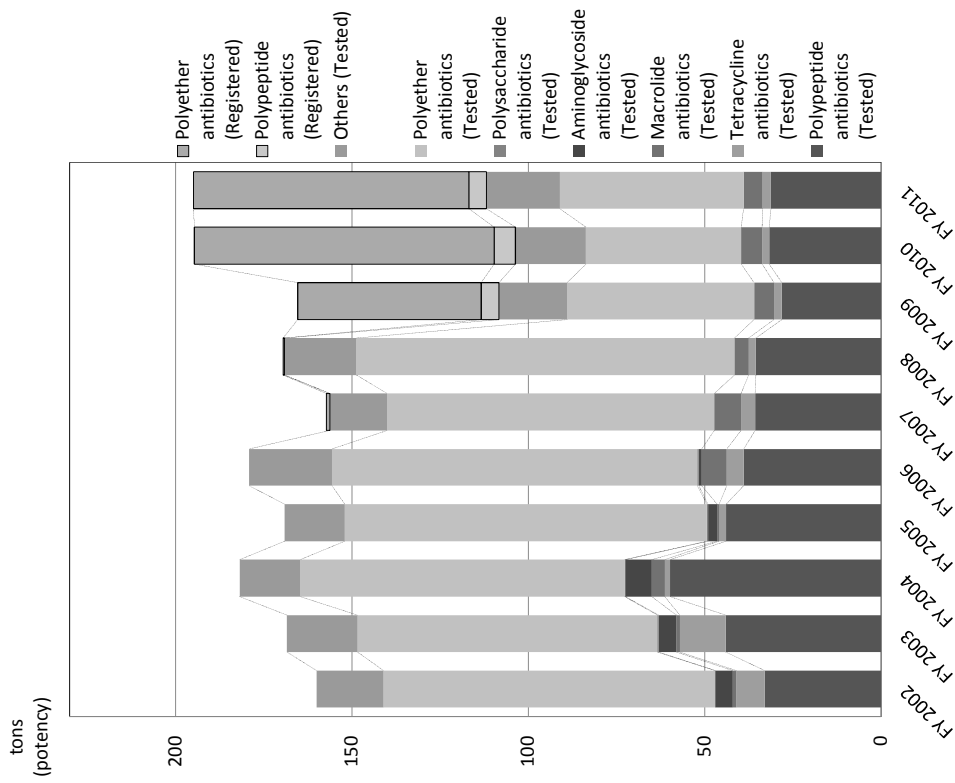


Figure 4: Changes in the testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives converted into potency (Sorted by category of antibiotics)

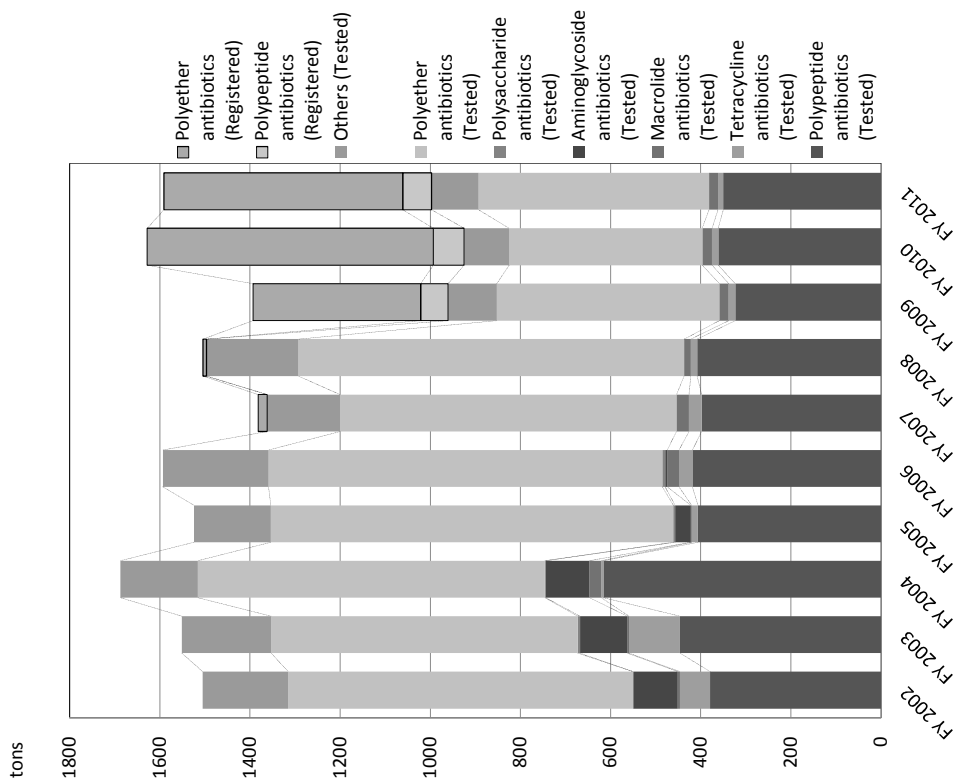


Figure 3: Changes in the testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives (Sorted by category of antibiotics)

Results of official testing of specified feed additives (FY 2012)

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 2012. The quantity and others of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2012 are also reported.

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 2012.

Eight business entities applied the official testing of specified feed additives. As for their manufacturing forms and others, four of the seven import raw materials for manufacturing or preparations by themselves or purchase them from other companies to manufacture preparations, and the other four import preparations and market them only.

Eleven kinds of specified feed additives (10 in the previous FY), which corresponded to 16 brands (16 in the previous FY), were applied. Of which 10 kinds (10 in the previous FY), 15 brands (14 in the previous FY), were dependent on foreign sources for their raw materials for manufacturing or preparations.

As for the import source countries of raw material for manufacturing and preparations, zinc bacitracin (preparation), colistin sulfate (raw material for manufacturing), alkyltrimethylammonium calcium oxytetracycline (raw material for manufacturing), and monensin sodium (raw material for manufacturing) were imported from China, salinomycin sodium (raw material for manufacturing) from China and Bulgaria, chlortetracycline (preparation) from Singapore, tylosin phosphate (preparation) and narasin (preparation) from the USA, avilamycin (preparation) from the UK and flavophospholipol (preparation) from Bulgaria. The number of the

import source countries was 5 (5 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 2010, 2011, and 2012.

In FY 2012, 190 cases (application: 190 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 954 tons and 109 tons (potency). The passed cases, the passed quantity, and the quantity converted from the actual quantity into potency decreased, 88.4%, 95.7%, and 97.0%, respectively, compared with the previous fiscal year.

The percentage of the specified feed additives in the total passed quantity by type was 31.1%, which was the highest one, for narasin (25.3% in the previous FY), followed in descending order by 24.8% for colistin sulfate (22.1 % in the previous FY), 24.7% for salinomycin sodium (25.1% in the previous FY), 8.2 % for avilamycin (10.4% in the previous FY), and 5.7 % for zinc bacitracin (5.0% 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 27.3% for narasin (22.5% in the previous FY), followed in descending order by 21.8% for colistin sulfate (19.7% in the previous FY), 21.7% for salinomycin sodium (22.4% in the previous FY), 14.3% for avilamycin (18.6% in the previous FY), and 5.7% for zinc bacitracin (5.3% in the previous FY).

The passed quantity and the quantity converted from the actual quantity into potency of zinc bacitracin, colistin sulfate, chlortetracycline, tylosin phosphate, flavophospholipol, narasin and monensin sodium increased compared with 2011, while those of nosiheptide, alkyltrimethylammonium calcium oxytetracycline, salinomycin sodium and avilamycin decreased. Enramycin, semduramicin sodium, and lasalocid sodium since FY 2010, virginiamycin since FY 2008, efrotomycin and sedecamycin 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 2010.

Enramycin and lasalocid sodium were not subjected to the testing, but were manufactured by the registered manufacturers of specified feed additives.

3. The number of the testing-passed cases and others 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 2012.

Compared between percentages of the refining grade and the feed grade based on the quantity converted from the actual quantity into potency, the feed grade accounted for 70.5 % of the total (72.4 % in the previous FY).

Both the refining grade and the feed grade are set for nosiheptide, colistin sulfate, and salinomycin sodium. In FY 2012, only the refining grade of colistin sulfate, only the feed grade of nosiheptide and salinomycin sodium were subjected to the testing.

4. Changes in the 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 2003 to 2012, respectively.

The passed quantity of the specified feed additives by category was on a declining trend with repeating increase and decrease since FY 2004, which was the peak, by FY 2008. In FY 2009, it significantly decreased because the manufacturing of some of the specified feed additives were transferred to that by the registered manufacturers of specified feed additives. It was lowest in FY 2010 over the last decade but slightly increased in FY 2011, and then again decreased in FY 2012 (95.7 % over the previous year). The quantity converted from the actual quantity into potency showed a similar trend.

As for the quantity converted from the actual quantity into potency of the specified feed additives by category, polyether antibiotics has changed at a rate of more than half of the total from FY 2003 to FY 2008 and in the 40% range since FY 2009. It accounted for 51.0 % of the total (46.6% in the previous FY), and polypeptide antibiotics accounted for 27.8% (27.9% in the previous FY).

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

Table 4 shows the number of the testing-past 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 2012.

The number of the testing-passed cases, the passed quantity and the quantity converted from the actual quantity into potency in FY 2012 were highest within the jurisdiction area of the Kobe center, followed by the jurisdiction areas of the Fukuoka center, and the headquarters.

The number of the passed cases, the passed quantity and the quantity converted from the actual quantity into potency increased within the jurisdiction areas of the Kobe and Fukuoka centers but decreased within the jurisdiction of the headquarters, 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 2012.

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

As of April in 2012, the 3rd plant, Kyushu Plant, Kohkin Chemical Co., Ltd. was registered as a place of business as a manufacturer of specified feed additives concerning semduramicin sodium and Tatsuno Factory, Scientific Feed Laboratory Co., Ltd., was registered as a place of business as a manufacturer of specified feed additives concerning salinomycin sodium, monensin sodium, lasalocid sodium, enramycin and colistin sulfate. In addition, the 3rd plant, Kyushu Plant, Kohkin Chemical Co., Ltd. and Tatsuno Factory, Scientific Feed Laboratory Co., Ltd. were registered as a place of business for nosiheptide in FY 2012.

Table 5 shows the manufactured quantity and the quantity converted from the actual quantity into potency of the specified feed additives by type by the registered manufacturers of specified feed additives in FY 2012. Moreover, lasalocid sodium, semduramicin, and enramycin, which have not undergone the testing as a specified feed additive in FY 2012, 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 2012 was 718 tons (121% over the previous year) and the quantity converted from the actual quantity into potency was 89 tons (potency) (107% over the previous year), which accounted for 45% of the total of quantity converted from the actual quantity into potency including the quantity that passed the testing.

Figures 3 and 4 show the changes in the total manufactured quantity of the specified feed additives, the total quantity that passed the testing of the specific feed additives by category and the quantity of the specified feed additives manufactured by the registered manufacturers of specified feed additives over the last decade from FY 2003 to FY 2012, and the total quantity converted from the actual quantity into potency. The total quantity converted from the actual quantity into potency increased slightly compared with last year. The descending order of the total manufactured quantity by type was salinomycin sodium (25.8%), narasin (17.7%), and colistin sulfate (14.7%). The descending order of the total quantity converted from the actual quantity into potency was salinomycin sodium (21.8%), monensin sodium (20.5%), and narasin (15.0%).

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 2012 were as follows.

- (1) Sixteen brands of 11 specified feed additives were applied for the official testing of specified feed additives by 8 business entities.
- (2) The manufacturing of raw materials or preparations for 15 brands of 10 specified feed additives was dependent on foreign sources.
- (3) The number of the passed cases, the passed quantity, and the quantity converted from the actual quantity into potency of the specified feed additives were 190 cases (application: 190 cases), 954 tons, and 109 tons (potency), respectively. All of them decreased compared to the previous fiscal year. There were no rejected cases.

- (4) The passed quantity of the specified feed additives was highest for narasin (31.1%), followed by colistin sulfate, salinomycin sodium, avilamycin, and zinc bacitracin in descending order.
- (5) The quantity converted from the actual quantity into potency of the passed specified feed additives was highest for narasin (27.3 %), followed by colistin sulfate, salinomycin sodium, avilamycin, and zinc bacitracin in descending order.
- (6) Compared between percentages of the refining grade and the feed grade on the testing-passed quantity converted from the actual quantity into potency of the specified feed additives, the feed grade accounted for 70.5 % of the total.
- (7) The changes in the quantity converted from the actual quantity into potency of the passed specified feed additives over the last decade show that they have decreased with repeating increase and decrease since FY 2004, was the lowest in the past 10 years in FY 2010, increased in FY 2011, and then again decreased in FY 2012.
- (8) The number of the passed cases, the passed quantity, and the quantity converted from the actual quantity into potency by each regional center were the highest within the jurisdiction of the Kobe center.
- (9) The specific feed additives manufactured by the registered manufacturers of specified feed additives were monensin sodium, lasalocid sodium, salinomycin sodium (feed grade), enramycin, nosiheptide (feed grade), colistin sulfate (refining grade) and semduramicin sodium. The quantity converted from the actual quantity into potency was in the same descending order.
- (10) The descending order of the total manufactured quantity consisting of the quantity of the specified feed additives which passed the testing and the quantity of the specified feed additives manufactured by the registered manufacturers of specified feed additives was salinomycin sodium (25.8%), narasin, and colistin sulfate. That of the quantity converted from the actual quantity into potency was salinomycin sodium (21.8%), monensin sodium, and narasin.

Table 1: Names of applicants and others for the official testing of the specified feed additives (FY 2012)

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 Yakuhin Kogyo Corporation	Kanagawa	Salinomycin sodium	0	100	
	Japan Nutrition Co., Ltd.	Ibaraki	Monensin sodium	0	200	
	TNB Co., Ltd.	*	Salinomycin sodium	0	100	
	Miyarisan Pharmaceutical Co., Ltd.	*	Chlortetracycline	0	100	
Kobe	Scientific Feed Laboratory Co., Ltd.	Hyogo	Flavophospholipol	0	80	
			Colistin sulfate		100	
			Tylosin phosphate		275	
	Eli Lilly Japan K. K.	*	Avilamycin	0	200	
Fukuoka			Narasin	0	100	
			Tylosin phosphate		275	
	Scientific Feed Laboratory Co., Ltd.	Miyazaki	Colistin sulfate		100	
			Alkyltrimethylammonium calcium oxytetracycline		400	
Total	Kohkin Chemical Co., Ltd.	Kagoshima	Salinomycin sodium	0	100	
			Nosineptide	0	40	
	Pfizer Japan Inc.	*	Zinc bacitracin	0	100	4,200 unit/g
				0	150	6,300 unit/g
	8 business entities	9 places			16 brands	

* Fallen under an importer

Table 2: Number of the testing-passed cases, passed quantity, and quantity converted into potency
(Sorted by the type of the antibiotics, FYs 2010 to 2012)

Category	Type of the specified feed additives	2010			2011			2012								
		Passed cases	Passed quantity kg	Composition ratio (%)	Quantity converted into potency kg(potency)	Composition ratio (%)	Passed cases	Passed quantity kg	Composition ratio (%)	Quantity converted into potency kg(potency)	Composition ratio (%)					
Polypeptide antibiotics	Zinc bacitracin	10	52,260.0	5.6	6,121.0	5.9	11	49,880.0	5.0	5,984.0	5.3	10	54,780.0	5.7	6,220.0	5.7
	Enramycin	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0
	Nosiheptide	26	88,360.0	9.6	3,534.4	3.4	22	79,760.0	8.0	3,190.4	2.9	2	8,000.0	0.8	320.0	0.3
	Virginiamycin	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0
	Colistin sulfate	57	220,360.0	23.8	22,036.0	21.3	55	220,000.0	22.1	22,000.0	19.7	60	236,200.0	24.8	23,620.0	21.8
	Subtotal	93	360,980.0	39.0	31,691.4	30.6	88	349,640.0	35.1	31,174.4	27.9	72	298,980.0	31.3	30,160.0	27.8
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	1	2,000.0	0.2	800.0	0.8	2	4,000.0	0.4	1,600.0	1.4	1	2,000.0	0.2	800.0	0.7
	Chlortetracycline	3	12,000.0	1.3	1,200.0	1.2	2	8,000.0	0.8	800.0	0.7	3	12,000.0	1.3	1,200.0	1.1
	Subtotal	4	14,000.0	1.5	2,000.0	1.9	4	12,000.0	1.2	2,400.0	2.1	4	14,000.0	1.5	2,000.0	1.8
Macrolide antibiotics	Tylosin phosphate	4	21,588.0	2.3	5,936.8	5.7	5	19,609.0	2.0	5,392.5	4.8	4	19,700.0	2.1	5,417.5	5.0
	Sedecamycin	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0
	Subtotal	4	21,588.0	2.3	5,936.8	5.7	5	19,609.0	2.0	5,392.5	4.8	4	19,700.0	2.1	5,417.5	5.0
Polysaccharide antibiotics	Flavophospholipol	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	1	1,250.0	0.1	100.0	0.1
	Subtotal	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	1	1,250.0	0.1	100.0	0.1
	Salinomycin sodium	38	154,120.0	16.7	15,412.0	14.9	64	250,612.0	25.1	25,061.2	22.4	58	235,178.0	24.7	23,517.8	21.7
Polyether antibiotics	Semduramicin sodium	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0
	Narasin	24	262,725.0	28.4	26,272.5	25.3	23	251,875.0	25.3	25,187.5	22.5	27	296,275.0	31.1	29,627.5	27.3
	Monensin sodium	4	11,600.0	1.3	2,320.0	2.2	3	9,260.0	0.9	1,862.0	1.7	3	10,860.0	1.1	2,172.0	2.0
	Lasalocid sodium	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0
	Subtotal	66	428,445.0	46.3	44,004.5	42.5	90	511,747.0	51.3	52,100.7	46.6	88	542,313.0	56.8	55,317.3	51.0
Others	Avilamycin	27	100,050.0	10.8	20,010.0	19.3	28	103,975.0	10.4	20,795.0	18.6	21	77,825.0	8.2	15,565.0	14.3
	Efrotomycin	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0
	Biozamycin	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0	0	0.0	0.0	0.0	0.0
	Subtotal	27	100,050.0	10.8	20,010.0	19.3	28	103,975.0	10.4	20,795.0	18.6	21	77,825.0	8.2	15,565.0	14.3
	Total	194	925,063.0	100.0	103,642.7	100.0	215	996,971.0	100.0	111,862.6	100.0	190	954,068.0	100.0	108,559.8	100.0
	Ratio to the previous fiscal year (%)	90.2	96.3		95.7		110.8	107.8		107.9		88.4	95.7		97.0	

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 from the actual quantity into potency
(Sorted by the grade of the preparation, FY 2012)

Category	Type of the specified feed additives	Refining grade			Feed grade		
		Passed cases	Passed quantity kg	Quantity converted into potency kg (potency)	Passed cases	Passed quantity kg	Quantity converted into potency kg (potency)
Polypeptide antibiotics	Zinc bacitracin				10	54,780.0	6,220.0
	Enramycin				-	-	-
	Nosiheptide	-	-	-	2	8,000.0	320.0
	Virginiamycin	-	-	-			
	Colistin sulfate	60	236,200.0	23,620.0	-	-	-
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	1	2,000.0	800.0			
	Chlortetracycline				3	12,000.0	1,200.0
Macrolide antibiotics	Sedecamycin	-	-	-			
	Tylosin phosphate	4	19,700.0	5,417.5			
Polysaccharide antibiotics	Flavophospholipol				1	1,250.0	100.0
	Salinomycin sodium	-	-	-	58	235,178.0	23,517.8
Polyether antibiotics	Semduramicin sodium	-	-	-			
	Narasin				27	296,275.0	29,627.5
	Monensin sodium	3	10,860.0	2,172.0			
	Lasalocid sodium	-	-	-			
Others	Avilamycin				21	77,825.0	15,565.0
	Efrotomycin	-	-	-			
	Bicozamycin	-	-	-			
Total		68	268,760.0	32,009.5	122	685,308.0	76,550.3
Proportion (%)		35.8	28.2	29.5	64.2	71.8	70.5

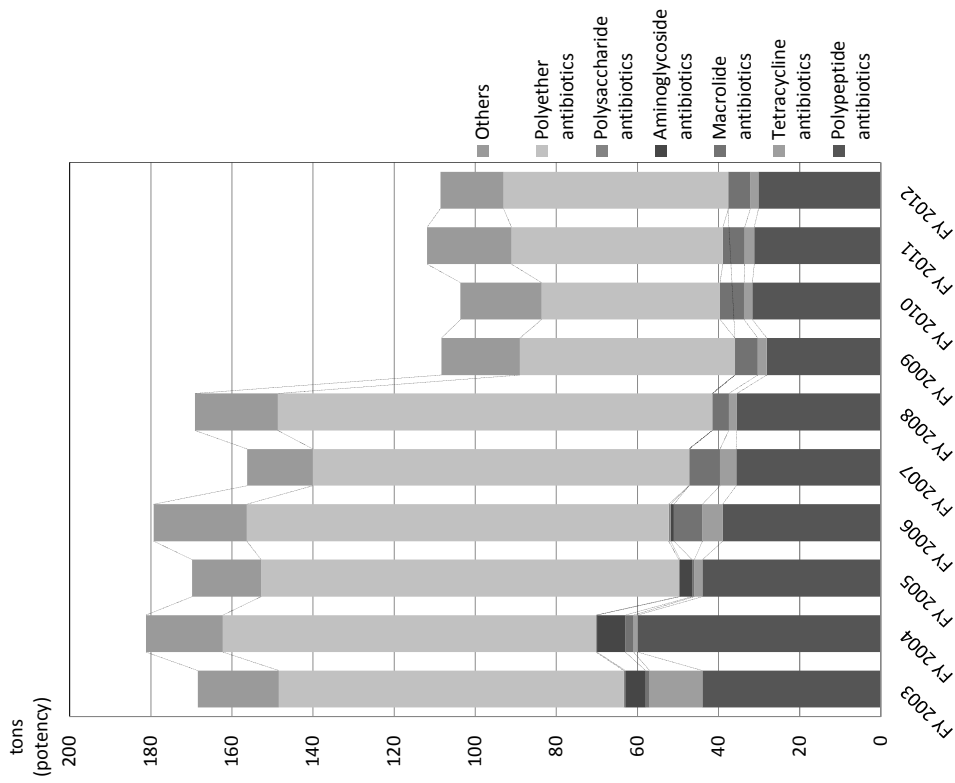


Figure 2: Changes in the testing-passed quantity of the specified feed additives converted into potency (Sorted by category of antibiotics)

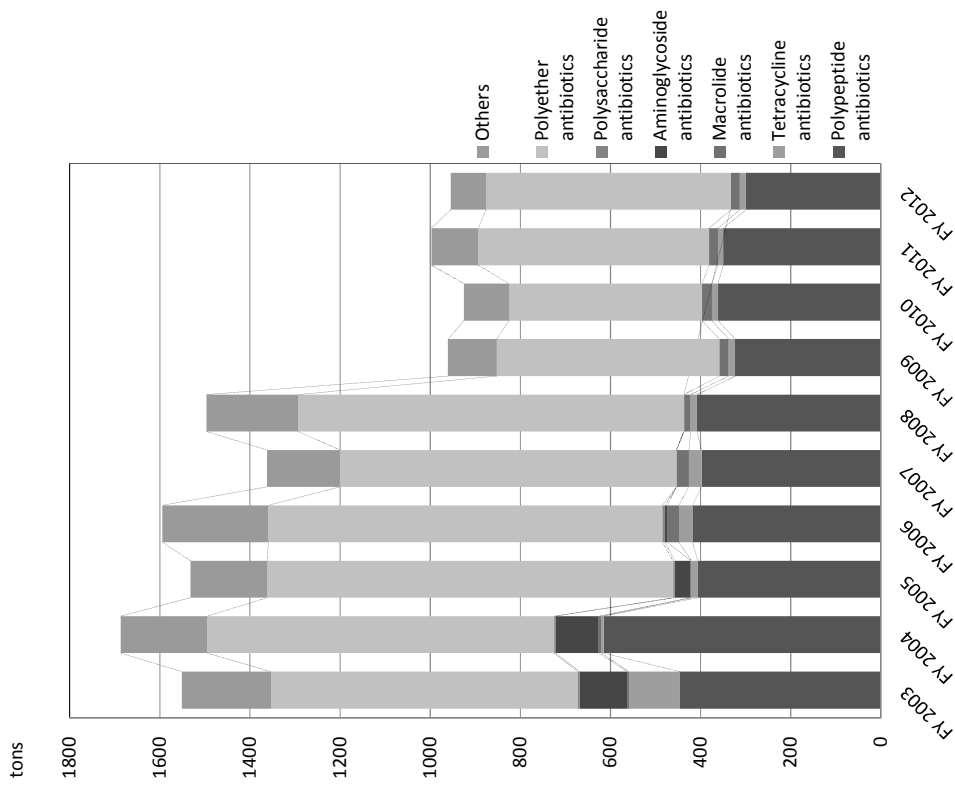


Figure 1: Changes in the testing-passed quantity of the specified feed additives (Sorted by category of antibiotics)

Table 4: Number of the testing-passed cases, passed quantity, and quantity converted from the actual quantity into potency
(Sorted by the jurisdiction area of FAMIC, FY 2012)

Contact office of FAMIC	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)
Headquarters	45 (61)	179,288 (241,752)	18,990 (26,097)
Sapporo	- (-)	- (-)	- (-)
Sendai	- (-)	- (-)	- (-)
Nagoya	- (-)	- (-)	- (-)
Kobe	88 (95)	533,800 (531,419)	64,610 (65,065)
Fukuoka	57 (59)	240,980 (223,800)	24,960 (20,700)
Total	190 (215)	954,068 (996,971)	108,560 (111,863)

Data of the previous year are in parentheses.

Table 5: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2012)

Category	Type of the specified feed additives	2012	
		Manufactured quantity kg	Quantity converted into potency kg(potency)
Polypeptide antibiotics	Enramycin	95,800	6,315
	Colistin sulfate (Refining grade)	9,280	928
	Nosiheptide (Feed grade)	74,180	2,967
	Subtotal	179,260	10,210
Polyether antibiotics	Salinomycin sodium (Feed grade)	195,540	19,554
	Semduramicin sodium	17,600	880
	Monensin sodium	191,620	38,324
	Lasalocid sodium	134,200	20,130
	Subtotal	538,960	78,888
Total		718,220	89,098
Ratio to the previous fiscal year (%)		121	107

(Hearing from each registered manufacturer of specified feed additives)

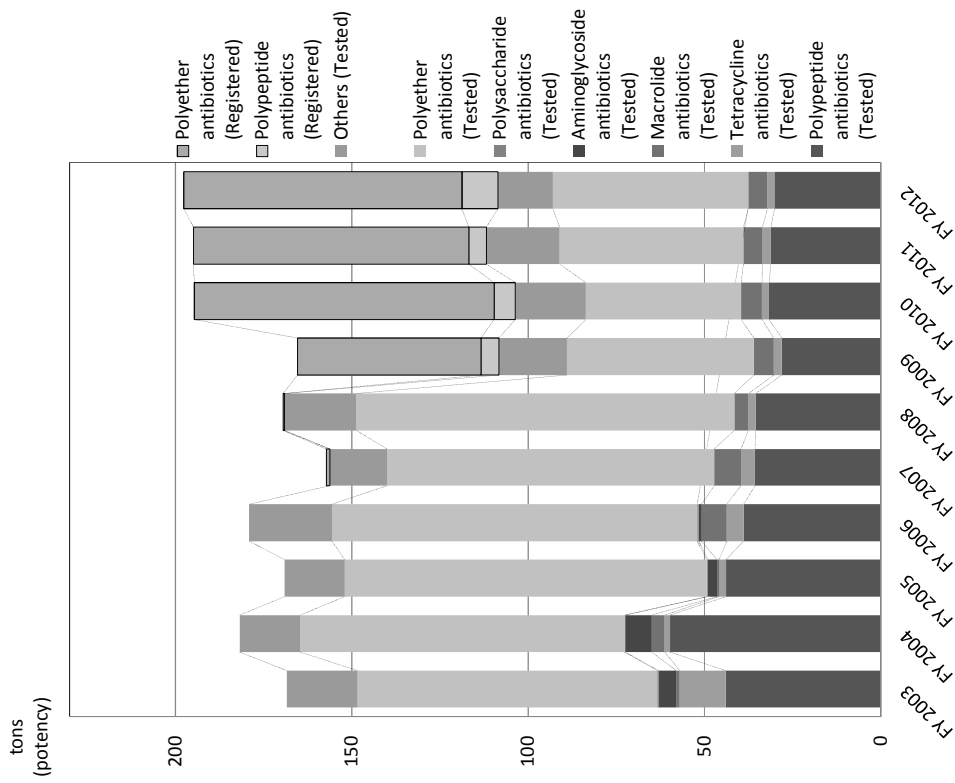


Figure 4: Changes in the testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives converted into potency (Sorted by category of antibiotics)

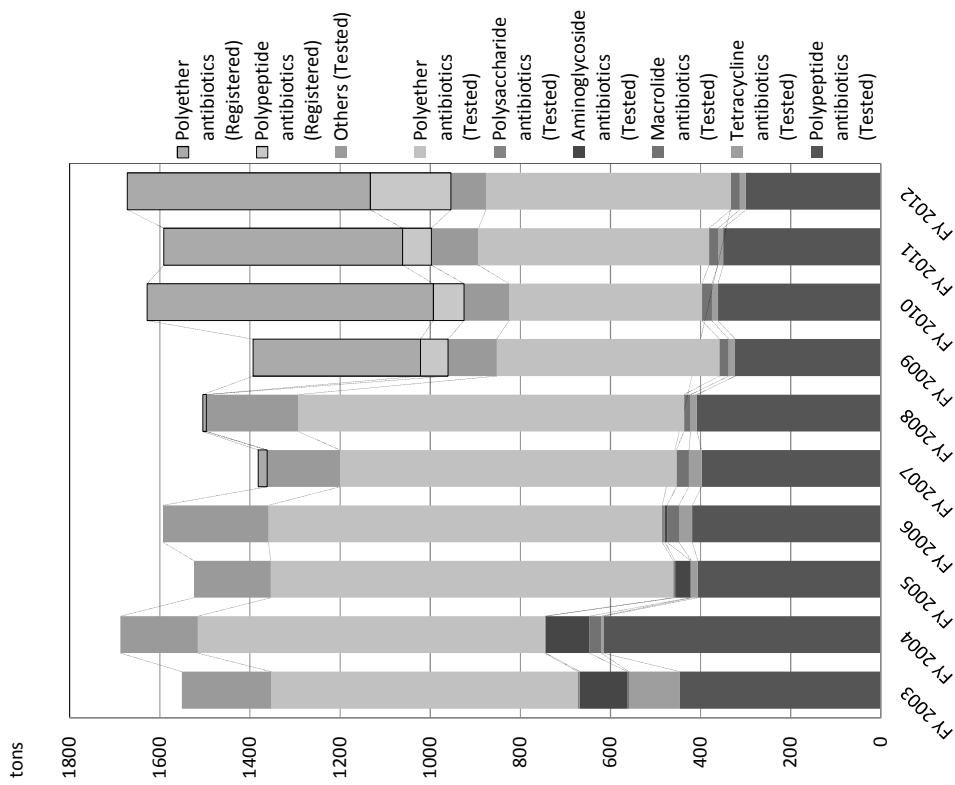


Figure 3: Changes in the testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives (Sorted by category of antibiotics)

Results of official testing of specified feed additives (FY 2013)

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 2013. The quantity and others of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2013 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 2013.

Nine business entities (8 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 four imported preparation.

Nine types of specified feed additives, corresponding to 15 brands, are applied for the testing in FY 2013 (11 types and 16 brands in the previous FY). The manufacturing of raw materials or preparations of all of them are dependent on foreign countries.

As for the import source countries of raw material for manufacturing or preparations: 1) China for zinc bacitracin (preparation) 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 flavophospholipol (preparation) and 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 2011, 2012, and 2013. 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 2013, 197 cases (application: 197 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 922 tons and 108 tons (potency), respectively. The passed cases, the passed quantity, and the quantity converted from the actual quantity into potency were 104%, 97%, and 99%, respectively, compared with the previous fiscal year. The cases increased but the quantity and the quantity converted from the actual quantity into potency slightly decreased.

The percentage of the specified feed additives in the total passed quantity by type was 33%, which was the highest one, for salinomycin sodium (25% in the previous FY), followed in descending order by 24% for colistin sulfate (25% in the previous FY), 21% for narasin (31% in the previous FY), 11% for avilamycin (8% in the previous FY), and 5% for zinc bacitracin (6% 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 29% for salinomycin sodium (22% in the previous FY), followed in descending order by 20% for colistin sulfate (22% in the previous FY), 19% for avilamycin (14% in the previous FY), 18% for narasin (27% in the previous FY), and 5% for zinc bacitracin (6% 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 chlortetracycline, tylosin phosphate, flavophospholipol, salinomycin sodium, and avilamycin increased, while those of zinc bacitracin, colistin sulfate, monensin sodium, and narasin decreased.

Nosiheptide and alkyltrimethylammonium calcium oxytetracycline, which were applied for the testing in the previous fiscal year, were not subjected to the testing. Enramycin, semduramicin sodium, and lasalocid sodium since FY 2010, virginiamycin since FY 2008, efrotomycin and sedecamycin 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 2013.

In addition, enramycin, nosiheptide, semduramicin sodium and 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 2013.

Compared between percentages of the refining grade and the feed grade based on the testing-passed quantity, the feed grade accounted for 73% of the total (72% in the previous FY). The feed grade also accounted for 73% of the total (71% 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 2013, only the refining grade of colistin sulfate 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 2004 to 2013, respectively.

The total of the testing-passed quantity was on a declining trend with repeating increase and decrease from FY 2004 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 2013, the polyether antibiotics accounted for 56% of the total (57% in the previous FY), followed by the polypeptide antibiotics, 29% (31% 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 more than 50% of the total from FY 2004 to FY 2008 and since FY 2009 has remained more than 40%. The polyether antibiotics accounted for 48% (51% in the previous FY), followed by the polypeptide antibiotics, at 25% (28% 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 2013.

The number of the testing-passed cases, the passed quantity and the quantity converted from the actual quantity into potency in FY 2013 were highest within the jurisdiction area of the Kobe center, followed by the jurisdiction areas of the Fukuoka center, and the headquarters.

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 headquarters and the Fukuoka center, but decreased within the jurisdiction areas of the Kobe 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 2013.

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

As of the end of March in 2014, the 3rd plant, Kyushu Plant, Kohkin Chemical Co., Ltd. is registered as a place of business as a manufacturer of specified feed additives concerning semduramicin sodium and nosiheptide, 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 2013. Moreover, semduramicin sodium, nosiheptide, lasalocid sodium and enramycin, which have not undergone the testing as a specified feed additive in FY 2013 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 2013 was 685 tons (95% over the previous year) and the quantity converted from the actual quantity into potency was 92 tons (potency) (103% over the previous year).

The descending order of the manufactured quantity in FY 2013 was monensin sodium, salinomycin sodium (feed grade), lasalocid sodium, enramycin, nosiheptide (feed grade), semduramicin sodium, and colistin sulfate (refining grade).

The descending order of the quantity converted from the actual quantity into potency was monensin sodium, lasalocid sodium, salinomycin sodium (feed grade), enramycin, nosiheptide (feed grade), semduramicin sodium, and colistin sulfate (refining grade).

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 2013 was highest for the polyether antibiotics, 1,074 tons (testing: 514 tons; registration: 560 tons), which accounted for 67% of the total. The descending order by type was salinomycin sodium (31%), monensin sodium (14%), and colistin sulfate (14%). The total quantity converted from the actual quantity into potency by category was also highest for the polyether antibiotics, 136 tons (testing: 52 tons; registration: 84 tons), which accounted for 68% of the total. The descending order by type was salinomycin sodium (25%), monensin sodium (23%), and colistin sulfate (11%).

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 2004 to FY 2013, 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 2004 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 2004 to FY 2009, increased in FY 2010, and since then has been on a slight increasing trend.

In FY 2013, 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 46% for the quantity converted from the actual quantity into potency (45% 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 2013 were as follows.

- (1) Fifteen brands of 9 specified feed additives were applied for the official testing of specified feed additives by 9 business entities. For all of them the manufacturing of raw materials or preparations was dependent on foreign sources.
- (2) The number of the passed cases, the passed quantity, and the quantity converted from the actual quantity into potency were 197 cases (application: 197 cases), 922 tons, and 108 tons (potency), respectively. The cases increased but 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 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 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 73% 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 monensin sodium, followed by salinomycin 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 lasalocid sodium and salinomycin 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, monensin sodium, and colistin sulfate in descending order. The total quantity converted from the actual quantity into potency was the same.

Table 1: Names of applicants and others for the official testing of the specified feed additives (FY 2013)

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	Salinomycin sodium	0	100	
			Monensin sodium		200	
	Japan Nutrition Co., Ltd.	Ibaraki	Salinomycin sodium	0	100	
	TNB Co., Ltd.	*	Chlortetracycline	0	100	
Kobe	Rokku Chemical Products Co., Ltd.	Shizuoka	Colistin sulfate		100	
	Miyarisan Pharmaceutical Co., Ltd.	*	Flavophospholipol	0	80	
	Scientific Feed Laboratory Co., Ltd.	Hyogo	Colistin sulfate		100	
			Tylosin phosphate		275	
Fukuoka	Eli Lilly Japan K. K.	*	Avilamycin	0	200	
			Narasin	0	100	
			Tylosin phosphate		275	
	Scientific Feed Laboratory Co., Ltd.	Miyazaki	Colistin sulfate		100	
Total	Kohkin Chemical Co., Ltd.	Kagoshima	Salinomycin sodium	0	100	4,200 unit/g
	Zoetis Japan Inc.	*	Zinc bacitracin	0	150	6,300 unit/g
	9 business entities	10 places			15 brands	

* Fallen under an importer

Table 2: Number of the testing-passed cases, passed quantity, and quantity converted into potency
(Sorted by the type of the antibiotics, FYs 2011 to 2013)

Category	Type of the specified feed additives	2011				2012				2013					
		Passed cases	Passed quantity kg	Composition ratio (%)	Quantity converted into potency kg(potency)	Passed cases	Passed quantity kg	Composition ratio (%)	Quantity converted into potency kg(potency)	Passed cases	Passed quantity kg	Composition ratio (%)	Quantity converted into potency kg(potency)	Composition ratio (%)	
															Composition ratio (%)
Polypeptide antibiotics	Zinc bacitracin	11	49,880	5	5,984	10	54,780	6	6,220	8	44,920	5	5,241	5	
	Enramycin	-	-	-	-	-	-	-	-	-	-	-	-	-	
	Nosiheptide	55	220,000	22	22,000	60	236,200	25	23,620	56	220,320	24	22,032	20	
	Virginiamycin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Colistin sulfate	22	79,760	8	3,190	2	8,000	1	320	-	-	-	-	-	
	Subtotal	88	349,640	35	31,174	72	298,980	31	30,160	64	265,240	29	27,273	25	
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline	2	8,000	1	800	3	12,000	1	1,200	1	16,000	2	1,600	1	
	Chlortetracycline	2	4,000	0	1,600	1	2,000	0	800	1	-	-	-	-	
	Subtotal	4	12,000	1	2,400	4	14,000	1	2,000	2	16,000	2	1,600	1	
Macrolide antibiotics	Tylosin phosphate	5	19,609	2	5,393	4	19,700	2	5,418	4	20,262	2	5,572	5	
	Sedecamycin	-	-	-	-	-	-	-	-	-	-	-	-	-	
	Subtotal	5	19,609	2	5,393	4	19,700	2	5,418	4	20,262	2	5,572	5	
Polysaccharide antibiotics	Flavophospholipol	-	-	-	-	1	1,250	0	100	1	2,500	0	200	0	
	Subtotal	-	-	-	-	1	1,250	0	100	1	2,500	0	200	0	
	Salinomycin sodium	3	9,260	1	1,852	3	10,860	1	2,172	2	7,940	1	1,588	1	
Polyether antibiotics	Semduramicin sodium	64	250,612	25	25,061	58	235,178	25	23,518	76	308,122	33	30,812	29	
	Narasin	-	-	-	-	-	-	-	-	-	-	-	-	-	
	Monensin sodium	-	-	-	-	-	-	-	-	-	-	-	-	-	
	Lasalocid sodium	23	251,875	25	25,188	27	296,275	31	29,628	18	197,625	21	19,763	18	
	Subtotal	90	511,747	51	52,101	88	542,313	57	55,317	96	513,687	56	52,163	48	
Others	Avilamycin	28	103,975	10	20,795	21	77,825	8	15,565	28	104,200	11	20,840	19	
	Efrotomycin	-	-	-	-	-	-	-	-	-	-	-	-	-	
	Biozamycin	-	-	-	-	-	-	-	-	-	-	-	-	-	
	Subtotal	28	103,975	10	20,795	21	77,825	8	15,565	28	104,200	11	20,840	19	
	Total	215	996,971	100	111,863	190	954,068	100	108,560	197	921,889	100	107,648	100	
	Ratio to the previous fiscal year (%)	111	108		108	88	96		97	104	97		99		

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 2013)

Category	Type of the specified feed additives	Refining grade			Feed grade		
		Passed cases	Passed quantity kg	Quantity converted into potency kg (potency)	Passed cases	Passed quantity kg	Quantity converted into potency kg (potency)
Polypeptide antibiotics	Zinc bacitracin				8	44,920	5,241
	Enramycin				-	-	-
	Nosiheptide				-	-	-
	Virginiamycin						
	Colistin sulfate	56	220,320	22,032	-	-	-
Tetracycline antibiotics	Alkyltrimethylammonium calcium oxytetracycline						
	Chlortetracycline				4	16,000	1,600
Macrolide antibiotics	Sedecamycin						
Polysaccharide antibiotics	Tylosin phosphate	4	20,262	5,572			
	Flavophospholipol				1	2,500	200
Polyether antibiotics	Salinomycin sodium				76	308,122	30,812
	Semduramicin sodium						
	Narasin				18	197,625	19,763
	Monensin sodium	2	7,940	1,588			
	Lasalocid sodium						
Others	Avilamycin				28	104,200	20,840
	Efrotomycin						
	Bicozamycin						
Total		62	248,522	29,192	135	673,367	78,456
Proportion (%)		31	27	27	69	73	73

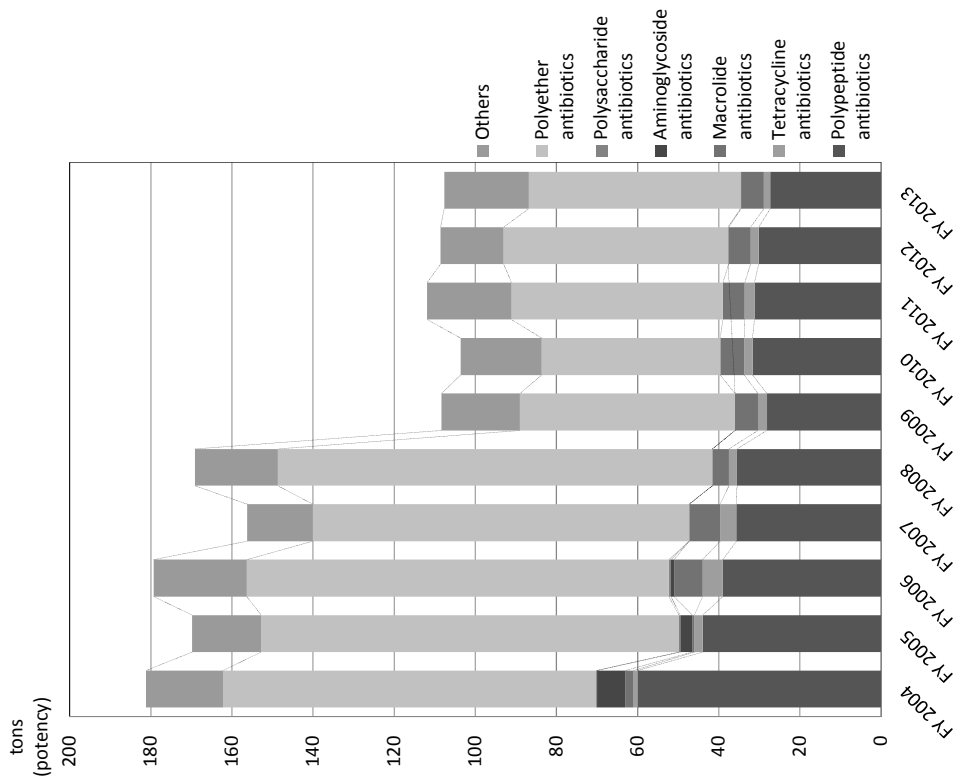


Figure 2: Changes in the testing-passed quantity of the specified feed additives converted into potency (Sorted by category of antibiotics)

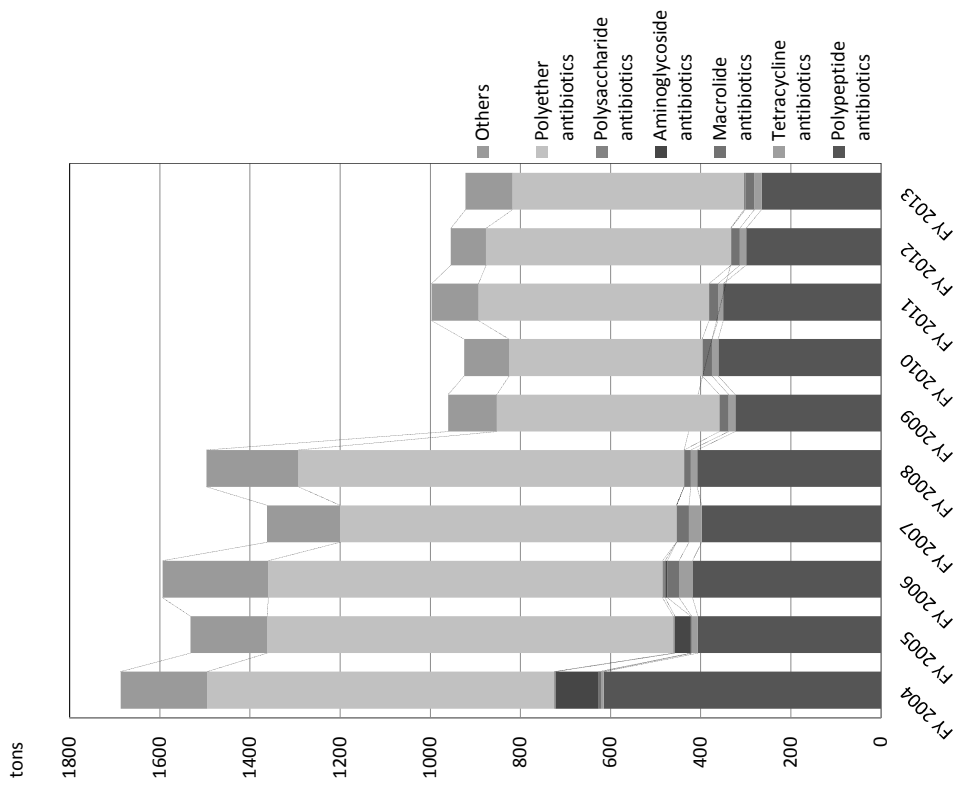


Figure 1: Changes in the testing-passed quantity of the specified feed additives (Sorted by category of antibiotics)

Table 4: Number of the testing-passed cases, passed quantity, and quantity converted into potency
 (Sorted by the jurisdiction area of FAMIC, FY 2013)

Contact office of FAMIC	Passed cases	Passed quantity kg	Quantity converted into potency kg(potency)
Headquarters	55 (45)	222,042 (179,288)	22,948 (18,990)
Sapporo	- (-)	- (-)	- (-)
Sendai	- (-)	- (-)	- (-)
Nagoya	- (-)	- (-)	- (-)
Kobe	79 (88)	433,867 (533,800)	57,353 (64,610)
Fukuoka	63 (57)	265,980 (240,980)	27,347 (24,960)
Total	197 (190)	921,889 (954,068)	107,648 (108,560)

Data of the previous year are in parentheses.

Table 5: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2013)

Category	Type of the specified feed additives	2013	
		Manufactured quantity kg	Quantity converted into potency kg(potency)
Polypeptide antibiotics	Enramycin	63,120	5,050
	Colistin sulfate (Refining grade)	4,100	410
	Nosiheptide (Feed grade)	57,720	2,309
	Subtotal	124,940	7,768
Polyether antibiotics	Salinomycin sodium (Feed grade)	191,700	19,170
	Semduramicin sodium	17,600	880
	Monensin sodium	222,380	44,476
	Lasalocid sodium	128,480	19,272
	Subtotal	560,160	83,798
Total		685,100	91,566
Ratio to the previous fiscal year (%)		95	103

(Hearing from each registered manufacturer of specified feed additives)

Table 6: Total manufactured quantity of the specified feed additives (FY 2013)

Category	Type of specified feed additives	Total quantity ^{*1}		Total quantity converted into potency ^{*2}		Composition ratio (%)
		(kg)	(%)	(kg(potency))	(%)	
Polypeptide antibiotics	Zinc bacitracin	44,920	3	5,241	3	3
	Enramycin	63,120	4	5,050	3	3
	Nosiheptide	224,420	14	22,442	11	11
	Virginiamycin	-	-	-	-	-
	Colistin sulfate	57,720	4	2,309	1	1
	Subtotal	390,180	24	35,041	18	18
Tetracycline antibiotics	Chlortetracycline	16,000	1	1,600	1	1
	Alkyltrimethylammonium calcium oxytetracycline	-	-	-	-	-
	Subtotal	16,000	1	1,600	1	1
Macrolide antibiotics	Tylosin phosphate	20,262	1	5,572	3	3
	Sedecamycin	-	-	-	-	-
	Subtotal	20,262	1	5,572	3	3
Polysaccharide antibiotics	Flavophospholipol	2,500	0	200	0	0
	Subtotal	2,500	0	200	0	0
Polyether antibiotics	Monensin sodium	230,320	14	46,064	23	23
	Salinomycin sodium	499,822	31	49,982	25	25
	Lasalocid sodium	128,480	8	19,272	10	10
	Semduramicin sodium	17,600	1	880	0	0
	Narasin	197,625	12	19,763	10	10
	Subtotal	1,073,847	67	135,961	68	68
Others	Avilamycin	104,200	6	20,840	10	10
	Bicozamycin	-	-	-	-	-
	Efrotomycin	-	-	-	-	-
	Subtotal	104,200	6	20,840	10	10
	Total	1,606,989	100	199,214	100	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

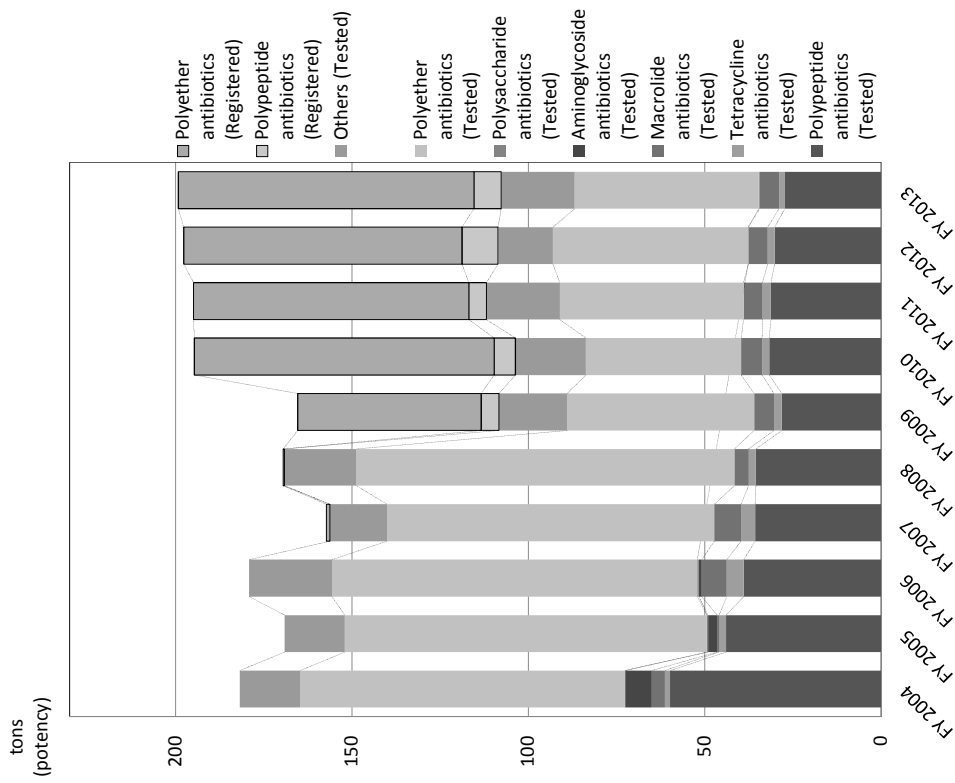


Figure 4: Changes in the testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives converted into potency (Sorted by category of antibiotics)

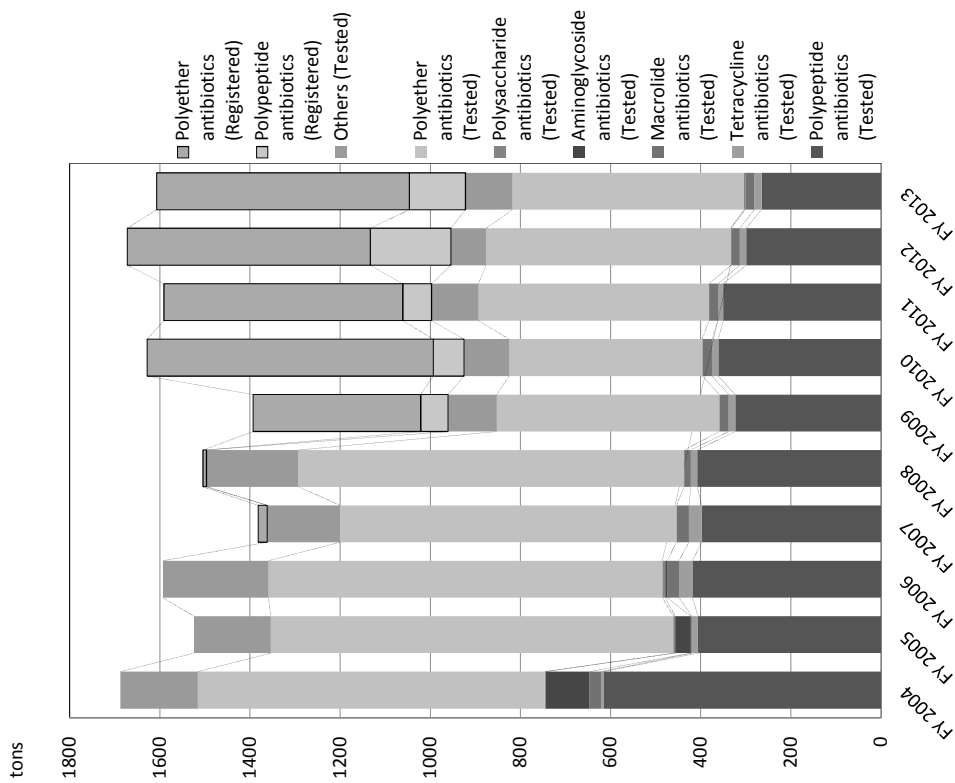


Figure 3: Changes in the testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives (Sorted by category of antibiotics)