

Results of Official Testing of Specified Feed Additives (FY 2019)

Specified feed additives mean the feed additives for which the standards are set in accordance with the provisions of Article 3, paragraph (1) of the [Act on Safety Assurance and Quality Improvement of Feeds](#) (Act No. 35 of 1953; hereinafter referred to as “Feed Safety Act”) and which are the antibacterial preparations specified in Article 2, item (ii) of the [Enforcement Order of the Act on Safety Assurance and Quality Improvement of Feeds](#) (Cabinet Order No. 198 of 1976). Only the specified feed additives, which the official testing are conducted by the Food and Agricultural Materials Inspection Center (hereinafter referred to as “FAMIC”) in accordance with the provisions of Article 5, paragraph (1) of the Feed Safety Act, may be distributed; provided, however, that only the specified feed additives, which are manufactured by the manufacturers of specified feed additives registered under Article 7, paragraph (1) of the Feed Safety Act (hereinafter referred to as “registered manufacturers of specified feed additives”), the indication referred to in Article 16, paragraph (1) of the same Act is placed and those manufactured by the foreign manufacturers of specified feed additives registered under Article 21, paragraph (1), and the indication referred to the paragraph (2) of the same Article is placed on, may be distributed.

The following report is the summary of the results of the specified feed additives which were applied for FAMIC and passed the official testing in the previous Japanese fiscal year (FY) 2019. The quantity and others of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2019 are also reported. As of the end of March in 2020, there was no foreign registered manufacturer of specified feed additives.

1. Names of applicants and others

Table 1 shows the names of applicants and others concerning the specified feed additives passed the official testing in FY 2019.

There were 6 applicants (5 in the previous FY) applied the official testing of the specified feed additives. The manufacturing forms and others of these applicants: two of them manufactured preparations, one of them imported raw materials for manufacturing and manufactured preparations, and the others imported preparations. All of the raw materials for manufacturing were manufactured in foreign countries.

There were 5 types of specified feed additives corresponding to 8 brands which passed the official testing in FY 2019 (6 types and 8 brands in the previous FY).

Raw materials for manufacturing or preparations were imported from: 1) the UK for avilamycin (preparation), 2) the USA for narasin (preparation), 3) Bulgaria for monensin sodium (raw material for manufacturing and preparation), 4) Bulgaria for flavophospholipol (preparation), 5) China and Bulgaria for salinomycin sodium (raw material for manufacturing), and 6) Bulgaria for salinomycin sodium (preparation). The number of the import source countries was 4 (4 in the previous FY).

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

Table 2 shows the results of the number of the official testing-passed cases, the official testing-

passed quantity, and the quantity converted from the actual quantity into potency of the specified feed additives by type in FYs 2017, 2018, and 2019.

122 cases were passed the official testing. The official testing-passed quantity and the quantity converted from the actual quantity into potency were 623 tons and 75 tons (potency) in FY 2019, respectively. Compared with the previous FY, the official testing-passed cases decreased, while the official testing-passed quantity and the quantity converted from the actual quantity into potency increased, and the ratio to the previous FY were 96.8 %, 105.7 %, and 108.3 %, respectively.

The percentage of the specified feed additives in the total official testing-passed quantity by type in FY 2019 was 44.1 %, which was the highest one, for salinomycin sodium (37.1 % in the previous FY), followed in descending order by 30.7 % for narasin (25.4 % in the previous FY), 14.2 % for avilamycin (22.2 % in the previous FY), 6.4 % for monensin sodium (2.1 % in the previous FY), and 4.7 % for flavophospholipol (0.0 % in the previous FY). The percentage of them in the total of the quantity converted from the actual quantity into potency in FY 2019 was 36.8 % for salinomycin sodium (31.8 % in the previous FY), followed in descending order by 25.6 % for narasin (21.8 % in the previous FY), 23.7 % for avilamycin (38.1 % in the previous FY), 10.7 % for monensin sodium (3.5 % in the previous FY), and 3.1 % for flavophospholipol (0.0 % in the previous FY).

Compared with the previous FY, the official testing-passed quantity and the quantity converted from the actual quantity into potency of salinomycin sodium, monensin sodium, and narasin increased, while those of avilamycin decreased. There was no apply for FAMIC of enramycin and nosiheptide which were applied in the previous FY, while there was apply for FAMIC of flavophospholipol which was not applied in the previous FY. Based on “Guidelines for Formulating Risk Management Measures for Antibacterial Feed Additives” of the Ministry of Agriculture, Forestry and Fisheries (hereinafter referred to as “MAFF”), alkyltrimethylammonium calcium oxytetracycline, chlortetracycline, and tylosin phosphate were revoked as the specified feed additives on the dates shown in Table 3.

Zinc bacitracin since FY 2016, lasalocid sodium since FY 2010, semduramicin sodium since FY 2007, and bicozamycin since FY 1999 have not been subjected to the official testing, and all of them were not subjected to in FY 2019 either.

In addition, lasalocid sodium were not subjected to the official testing, but were manufactured by the registered manufacturers of specified feed additives as shown in Table 4.

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

The specified feed additives are classified as the refining grade or the feed grade according to the difference of the post-cultivation manufacturing methods. The former is derived from the high purity raw materials for manufacturing in which the only active constituent of an antibiotic is extracted from a culture solution and then refined, while the latter is derived from the raw materials for manufacturing in which a culture solution containing the active consistent of an antibiotics, a medium component and a fungus compound used for manufacturing is dried.

Table 5 shows the number of the official testing-passed cases, the official testing-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 2019.

The feed grade of the specified feed additives accounted for; 95.9 % of the total official testing-passed cases (83.3% in the previous FY), 93.6 % of the total official testing-passed quantity (85.6 % in the previous FY), and 89.3 % of the total quantity converted from the actual quantity into potency (92.2 % in the previous FY).

Both the feed grade and refining grade standards are provided for nosiheptide and salinomycin sodium. Only the feed grade of salinomycin sodium was subjected to the official testing in FY 2019.

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

Figure 1 and 2 shows the changes in the official 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 FY 2010 to FY 2019, respectively.

The total of the official testing-passed quantity had been showing a tendency to decrease while increasing or decreasing, and in particular, FY 2017 and FY 2018 significantly decreased by 20 % compared with the previous FY, respectively. The quantity converted from the actual quantity into potency also showed the same tendency.

As for the official testing-passed quantity of the specified feed additives by category, polyether antibiotics was highest from FY 2011 to FY 2019 and has hovered at a rate of around 50 % of the total. The descending order by category was the polyether antibiotics and the polypeptide antibiotics until FY 2017. But the descending order by category was the polyether antibiotics and the others after FY 2018. The polyether antibiotics accounted for 81.2 % of the total (64.5 % in the previous FY), followed by the others, at 14.2 % (22.2 % in the previous FY) in FY 2019.

The quantity converted from the actual quantity into potency showed the same tendency until FY 2016. But from FY 2017, the order of the polypeptide antibiotics and the others was reserved. In FY 2019 the polyether antibiotics accounted for 73.2 % (57.1 % in the previous FY), followed by the others, at 23.7 % (38.1 % in the previous FY), and there were no applications for polypeptides, tetracyclines, and macrolides.

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

As of the end of March in 2020, the 3rd plant, Kyushu Plant, Kohkin Chemical Co., Ltd. is registered as a place of business as a manufacturer of specified feed additives concerning nosiheptide, and Tatsuno Factory, Scientific Feed Laboratory Co., Ltd., is registered as a place of business as a manufacturer of specified feed additives concerning enramycin, lasalocid sodium, monensin sodium, nosiheptide, and salinomycin sodium. The 3rd plant, Kyusyu Plant, Kohkin Chemical Co., Ltd. has not manufactured any registered specified feed additives from FY 2017 to FY 2019.

Table 4 shows the manufactured quantity and the quantity converted from the actual quantity into

potency of the specified feed additives by the registered manufacturers of specified feed additives in FY 2019. Moreover, lasalocid sodium which have not undergone the official testing as a specified feed additive showed by Table 2 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 2019 was 908 tons (100.2 % over the previous FY) and the quantity converted from the actual quantity into potency was 126 tons (potency) (98.6 % over the previous FY) shown in Table 4.

The descending order of the manufactured quantity in FY 2019 was salinomycin sodium, monensin sodium, lasalocid sodium, nosiheptide, and enramycin.

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

6. Total manufactured quantity of the specified feed additives

Table 6 shows the total manufactured quantity and the total quantity converted from the actual quantity into potency in FY 2019, which are the total of the official 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 2019 was highest for the polyether antibiotics, 1,304 tons (official testing: 506 tons; registration: 798 tons), which accounted for 85.2 % of the total. The descending order by type was salinomycin sodium (38.9 %), monensin sodium (23.2 %), and narasin (12.5 %). The total quantity converted from the actual quantity into potency by category was also highest for the polyether antibiotics, 174 tons (official testing: 55 tons; registration: 119 tons), which accounted for 86.8 % of the total. The descending order by type was monensin sodium (35.5 %), salinomycin sodium (29.7 %), and lasalocid sodium (12.1 %).

Figure 3 and 4 shows the changes in the total manufactured quantity and the total quantity converted from the actual quantity into potency of the specified feed additives by category over the last decade, from FY 2010 to FY 2019, respectively.

The registered manufacturers have manufactured specified feed additives since FY 2007. The manufacturing of specified feed additives by the registered manufacturers increased due to the significant addition of registered brands of the specified feed additives in FY 2009. Since then, it has been increasing year by year, and since FY 2017, it has exceeded the number of products that have passed the official test.

The percentage of production by registered manufacturers accounted for; 59.3 % of the total manufactured quantity (60.6 % in the previous FY) and 62.8 % of the total quantity converted from the actual quantity into potency of the specified feed additives (65.0 % in the previous FY) in FY 2019, respectively.

7. Summary

A. The results of the official testing of the specified feed additives and the manufacturing by the

registered manufacturers of specified feed additives in FY 2019 were as follows.

- (a) There were 5 types of specified feed additives, corresponding to 8 brands, that were applied by 6 business entities and passed the official testing.
- (b) The number of the official testing-passed cases, the official testing-passed quantity, and the quantity converted from the actual quantity into potency were 122 cases, 623 tons, and 75 tons (potency), respectively. Compared to the previous FY, the official testing-passed cases decreased, while the official testing-passed quantity and the quantity converted from the actual quantity into potency increased.
- (c) Compared between percentages of the refining grade and the feed grade on the official testing-passed quantity, feed grade accounted for 93.6 %. The quantity converted from the actual quantity into potency of the feed grade accounted for 89.3 %.
- (d) The official testing-passed quantity of the specified feed additives by type was highest of salinomycin sodium, followed by narasin and avilamycin in descending order. The quantity converted from the actual quantity into potency of the specified feed additives passed the official testing by type showed the same result.
- (e) The official testing-passed quantity of the specified feed additives by category was highest of polyether antibiotics, followed by the others and phosphoglycolipid antibiotics in decreasing order. The quantity converted from the actual quantity into potency of the specified feed additives by category showed the same result.

B. The results of the manufacturing of the specified feed additives by the registered manufacturers of specified feed additives in FY 2019 were as follows.

- (a) There were 2 factories of 2 business entities that have registered manufacturers of specified feed additives.
- (b) In fact that one factory of one business entity manufactured 5 types of the specified feed additives, and the manufactured quantity and the quantity converted from the actual quantity into potency of the specified feed additives were 908 ton, and 126 ton, respectively. The type and the quantity of manufactured by registered manufacturers increased, but the quantity converted from the actual quantity into potency (of the specified feed additives) decreased in compared with FY 2018.
- (c) The quantity of the specified feed additives manufactured by the registered manufacturers of specified feed additives by type was highest for salinomycin sodium, followed by monensin sodium and lasalocid sodium in descending order. The quantity converted from the actual quantity into potency of the specified feed additives manufactured by the registered manufacturers of specified feed additives by type was highest for monensin sodium, followed by salinomycin sodium and lasalocid sodium in descending order.

C. The results of the total quantity of the specified feed additives in FY 2019 were as follows.

- (a) There were 3 types of the specified feed additives that were revoked from April 1, 2019 to April 1, 2020.
- (b) The total manufactured quantity and others which are the total of the official 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 narasin in descending order. The total quantity converted from the actual quantity into potency was monensin sodium, salinomycin sodium, and lasalocid sodium in descending order.

Table 1: Names of applicants and others for the official testing of the specified feed additives (FY 2019)

Contact office of FAMIC	Name of applicant	Place of manufacturing	Type of the specified feed additives	Feed grade	Content potency (mg (potency)/g)
Headquarters	Japan Nutrition Co., Ltd.	Ibaraki	Salinomycin sodium	○	100
	Miyarisan Pharmaceutical Co., Ltd.	*	Flavophospholipol	○	80
	Nichiku Yakuin Kogyo Corporation	Kanagawa	Monensin sodium		200
			Salinomycin sodium	○	100
	Rokku Chemical Products Co., Ltd.	Shizuoka	Salinomycin sodium	○	100
Kobe	Elanco Japan K.K.	*	Avilamycin	○	200
			Narasin	○	100
	Huvepharma Japan Co., Ltd.	*	Flavophospholipol	○	80
			Monensin sodium		200
			Salinomycin sodium	○	100
Total	6 business entities	3 places	5 types (8 brands)		

The symbol(*) denoted an importer.

Table 2: Number of the official testing-passed cases, official testing-passed quantity, and quantity converted into potency of specified feed additives (Sorted by the type of the antibiotics, FYs 2017 to 2019)

Category	Type of the specified feed additives	FY 2017					FY 2018					FY 2019				
		Passed cases	Passed quantity kg	Compo- sition ratio (%)	Quantity converted into potency kg(potency)	Compo- sition ratio (%)	Passed cases	Passed quantity kg	Compo- sition ratio (%)	Quantity converted into potency kg(potency)	Compo- sition ratio (%)	Passed cases	Passed quantity kg	Compo- sition ratio (%)	Quantity converted into potency kg(potency)	Compo- sition ratio (%)
Polypeptide	Enramycin	2	4,940	0.7	395	0.5	2	5,380	0.9	430	0.6	—	—	—	—	—
	Nosiheptide	20	62,200	8.6	2,488	3.1	18	72,720	12.3	2,909	4.2	—	—	—	—	—
	Zinc bacitracin	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	37	127,940	17.7	8,963	11.0	20	78,100	13.2	3,339	4.9	0	0	0	0	0
Tetracycline	Alkyltrimethylammonium calcium oxytetracycline	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Chlortetracycline	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Macrolide	Tylosin phosphate	3	12,611	1.7	3,468	4.3	—	—	—	—	—	—	—	—	—	—
	Subtotal	3	12,611	1.7	3,468	4.3	0	0	0	0	0	0	0	0	0	0
Phosphoglycolipid	Flavophospholipol	1	1,250	0.2	100	0.1	—	—	—	—	—	8	29,250	4.7	2,340	3.1
	Subtotal	1	1,250	0.2	100	0.1	0	0	0	0	0	8	29,250	4.7	2,340	3.1
Polyether	Lasalocid sodium	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Monensin sodium	2	8,020	1.1	1,604	2.0	3	12,160	2.1	2,432	3.5	5	39,960	6.4	7,992	10.7
	Narasin	22	230,550	31.8	23,055	28.3	14	149,825	25.4	14,983	21.8	21	191,000	30.7	19,100	25.6
	Salinomycin sodium	60	244,487	33.8	24,449	30.0	53	218,560	37.1	21,856	31.8	64	274,626	44.1	27,463	36.8
	Semduramicin sodium	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	84	483,057	66.7	49,108	60.3	70	380,545	64.5	39,271	57.1	90	505,586	81.2	54,555	73.2
Others	Avilamycin	27	99,050	13.7	19,810	24.3	36	130,975	22.2	26,195	38.1	24	88,175	14.2	17,635	23.7
	Bicozamycin	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	27	99,050	13.7	19,810	24.3	36	130,975	22.2	26,195	38.1	24	88,175	14.2	17,635	23.7
Total		152	723,908	100.0	81,449	100.0	126	589,620	100.0	68,805	100.0	122	623,011	100.0	74,530	100.0
Ratio to the previous fiscal year (%)		79.2	83.1		87.5		82.9	81.4		84.5		96.8	105.7		108.3	

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

Table 3: List of the specified feed additives that were revoked by MAFF

Type of the specified feed additives	Date of revocation
Tylosin phosphate	May 1, 2019
Alkyltrimethylammonium calcium oxytetracycline	December 27, 2019
Chlortetracycline	December 27, 2019
3 types	

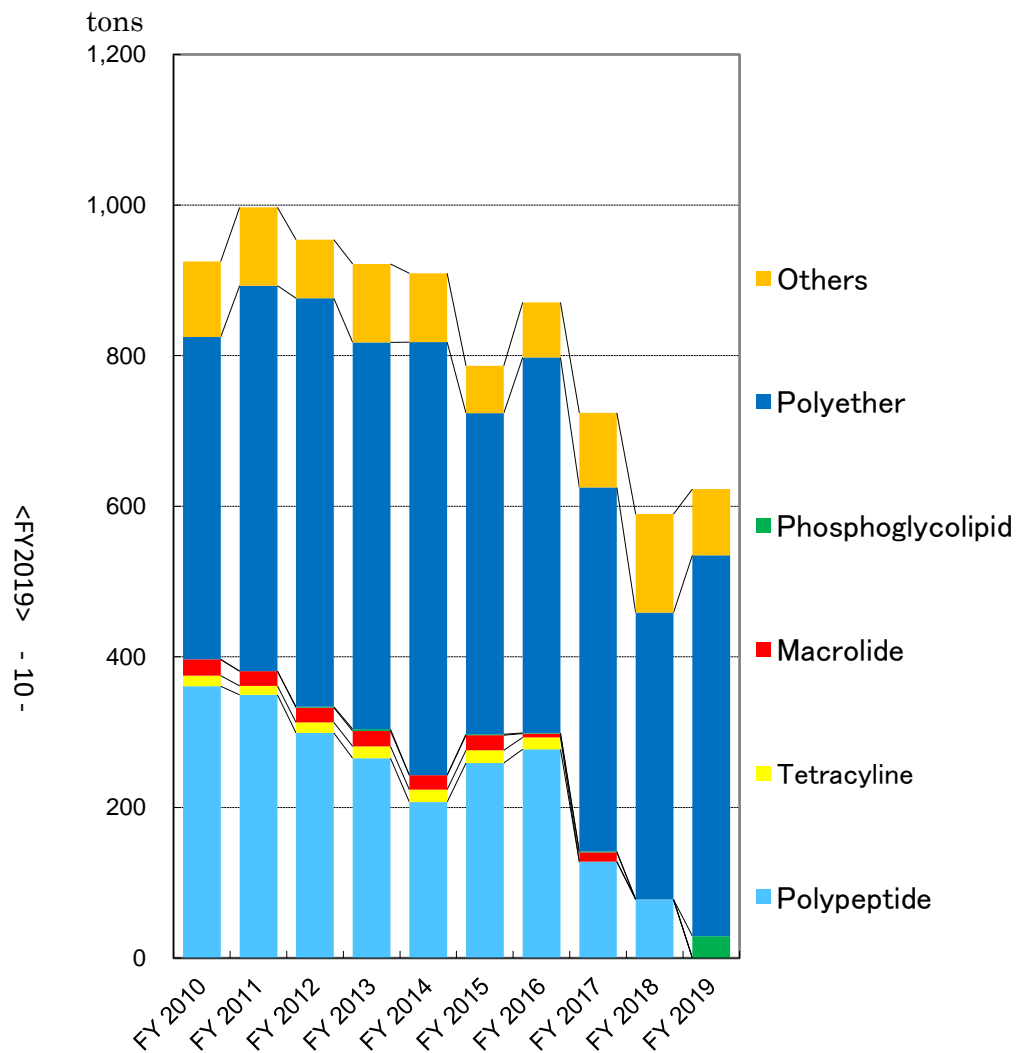


Figure 1: Changes in the official testing-passed quantity of the specified feed additives (Sorted by category of antibiotics)

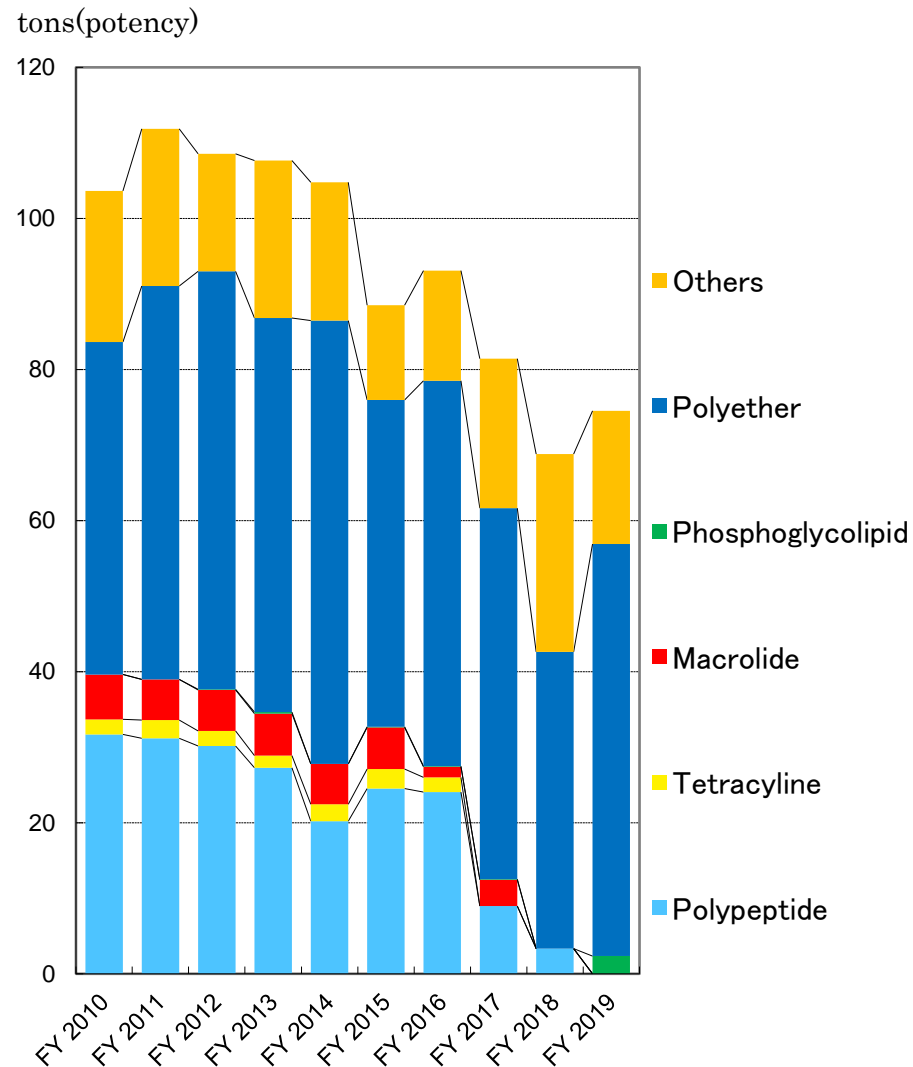


Figure 2: Changes in the official testing-passed quantity of the specified feed additives converted into potency (Sorted by category of antibiotics)

Table 4: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2018 and 2019)

Category	Type of the specified feed additives	FY 2018		FY 2019	
		Manufactured quantity* kg	Quantity converted into potency kg(potency)	Manufactured quantity* kg	Quantity converted into potency kg(potency)
Polypeptide	Enramycin	75,340	6,027	50,400	4,032
	Nosiheptide	—	—	59,540	2,382
	Subtotal	75,340	6,027	109,940	6,414
Polyether	Lasalocid sodium	98,160	14,724	161,720	24,258
	Monensin sodium	336,800	67,360	315,980	63,196
	Salinomycin sodium	396,260	39,626	320,600	32,060
	Subtotal	831,220	121,710	798,300	119,514
Total		906,560	127,737	908,240	125,928
Ratio to the previous fiscal year (%)		106.4	104.2	100.2	98.6

* Heard from each registered manufacturer of specified feed

Table 5: Number of the official testing-passed cases, official testing-passed quantity, and quantity converted into potency
(Sorted by the grade of the preparation, FY 2019)

Category	Type of the specified feed additives	Refining grade			Feed grade		
		Passed cases	Passed quantity kg	Quantity converted into kg(potency)	Passed cases	Passed quantity kg	Quantity converted into kg(potency)
Polypeptide	Enramycin	/	/	/	—	—	—
	Nosiheptide	—	—	—	—	—	—
	Zinc bacitracin	/	/	/	—	—	—
Tetracycline	Alkyltrimethylammonium calcium oxytetracycline	—	—	—	/	/	/
	Chlortetracycline	/	/	/	—	—	—
Macrolide	Tylosin phosphate	—	—	—	/	/	/
Phosphoglycolipid	Flavophospholipol	/	/	/	8	29,250	2,340
Polyether	Lasalocid sodium	—	—	—	/	/	/
	Monensin sodium	5	39,960	7,992	/	/	/
	Narasin	/	/	/	21	191,000	19,100
	Salinomycin sodium	—	—	—	64	274,626	27,463
	Semduramicin sodium	—	—	—	/	/	/
Others	Avilamycin	/	/	/	24	88,175	17,635
	Bicozamycin	—	—	—	/	/	/
Total		5	39,960	7,992	117	583,051	66,538
Proportion (%)		4.1	6.4	10.7	95.9	93.6	89.3

Note:Oblique lines mean that there is no standard for the category.

Table 6: Total manufactured quantity of the specified feed additives (FY 2019)

Category	Type of specified feed additives	Total quantity *1	Composition ratio	Total quantity converted into potency *2	Composition ratio
		kg	(%)	kg(potency)	(%)
Polypeptide	Enramycin	50,400	3.3	4,032	2.0
	Nosiheptide	59,540	3.9	2,382	1.2
	Zinc bacitracin	—	—	—	—
	Subtotal	109,940	7.2	6,414	3.2
Tetracycline	Alkyltrimethylammonium calcium oxytetracycline	—	—	—	—
	Chlortetracycline	—	—	—	—
	Subtotal	—	—	—	—
Macrolide	Tylosin phosphate	—	—	—	—
	Subtotal	—	—	—	—
Phosphoglycolipid	Flavophospholipol	29,250	1.9	2,340	1.2
	Subtotal	29,250	1.9	2,340	1.2
Polyether	Lasalocid sodium	161,720	10.6	24,258	12.1
	Monensin sodium	355,940	23.2	71,188	35.5
	Narasin	191,000	12.5	19,100	9.5
	Salinomycin sodium	595,226	38.9	59,523	29.7
	Semduramicin sodium	—	—	—	—
	Subtotal	1,303,886	85.2	174,069	86.8
Others	Avilamycin	88,175	5.8	17,635	8.8
	Bicozamycin	—	—	—	—
	Subtotal	88,175	5.8	17,635	8.8
Total		1,531,251	100.0	200,458	100.0

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

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

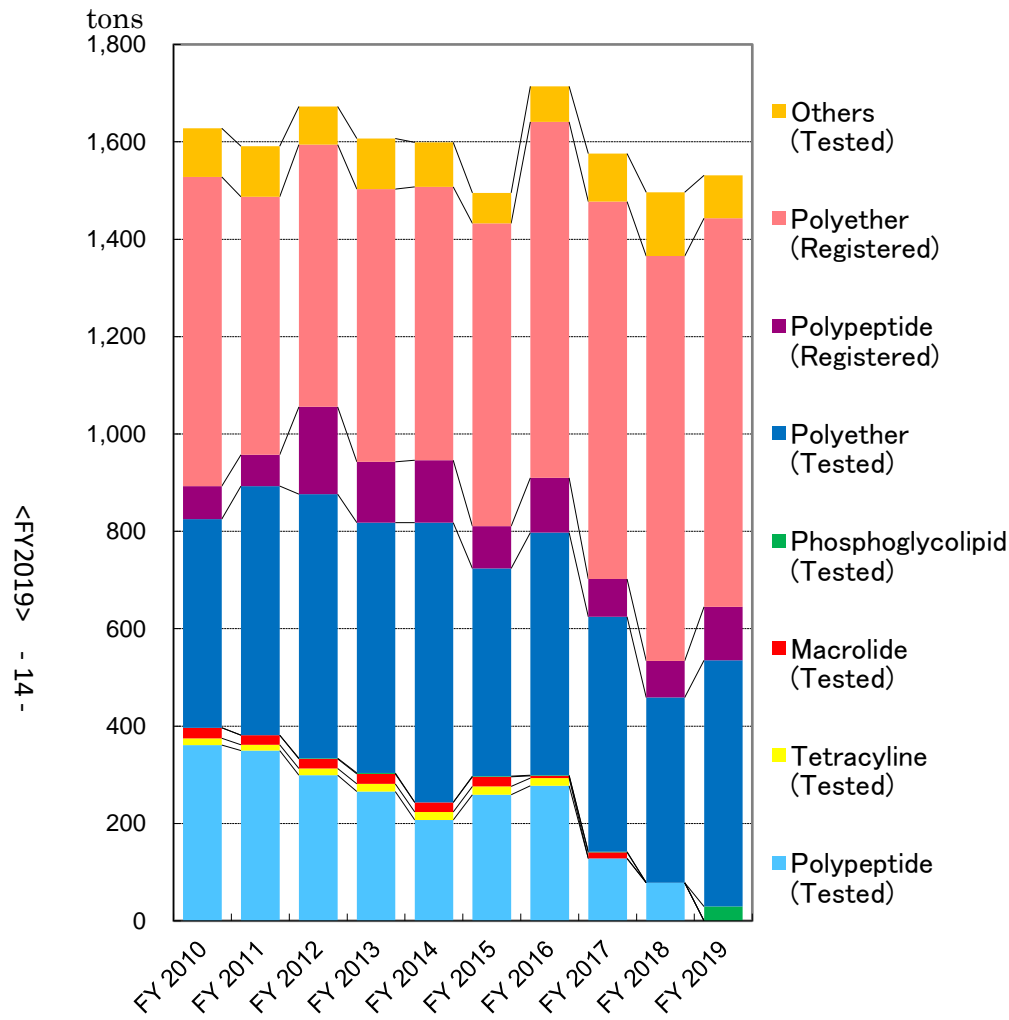


Figure 3: Changes in the official testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives (Sorted by category of antibiotics)

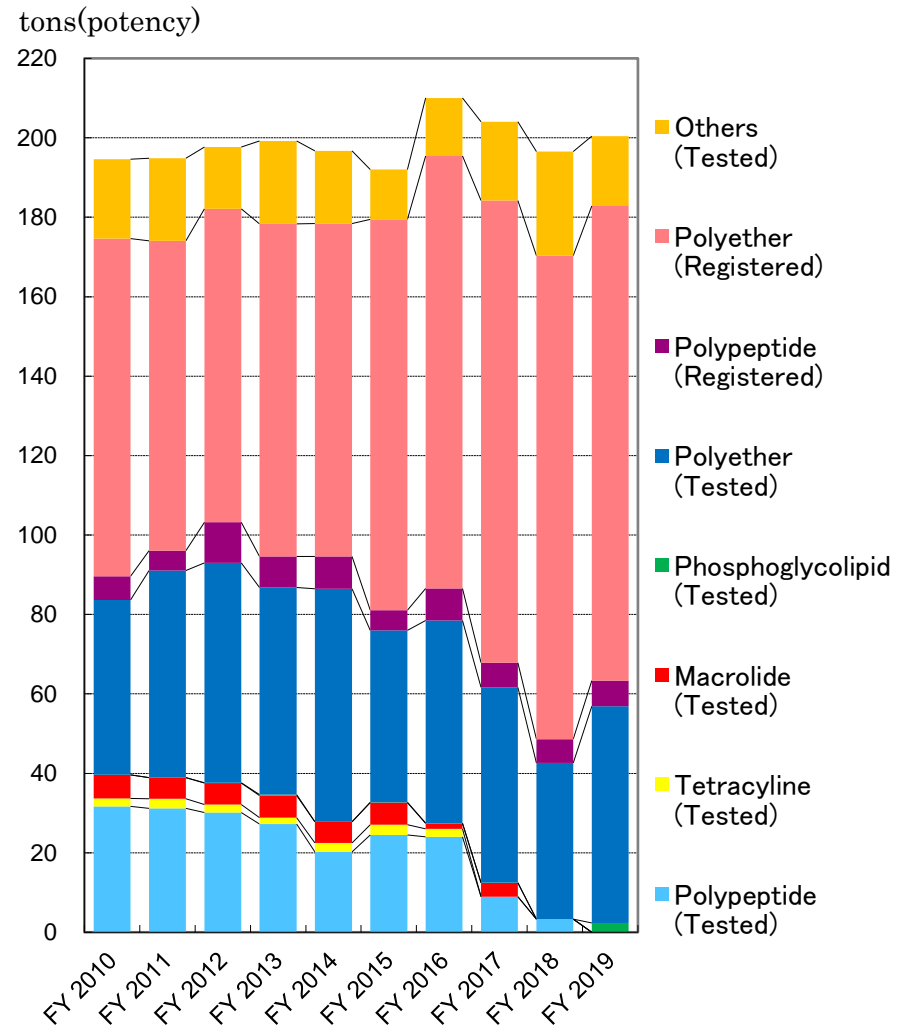


Figure 4: Changes in the official testing-passed quantity and the quantity manufactured by the registered manufacturers of the specified feed additives converted into potency (Sorted by category of antibiotics)