

Results of Official Testing of Specified Feed Additives (FY 2020)

Food and Agricultural Materials Inspection Center

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) 2020. The quantity and others of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2020 are also reported. As of the end of March in 2021, 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 2020.

There were 4 applicants (6 in the previous FY) applied the official testing of the specified feed additives. The manufacturing forms and others of these applicants were as follows: one 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 6 types of specified feed additives corresponding to 8 brands which passed the official testing in FY 2020 (5 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 (preparation), 4) Bulgaria for flavophospholipol (preparation), 5) China and Bulgaria for salinomycin sodium (raw material for manufacturing), 6) Bulgaria for salinomycin sodium (preparation), and 7) China for enramycin (raw material for manufacturing). 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 (OTPC) , the official testing-passed quantity (OTPQ) , and the quantity converted from the actual quantity into potency (QCAQP) of the specified feed additives by type in FYs 2018, 2019, and 2020.

133 cases were passed the official testing. OTPQ and QCAQP were 842 tons and 95 tons (potency) in FY 2020, respectively. Compared with the previous FY, OTPC and OTPQ and QCAQP increased, and the ratio to the previous FY were 109.0 %, 135.2 %, and 127.0 %, respectively.

The percentage of the specified feed additives in the total OTPQ by type in FY 2020 was 53.9 %, which was the highest one, for salinomycin sodium (44.1 % in the previous FY), followed in descending order by 31.6 % for narasin (30.7 % in the previous FY), 7.1 % for avilamycin (14.2 % in the previous FY), 5.0 % for flavophospholipol (4.7 % in the previous FY), 2.1 % for monensin sodium (6.4 % in the previous FY), and 0.3 % for enramycin (no application in the previous FY). The percentage of them in the total of QCAQP in FY 2020 was 51.8 % for salinomycin sodium (36.8 % in the previous FY), followed in descending order by 28.1 % for narasin (25.6 % in the previous FY), 12.6 % for avilamycin (23.7 % in the previous FY), 3.8 % for monensin sodium (10.7 % in the previous FY), 3.5 % for flavophospholipol (3.1 % in the previous FY), and 0.2 % for enramycin (no application in the previous FY).

Compared with the previous FY, OTPQ and QCAQP of salinomycin sodium, narasin, and flavophospholipol increased, while those of avilamycin, and monensin sodium decreased. There were applications for enramycin which was not applied in the previous FY.

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 2020 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 OTPC 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 3 shows the number of OTPC, OTPQ, and QCAQP of the specified feed additives by refining grade and feed grade in FY 2020.

The feed grade of the specified feed additives accounted for; 98.5 % of OTPC (95.9 % in the previous FY), 97.9 % of OTPQ (93.6 % in the previous FY), and 96.2 % of QCAQP (89.3 % in the previous FY).

Both the feed grade and refining grade standards are provided for nosiheptide and salinomycin sodium, although there were no applications for both grade of nosiheptide in FY 2020. Only the feed grade of salinomycin sodium was subjected to the official testing in FY 2020.

4. Changes in OTPQ and others of the specified feed additives by category

Figure 1 and 2 shows the changes in OTPQ and QCAQP by category of the specified feed additives over the last decade, from FY 2011 to FY 2020, respectively.

The total of OTPQ had been showing a tendency to decrease while increasing or decreasing, and in particular, FY 2020 significantly increased by 30 % compared with the previous FY, respectively. QCAQP also showed the same tendency.

As for OTPQ of the specified feed additives by category, polyether antibiotics was highest and has hovered at a rate of around 50 % of the total. The polyether antibiotics accounted for 87.6 % of the total (81.2 % in the previous FY), 7.0 % for orthosomycin antibiotics (14.2 % in the previous FY), 5.0 % for phosphoglycolipid antibiotics (4.7 % in the previous FY), and 0.4 % for polypeptide antibiotics (no application in the previous FY) in FY 2020.

QCAQP showed the same tendency. In FY 2020 the polyether antibiotics accounted for 83.7 % (73.2 % in the previous FY), 12.6 % for orthosomycin antibiotics (23.7 % in the previous FY), 3.5 % for phosphoglycolipid antibiotics (3.1 % in the previous FY), and 0.2 % for polypeptide antibiotics (no application in the previous FY).

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

As of the end of March in 2021, 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, and the 3rd plant, Kyushu Plant, Kohkin Chemical Co., Ltd. is registered as a place of business as a manufacturer of specified feed additives concerning nosiheptide. The 3rd plant, Kyusyu Plant, Kohkin Chemical Co., Ltd. has not manufactured any registered specified feed additives from FY 2017 to FY 2020, and registration of manufacturers was revoked on April 16, 2021.

Table 4 shows the manufactured quantity and QCAQP of the specified feed additives by the registered manufacturers of specified feed additives in FY 2020. Moreover, lasalocid sodium and nosiheptide 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 2020 was 813 tons (89.5 % over the previous FY) and QCAQP was 120 tons (potency) (95.4 % over the previous FY) shown in Table 4.

The descending order of the manufactured quantity in FY 2020 was monensin sodium, lasalocid sodium, salinomycin sodium, nosiheptide, and enramycin.

The descending order of QCAQP was monensin sodium, lasalocid sodium, salinomycin sodium, enramycin, and nosiheptide.

6. Total manufactured quantity of the specified feed additives

Table 5 shows the total manufactured quantity and the total QCAQP in FY 2020, which are the total of OTPQ of the specified feed additives and the quantity manufactured by the registered manufacturers (QMRM) of specified feed additives.

The total manufactured quantity by category in FY 2020 was highest for the polyether antibiotics, 1,425 tons (official testing: 738 tons; registration: 687 tons), which accounted for 86.1 % of the total. The descending order by type was salinomycin sodium (36.3 %), monensin sodium (22.3 %), and narasin (16.1 %). The total QCAQP by category was also highest for the polyether antibiotics, 192 tons (potency) (official testing: 79 tons (potency); registration: 113 tons (potency)), which accounted for 89.6 % of the total. The descending order by type was monensin sodium (34.4 %), salinomycin sodium (29.6 %), and lasalocid sodium (13.2 %).

Figure 3 and 4 shows the changes in the total manufactured quantity and the total QCAQP of the specified feed additives by category over the last decade, from FY 2011 to FY 2020, respectively. The registered manufacturers have manufactured specified feed additives since FY 2007. Since then, it has been increasing year by year, and since FY 2017 until FY 2019, it has exceeded the number of products that have passed the official test.

The percentage of production by registered manufacturers accounted for; 49.1 % of the total manufactured quantity (59.3 % in the previous FY) and 55.9 % of the total QCAQP of the specified feed additives (62.8 % in the previous FY) in FY 2020, 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 2020 were as follows.

- (a) There were 6 types of specified feed additives, corresponding to 8 brands, that were applied by 4 business entities and passed the official testing.
- (b) The number of OTPC, OTPQ, and QCAQP were 133 cases, 842 tons, and 95 tons (potency), respectively. Compared to the previous FY, OTPC and OTPQ and QCAQP increased.
- (c) Compared between percentages of the refining grade and the feed grade on OTPQ, feed grade accounted for 97.9 %. QCAQP of the feed grade accounted for 96.2 %.
- (d) OTPQ of the specified feed additives by type was highest of salinomycin sodium, followed by narasin and avilamycin in descending order. QCAQP of the specified feed additives passed the official testing by type showed the same result.
- (e) As for OTPQ of the specified feed additives by category, polyether antibiotics and phosphoglycolipid antibiotics increased, while orthosomycin antibiotics decreased in FY 2020 compared with previous FY. QCAQP 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 2020 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 QCAQP of the specified feed additives were 813 tons, and 120 tons (potency), respectively. The type and the quantity of manufactured by registered manufacturers and QCAQP (of the specified feed additives) decreased in FY 2020 compared with previous FY.
- (c) The quantity of the specified feed additives manufactured and QCAQP of the specified feed additives manufactured by the registered manufacturers by type was highest for monensin sodium, followed by lasalocid sodium and salinomycin sodium in descending order.

C. The results of the total quantity of the specified feed additives in FY 2020 were as follows.

The total manufactured quantity and others which are the total of OTPQ of the specified feed additives and the QMRM of specified feed additives by type was salinomycin sodium, monensin sodium, and narasin in descending order. The total QCAQP 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 2020)

Contact office of FAMIC *1	Name of applicant	Place of manufacturing	Type of the specified feed additives	Feed grade	Content potency (mg (potency)/g)
Headquarters	Elanco Japan K.K. *2*3	—	Avilamycin	○	200
			Narasin	○	100
	Japan Nutrition Co., Ltd.	Ibaraki	Salinomycin sodium	○	100
	Rokku Chemical Products Co., Ltd.	Shizuoka	Enramycin	○	80
			Salinomycin sodium	○	100
Kobe	Elanco Japan K.K. *2*3	—	Avilamycin	○	200
			Narasin	○	100
	Huvepharma Japan Co., Ltd. *2	—	Salinomycin sodium	○	100
			Salinomycin sodium	○	200
			Monensin sodium		200
			Flavophospholipol	○	80
Total	4 business entities	2 places	6 types (8 brands)		

*1 Headquarters district : Kanto / Koshinetsu / Shizuoka, Kobe district : Kinki / Chugoku (excluding Yamaguchi) / Shikoku

*2 Importer

*3 Changed to headquarters district from July due to warehouse integration

Table 2: Number of OTPC, OTPQ, and QCAQP of specified feed additives (Sorted by the type of the antibiotics, FYs 2018 to 2020)

Category	Type of the specified feed additives	FY 2018					FY 2019					FY 2020				
		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 (%)	Passed cases	Passed quantity (kg)	Composition ratio (%)	Quantity converted into potency (kg(potency))	Composition ratio (%)
Polypeptide	Zinc bacitracin	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Enramycin	2	5,380	0.9	430	0.6	—	—	—	—	—	2	2,780	0.3	222	0.2
	Nosiheptide	18	72,720	12.3	2,909	4.2	—	—	—	—	—	—	—	—	—	—
	Subtotal	20	78,100	13.2	3,339	4.9	0	0	0.0	0	0.0	2	2,780	0.3	222	0.2
Phosphoglycolipid	Flavophospholipol	—	—	—	—	—	8	29,250	4.7	2,340	3.1	5	41,900	5.0	3,352	3.5
	Subtotal	0	0	0.0	0	0.0	8	29,250	4.7	2,340	3.1	5	41,900	5.0	3,352	3.5
Polyether	Salinomycin sodium	53	218,560	37.1	21,856	31.8	64	274,626	44.1	27,463	36.8	79	454,195	53.9	49,017	51.8
	Semduramicin sodium	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Narasin	14	149,825	25.4	14,983	21.8	21	191,000	30.7	19,100	25.6	29	266,050	31.6	26,605	28.1
	Monensin sodium	3	12,160	2.1	2,432	3.5	5	39,960	6.4	7,992	10.7	2	18,000	2.1	3,600	3.8
	Lasalocid sodium	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	70	380,545	64.5	39,271	57.1	90	505,586	81.2	54,555	73.2	110	738,245	87.6	79,222	83.7
Orthosomycin	Avilamycin	36	130,975	22.2	26,195	38.1	24	88,175	14.2	17,635	23.7	16	59,425	7.1	11,885	12.6
	Subtotal	36	130,975	22.2	26,195	38.1	24	88,175	14.2	17,635	23.7	16	59,425	7.1	11,885	12.6
Others	Bicozamycin	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0	0.0	0	0.0
Total		126	589,620	100.0	68,805	100.0	122	623,011	100.0	74,530	100.0	133	842,350	100.0	94,681	100.0
Ratio to the previous fiscal year (%)		82.9	81.4	—	84.5	—	96.8	105.7	—	108.3	—	109.0	135.2	—	127.0	—

— : No application

Table 3: Number of OTPC, OTPQ, and QCAQP
(Sorted by the grade of the preparation, FY2020)

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	Zinc bacitracin	/	/	/	—	—	—
	Enramycin	/	/	/	2	2,780	222
	Nosiheptide	—	—	—	—	—	—
Phosphoglycolipid	Flavophospholipol	/	/	/	5	41,900	3,352
Polyether	Salinomycin sodium	—	—	—	79	454,195	49,017
	Semduramicin sodium	—	—	—	/	/	/
	Narasin	/	/	/	29	266,050	26,605
	Monensin sodium	2	18,000	3,600	/	/	/
	Lasalocid sodium	—	—	—	/	/	/
Orthosomycin	Avilamycin	/	/	/	16	59,425	11,885
Others	Bicozamycin	—	—	—	/	/	/
Total		2	18,000	3,600	131	824,350	91,081
Proportion (%)		1.5	2.1	3.8	98.5	97.9	96.2

— : No application

/ : No standard

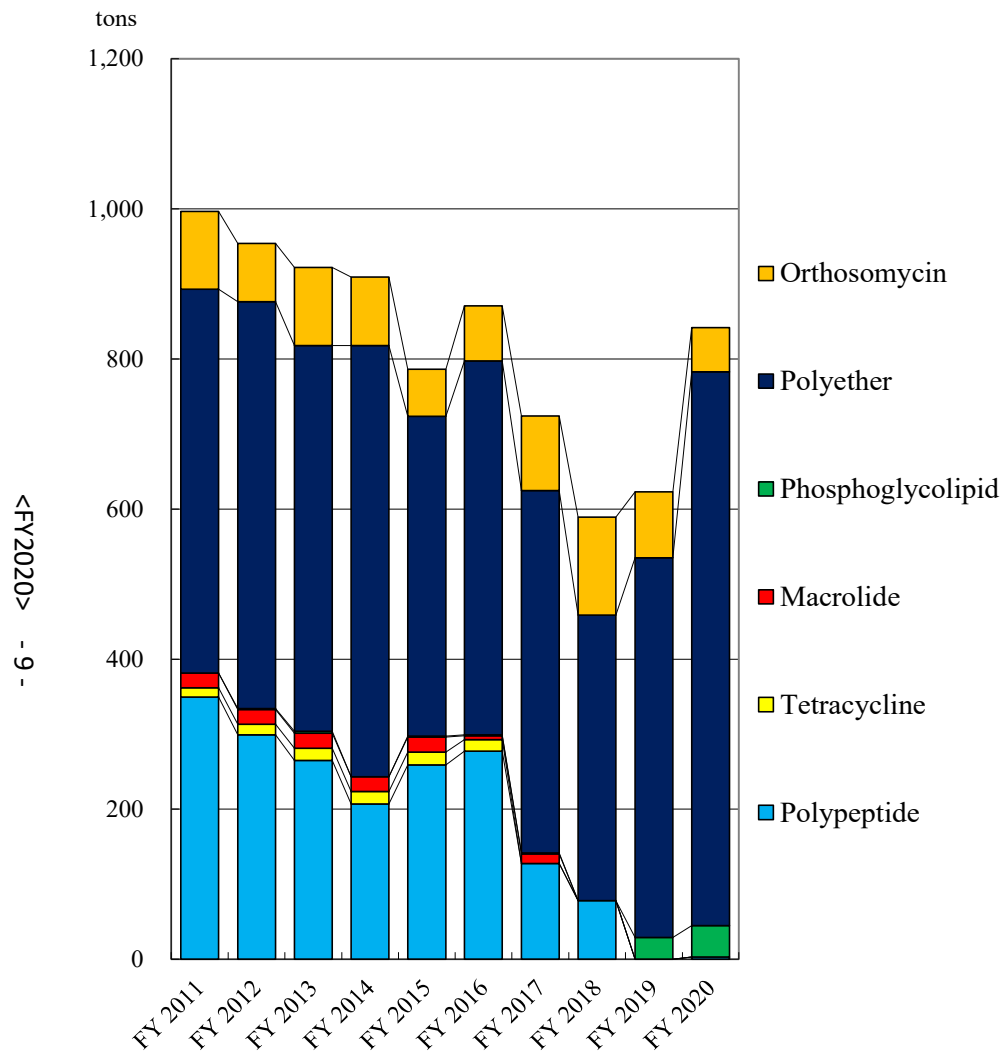


Figure 1: Changes in OTPQ of the specified feed additives (Sorted by category of antibiotics)

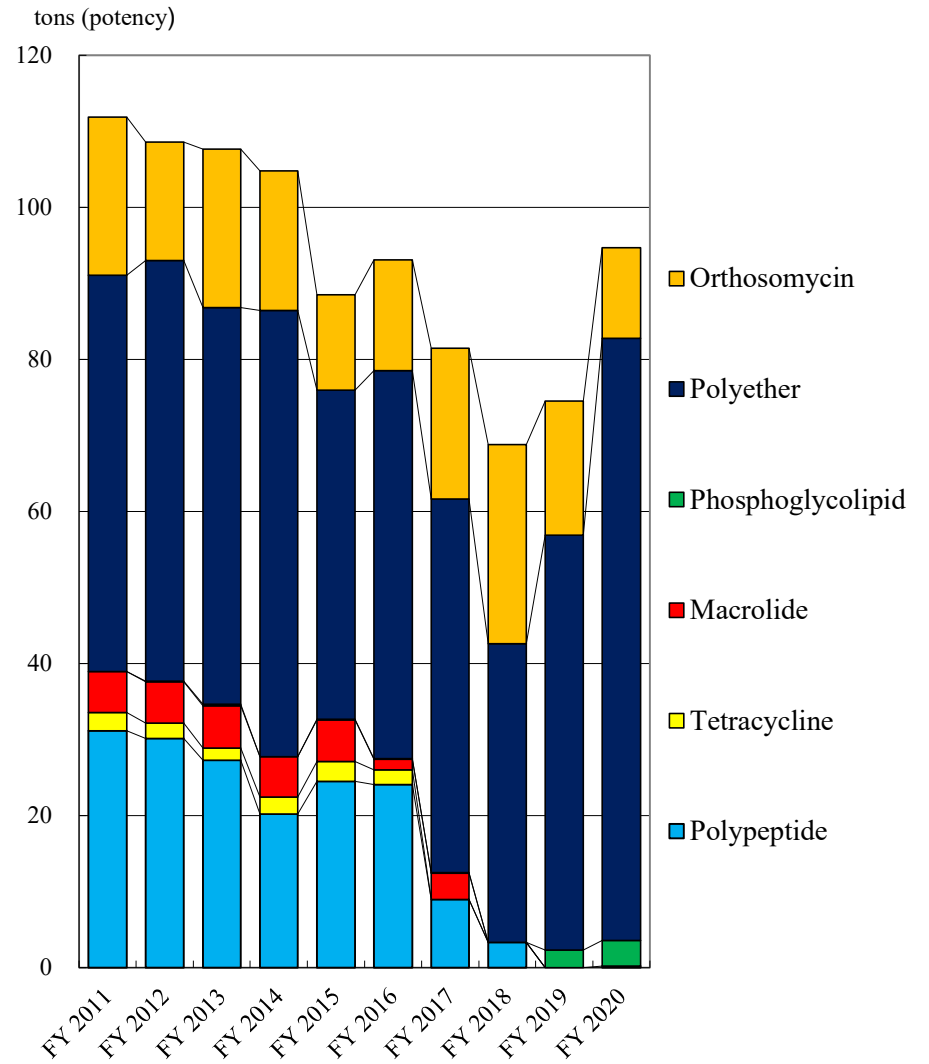


Figure 2: Changes in the official testing-passed QACQP (Sorted by category of antibiotics)

Table 4: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2019 and 2020)

Category	Type of the specified feed additives	FY 2019		FY 2020	
		Manufactured quantity* (kg)	Quantity converted into potency (kg(potency))	Manufactured quantity* (kg)	Quantity converted into potency (kg(potency))
Polypeptide	Enramycin	50,400	4,032	44,920	3,594
	Nosiheptide	59,540	2,382	80,940	3,238
	Subtotal	109,940	6,414	125,860	6,831
Polyether	Salinomycin sodium	320,600	32,060	146,380	14,638
	Monensin sodium	315,980	63,196	351,520	70,304
	Lasalocid sodium	161,720	24,258	188,840	28,326
	Subtotal	798,300	119,514	686,740	113,268
Total		908,240	125,928	812,600	120,099
Ratio to the previous fiscal year (%)		100.2	98.6	89.5	95.4

* Heard from each registered manufacturer of specified feed additives

Table 5: Total manufactured quantity of the specified feed additives (FY 2020)

Category	Type of specified feed additives	Total quantity *1	Composition ratio	Total quantity converted into potency *2	Composition ratio
		(kg)	(%)	(kg(potency))	(%)
Polypeptide	Zinc bacitracin	—	—	—	—
	Enramycin	47,700	2.9	3,816	1.8
	Nosiheptide	80,940	4.9	3,238	1.5
	Subtotal	128,640	7.8	7,054	3.3
Phosphoglycolipid	Flavophospholipol	41,900	2.5	3,352	1.6
	Subtotal	41,900	2.5	3,352	1.6
Polyether	Salinomycin sodium	600,575	36.3	63,655	29.6
	Semduramycin sodium	—	—	—	—
	Narasin	266,050	16.1	26,605	12.4
	Monensin sodium	369,520	22.3	73,904	34.4
	Lasalocid sodium	188,840	11.4	28,326	13.2
	Subtotal	1,424,985	86.1	192,490	89.6
Orthosomycin	Avilamycin	59,425	3.6	11,885	5.5
	Subtotal	59,425	3.6	11,885	5.5
Others	Bicozamycin	—	—	—	—
	Subtotal	0	0.0	0	0.0
Total		1,654,950	100.0	214,781	100.0

— : No application

*1 The total quantity of the specified feed additives of OTPQ and QMRM

*2 The total quantity converted into potency of OTPQ and QMRM

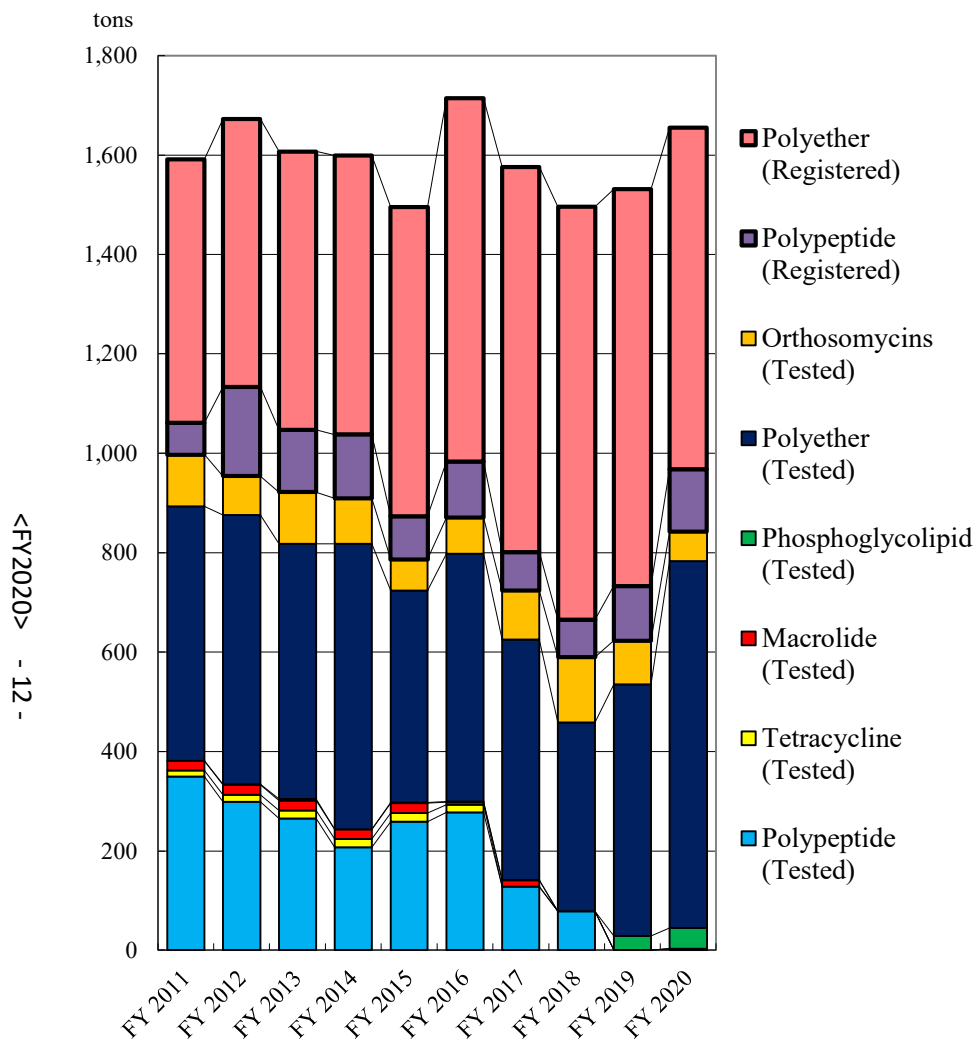


Figure 3: Changes in OTPQ and the QMRM of the specified feed additives (Sorted by category of antibiotics)

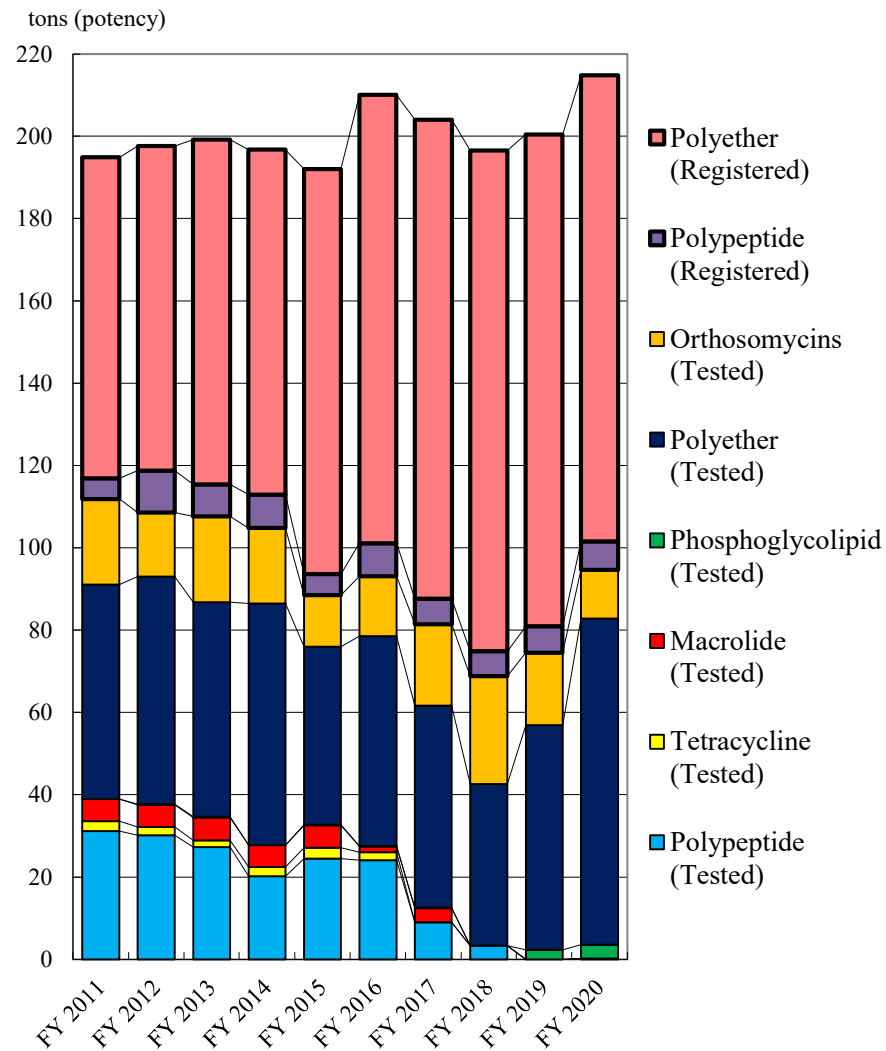


Figure 4: Changes in OTPQ and the QMRM of the specified feed additives converted into potency (Sorted by category of antibiotics)