

Results of Official Testing of Specified Feed Additives in Japan (fiscal year 2022)

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](#) in Japan (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 [Order for Enforcement 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 Japanese fiscal year (FY) 2022. The quantity and others of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2022 are also reported. As of the end of March in 2023, 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 2022.

There were 4 applicants (3 in the previous FY) applied the official testing of the specified feed additives. The number of applicants increased by one because 1 applicant that did not apply in FY 2021 resumed production. The manufacturing forms and others of these applicants were as follows: one of them manufactured preparations, and the others imported preparations. All of the raw materials for manufacturing domestically were manufactured in foreign countries.

There were 6 types of specified feed additives corresponding to 9 brands which passed the official testing in FY 2022 (5 types and 7 brands in the previous FY).

Preparations were imported from: the UK for avilamycin, the USA for narasin , Bulgaria for flavophospholipol, salinomycin sodium and monensin sodium. Raw materials for manufacturing were imported from: China for salinomycin sodium and enramycin. 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 (hereinafter referred to as “OTPC”) , the official testing-passed quantity (hereinafter referred to as “OTPQ”) , and the quantity converted from the actual quantity into potency (hereinafter referred to as “QCAQP”) of the specified feed additives by type in FYs 2020, 2021, and 2022.

97 cases were passed the official testing. OTPQ and QCAQP were 631 tons and 83 tons (potency) in FY 2022, respectively. Compared with the previous FY, OTPC and OTPQ and QCAQP decreased, and the ratio to the previous FY were 142.6 %, 116.5 %, and 117.7 %, respectively. This may be due to the increase in the number of applicants that did not manufacture in FYs 2021 have resumed manufacture.

The percentage of the specified feed additives in the total OTPQ by type in FY 2022 was 48.3 %, which was the highest one, for salinomycin sodium (58.2 % in the previous FY), followed in descending order by 33.0 % for narasin (26.3 % in the previous FY), 9.5 % for avilamycin (11.5 % in the previous FY), 7.3 % for flavophospholipol (3.3 % in the previous FY), 1.3 % for monensin sodium (0 % in the previous FY), and 0.7 % for enramycin (0.7 % in the previous FY).

The percentage of them in the total of QCAQP in FY 2022 was 53.8 % for salinomycin sodium (59.8 % in the previous FY), followed in descending order by 25.0 % for narasin (20.1 % in the previous FY), 14.4 % for avilamycin (17.7 % in the previous FY), 4.4 % for flavophospholipol (2.0 % in the previous FY), 1.9 % for monensin sodium (0 % in the previous FY), and 0.4 % for enramycin (0.4 % in the previous FY).

As for OTPQ of the specified feed additives by category, for 82.6 % the polyether antibiotics accounted (84.4 % in the previous FY), 9.5 % for orthosomycin antibiotics (11.5 % in the previous FY), 7.3 % for phosphoglycolipid antibiotics (3.3 % in the previous FY), and 0.7 % for polypeptide antibiotics (0.7 % in the previous FY) in FY 2021.

Compared with the previous FY, OTPQ and QCAQP of avilamycin decreased, while those of enramycin, flavophospholipol, narasin, and monensin sodium increased. In addition, in salinomycin sodium, OTPQ decreased and QCAQP increased, because the proportion of preparations containing 200 mg(potency)/g increasds.

Similarly, the comparison with the specified feed additives by category in the previous FY shows that, OTPQ and QCAQP of orthosomycin antibiotics decreased, while those of polypeptide antibiotics, phosphoglycolipid antibiotics and polyether antibiotics increased.

Nosiheptide since FY 2019, 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 2022 either.

In addition, lasalocid sodium, and nosiheptide were manufactured by the registered manufacturers of specified feed additives as shown in Table 4 below.

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 2022.

The feed grade of the specified feed additives accounted for; 97.9 % of the total official testing-passed cases (100% in the previous FY), 98.7 % of the total official testing-passed quantity (100% in the previous FY), and 98.1 % of the total quantity converted from the actual quantity into potency (100 % 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 2022. Only the feed grade of salinomycin sodium was subjected to the official testing in FY 2022.

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

As of the beginning of April in 2022, 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, is registered as a place of business as a manufacturer of specified feed additives concerning nosiheptide.

Table 4 shows the manufactured quantity and QCAQP of the specified feed additives by the registered manufacturers of specified feed additives in FY 2022. Moreover, lasalocid sodium, monensin 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 2022 was 793 tons (93.6 % over the previous FY) and QCAQP was 119 tons (potency) (96.3 % over the previous FY) shown in Table 4.

The descending order of the manufactured quantity in FY 2022 was monensin sodium, salinomycin sodium, lasalocid sodium, nosiheptide, and enramycin.

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

5. Total manufactured quantity of the specified feed additives

Table 5 shows the total manufactured quantity and the total QCAQP in FY 2022, 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 2022 was the highest for the polyether antibiotics, 1,179 tons (official testing: 521 tons; registration: 658 tons), which accounted for 82.8 % of the total. The descending order by type was salinomycin sodium (31.3 %), monensin sodium (27.3 %), and narasin (14.6 %). The total QCAQP by category was also highest for the polyether antibiotics, 178 tons (potency) (official testing: 67 tons (potency); registration: 111 tons (potency)), which accounted for 88.1 % of the total. The descending order by type was monensin sodium (38.5 %), salinomycin sodium (29.2 %), and narasin (10.3 %).

Figures 1 and 2 show the changes in the total manufactured quantity and the total QCAQP of the specified feed additives by category over the last decade, from FY 2013 to FY 2022, respectively. The total of manufactured quantity showed a tendency to decrease while increasing or decreasing. Total QCAQP (Fig.2) showed unchanged approximately.

OTPC had been showing a tendency to decrease while increasing or decreasing. QCAQP of the specified feed additives passed the official testing also showed the same tendency.

The registered manufacturers have manufactured specified feed additives since FY 2007. Since then, it has been increasing year by year. QMRM has exceeded OTPQ since FY 2017 until FY 2019 and since FY 2021. The percentage of production by registered manufacturers accounted for; 55.7 % of the total manufactured quantity (61.0 % in the previous FY) and 58.8 % of the total QCAQP of the specified feed additives (63.5 % in the previous FY) in FY 2022, respectively.

7. Summary

A. The results of the official testing of the specified feed additives in FY 2022 were as follows.

- (a) There were 6 types of specified feed additives, corresponding to 9 brands, that were applied by 4 business entities and passed the official testing.
- (b) The number of OTPC, OTPQ, and QCAQP were 97 cases, 631 tons, and 83 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 98.7%. QCAQP of the feed grade accounted for 98.1 %.
- (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, orthosomycin antibiotics decreased, while polypeptide antibiotics, phosphoglycolipid antibiotics and polyether antibiotics increased in FY 2022 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 2022 were as follows.

- (a) There were 1 factories of 1 business entities that have registered manufacturers of specified feed additives. That entity manufactured 5 types of the specified feed additives, and the manufactured quantity and the QCAQP of the specified feed additives were 793 tons, and 119

tons (potency), respectively. The type and the quantity of manufactured by registered manufacturers and QCAQP (of the specified feed additives) decreased in FY 2022 compared with previous FY.

(b) The quantity of the specified feed additives manufactured by type was the highest for monensin sodium, followed by salinomycin sodium and lasalocid sodium in descending order. The QCAQP of the specified feed additives manufactured by the registered manufacturers was highest for monensin sodium, followed by lasalocid sodium and salinomycin sodium in descending order.

C. The results of the total quantity and others of the specified feed additives in FY 2022 were as follows.

The total manufactured quantity 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 narasin in descending order.

Table 1: Names of applicants and others for the official testing of the specified feed additives (FY 2022)

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	—	Avilamycin	✓	200
			Narasin	✓	100
	Japan Nutrition Co., Ltd.	Ibaraki	Salinomycin sodium	✓	100
	Rokku Chemical Products Co., Ltd.	Shizuoka	Enramycin	✓	80
			Salinomycin sodium	✓	100
Kobe	Huvepharma Japan Co., Ltd. *2	—	Salinomycin sodium	✓	100
			Salinomycin sodium	✓	200
			Monensin sodium		200
			Flavophospholipol	✓	80
Total	4 business entities	2 place	6 types (9 brands)		

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

*2 Importer

Table 2: Number of OTPC, OTPQ, and QCAQP of specified feed additives (Sorted by the type of the antibiotics, FYs 2020 to 2022)

Category	Type of the specified feed additives	FY 2020					FY 2021					FY 2022				
		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	2,780	0.3	222	0.2	3	3,720	0.7	298	0.4	2	4,120	0.7	330	0.4
	Nosiheptide	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	2	2,780	0.3	222	0.2	3	3,720	0.7	298	0.4	2	4,120	0.7	330	0.4
Phosphoglycolipid	Flavophospholipol	5	41,900	5.0	3,352	3.5	2	18,000	3.3	1,440	2.0	8	46,000	7.3	3,680	4.4
Polyether	Salinomycin sodium	79	454,195	53.9	49,017	51.8	33	315,220	58.2	42,322	59.8	48	304,685	48.3	44,841	53.8
	Semduramicin sodium	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Narasin	29	266,050	31.6	26,605	28.1	13	142,300	26.3	14,230	20.1	20	208,625	33.0	20,863	25.0
	Moneansin sodium	2	18,000	2.1	3,600	3.8	—	—	—	—	—	2	8,000	1.3	1,600	1.9
	Lasalocid sodium	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Subtotal	110	738,245	87.6	79,222	83.7	46	457,520	84.4	56,552	79.9	70	521,310	82.6	67,304	80.8	
Orthosomycin	Avilamycin	16	59,425	7.1	11,885	12.6	17	62,550	11.5	12,510	17.7	17	59,950	9.5	11,990	14.4
Others	Bic oxamycin	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Total		133	842,350	100.0	94,681	100.0	68	541,790	100.0	70,800	100.0	97	631,380	100.0	83,303	100.0
Ratio to the previous fiscal year (%)		109.0	135.2	—	127.0	—	51.1	64.3	—	74.8	—	142.6	116.5	—	117.7	—

— : No application

Table 3: Number of OTPC, OTPQ, and QCAQP (Sorted by the grade of the preparation, FY2022)

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	4,120	330
	Nosiheptide	—	—	—	—	—	—
Phosphoglycolipid	Flavophospholipol	/	/	/	8	46,000	3,680
Polyether	Salinomycin sodium	—	—	—	48	304,685	44,841
	Semduramicin sodium	—	—	—	/	/	/
	Narasin	/	/	/	20	208,625	20,863
	Monensin sodium	2	8,000	1,600	/	/	/
	Lasalocid sodium	—	—	—	/	/	/
Orthosomycin	Avilamycin	/	/	/	17	59,950	11,990
Others	Bicozamycin	—	—	—	/	/	/
Total		2	8,000	1,600	95	623,380	81,703
Proportion (%)		2.1	1.3	1.9	97.9	98.7	98.1

— : No application

/ : No standard

Table 4: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2021 and 2022)

Category	Type of the specified feed additives	FY 2021		FY 2022	
		Manufactured quantity* (kg)	Quantity converted into potency (kg(potency))	Manufactured quantity* (kg)	Quantity converted into potency (kg(potency))
Polypeptide	Enramycin	83,560	6,685	64,340	5,147
	Nosiheptide	84,720	3,389	70,800	2,832
	Subtotal	168,280	10,074	135,140	7,979
Polyether	Salinomycin sodium	153,580	15,358	140,840	14,084
	Monensin sodium	379,760	75,952	380,560	76,112
	Lasalocid sodium	145,860	21,879	136,780	20,517
	Subtotal	679,200	113,189	658,180	110,713
Total		847,480	123,263	793,320	118,692
Ratio to the previous fiscal year (%)		104.3	102.6	93.6	96.3

* Heard from registered manufacturer of specified feed

Table 5: Total manufactured quantity of the specified feed additives (FY 2022)

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	68,460	4.8	5,477	2.7
	Nosiheptide	70,800	5.0	2,832	1.4
	Subtotal	139,260	9.8	8,309	4.1
Phosphoglycolipid	Flavophospholipol	46,000	3.2	3,680	1.8
Polyether	Salinomycin sodium	445,525	31.3	58,925	29.2
	Semduramycin sodium	—	—	—	—
	Narasin	208,625	14.6	20,863	10.3
	Monensin sodium	388,560	27.3	77,712	38.5
	Lasalocid sodium	136,780	9.6	20,517	10.2
	Subtotal	1,179,490	82.8	178,017	88.1
Orthosomycin	Avilamycin	59,950	4.2	11,990	5.9
Others	Bicozamycin	—	—	—	—
	Total	1,424,700	100.0	201,995	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

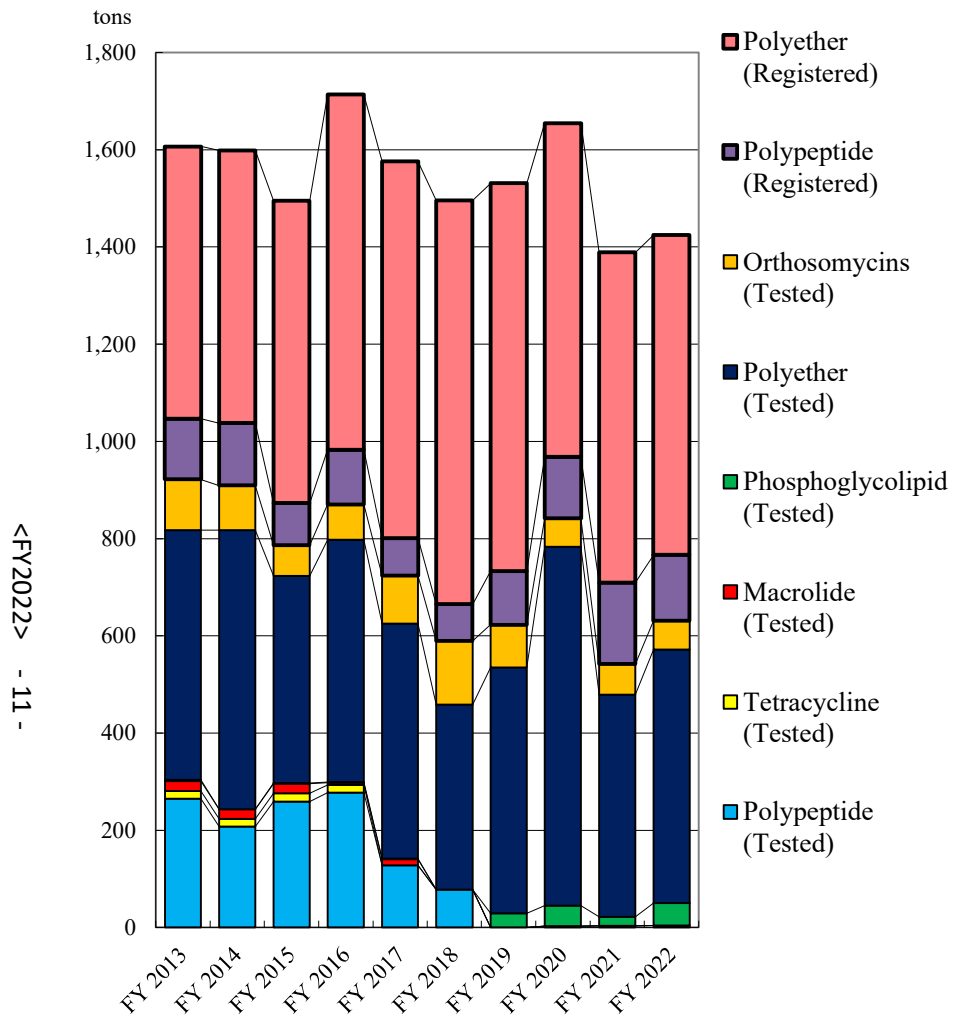


Figure 1: Changes in OTPQ and the QMRM of the specified feed additives (Sorted by category of antibiotics)

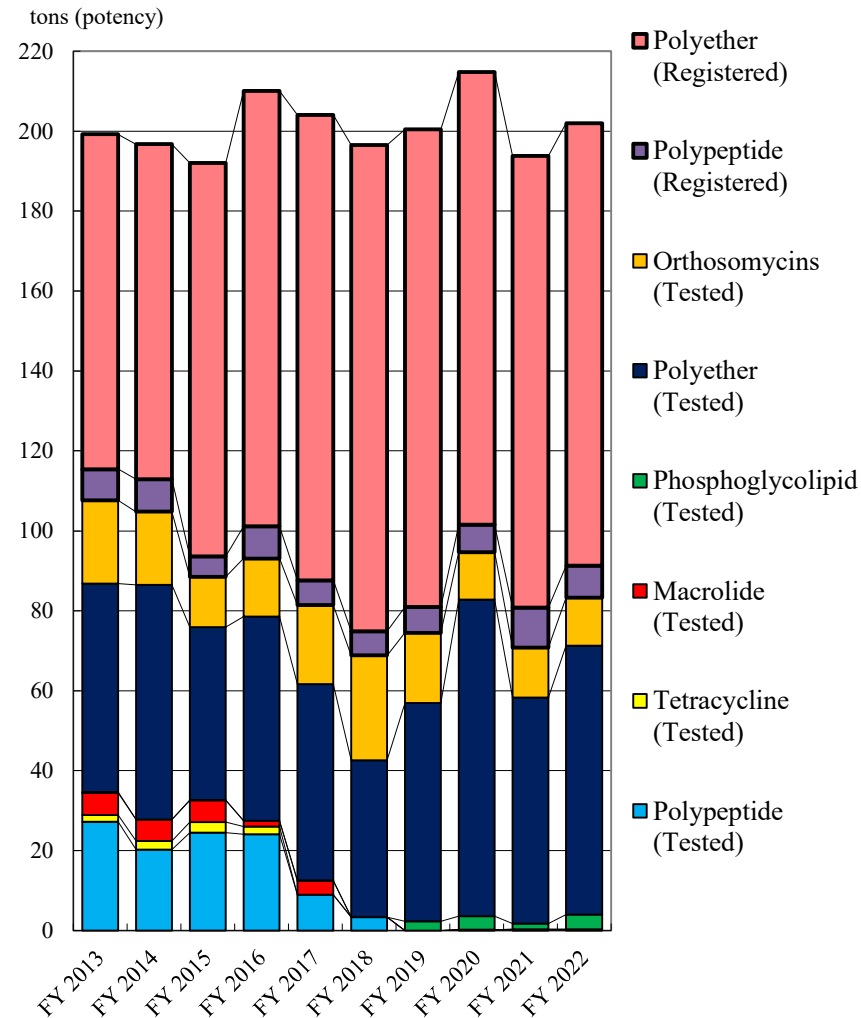


Figure 2: Changes in OTPQ and the QMRM of the specified feed additives converted into potency (Sorted by category of antibiotics)