

Results of Official Testing of Specified Feed Additives in Japan (FY 2021)

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) 2021. The quantity and others of the specified feed additives manufactured by the registered manufacturers of specified feed additives in FY 2021 are also reported. As of the end of March in 2022, 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 2021.

There were 3 applicants (4 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, and the others imported preparations. All of the raw materials for manufacturing domestically were manufactured in foreign countries.

There were 5 types of specified feed additives corresponding to 7 brands which passed the official testing in FY 2021 (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 flavophospholipol (preparation), 4) China for salinomycin sodium (raw material for manufacturing), 5) Bulgaria for salinomycin sodium (preparation), and 6) 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 2019, 2020, and 2021.

68 cases were passed the official testing. OTPQ and QCAQP were 542 tons and 71 tons (potency) in FY 2021, respectively. Compared with the previous FY, OTPC and OTPQ and QCAQP decreased, and the ratio to the previous FY were 51.1 %, 64.3 %, and 74.8 %, respectively. This may be due to the decrease in the number of applicants mentioned earlier.

The percentage of the specified feed additives in the total OTPQ by type in FY 2021 was 58.2 %, which was the highest one, for salinomycin sodium (53.9 % in the previous FY), followed in descending order by 26.3 % for narasin (31.6 % in the previous FY), 11.5 % for avilamycin (7.1 % in the previous FY), 3.3 % for flavophospholipol (5.0 % in the previous FY), and 0.7 % for enramycin (0.3 % in the previous FY).

The percentage of them in the total of QCAQP in FY 2021 was 59.8 % for salinomycin sodium (51.8 % in the previous FY), followed in descending order by 20.1 % for narasin (28.1 % in the previous FY), 17.7 % for avilamycin (12.6 % in the previous FY), 2.0 % for flavophospholipol (3.5 % in the previous FY), and 0.4 % for enramycin (0.2 % in the previous FY).

As for OTPQ of the specified feed additives by category, for 84.4 % the polyether antibiotics accounted (87.6 % in the previous FY), 11.5 % for orthosomycin antibiotics (7.1 % in the previous FY), 3.3 % for phosphoglycolipid antibiotics (5.0 % in the previous FY), and 0.7 % for polypeptide antibiotics (0.3 % in the previous FY) in FY 2021.

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

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

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 2021 either.

In addition, lasalocid sodium, monensin 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 2021.

There were not applications for refining grade. Therefore, only the feed grade was subjected to the official testing in FY 2021.

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 2021. Only the feed grade of salinomycin sodium was subjected to the official testing in FY 2021.

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

As of the beginning of April 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 2021, 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 2021. 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 2021 was 847 tons (104.3 % over the previous FY) and QCAQP was 123 tons (potency) (102.6 % over the previous FY) shown in Table 4.

The descending order of the manufactured quantity in FY 2021 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 2021, 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 2021 was the highest for the polyether antibiotics, 1,137 tons (official testing: 458 tons; registration: 679 tons), which accounted for 81.8 % of the total. The descending order by type was salinomycin sodium (33.7 %), monensin sodium (27.3 %), and lasalocid sodium (10.5 %). The total QCAQP by category was also highest

for the polyether antibiotics, 170 tons (potency) (official testing: 57 tons (potency); registration: 113 tons (potency)), which accounted for 87.5 % of the total. The descending order by type was monensin sodium (39.1 %), salinomycin sodium (29.7 %), and lasalocid sodium (11.3 %).

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 2012 to FY 2021, 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 OTPC since FY 2017 until FY 2019 and FY 2021. The percentage of production by registered manufacturers accounted for; 61.0 % of the total manufactured quantity (49.1 % in the previous FY) and 63.5 % of the total QCAQP of the specified feed additives (55.9 % in the previous FY) in FY 2021, respectively.

7. Summary

A. The results of the official testing of the specified feed additives in FY 2021 were as follows.

- (a) There were 5 types of specified feed additives, corresponding to 7 brands, that were applied by 3 business entities and passed the official testing.
- (b) The number of OTPC, OTPQ, and QCAQP were 68 cases, 542 tons, and 71 tons (potency), respectively. Compared to the previous FY, OTPC and OTPQ and QCAQP decreased.
- (c) There were not applications for refining grade, only the feed grade was subjected to the official testing.
- (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 and polypeptide antibiotics increased, while phosphoglycolipid antibiotics and polyether antibiotics decreased in FY 2021 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 2021 were as follows.

- (a) There were 2 factories of 2 business entities that have registered manufacturers of specified feed additives. The one factory of one business entity was revoked in the middle of the fiscal year.
- (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 847 tons, and 123 tons (potency), respectively. The type and the quantity of manufactured by registered manufacturers and QCAQP (of the specified feed additives) increased in FY 2021 compared with previous FY.

(c) 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 2021 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 lasalocid sodium 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 2021)

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
	Rokku Chemical Products Co., Ltd.	Shizuoka	Enramycin	✓	80
			Salinomycin sodium	✓	100
Kobe	Huvepharma Japan Co., Ltd. *2	—	Salinomycin sodium	✓	100
			Salinomycin sodium	✓	200
			Flavophospholipol	✓	80
Total	3 business entities	1 place	5 types (7 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 2019 to 2021)

Category	Type of the specified feed additives	FY 2019					FY 2020					FY 2021				
		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
	Nosiheptide	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	0	0	0.0	0	0.0	2	2,780	0.3	222	0.2	3	3,720	0.7	298	0.4
Phosphoglycolipid	Flavophospholipol	8	29,250	4.7	2,340	3.1	5	41,900	5.0	3,352	3.5	2	18,000	3.3	1,440	2.0
Polyether	Salinomycin sodium	64	274,626	44.1	27,463	36.8	79	454,195	53.9	49,017	51.8	33	315,220	58.2	42,322	59.8
	Semduramicin sodium	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Narasin	21	191,000	30.7	19,100	25.6	29	266,050	31.6	26,605	28.1	13	142,300	26.3	14,230	20.1
	Monensin sodium	5	39,960	6.4	7,992	10.7	2	18,000	2.1	3,600	3.8	—	—	—	—	—
	Lasalocid sodium	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	90	505,586	81.2	54,555	73.2	110	738,245	87.6	79,222	83.7	46	457,520	84.4	56,552	79.9
Orthosomycin	Avilamycin	24	88,175	14.2	17,635	23.7	16	59,425	7.1	11,885	12.6	17	62,550	11.5	12,510	17.7
Others	Bicozamycin	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Total		122	623,011	100.0	74,530	100.0	133	842,350	100.0	94,681	100.0	68	541,790	100.0	70,800	100.0
Ratio to the previous fiscal year (%)		96.8	105.7	/	108.3	/	109.0	135.2	/	127.0	/	51.1	64.3	/	74.8	/

— : No application

Table 3: Number of OTPC, OTPQ, and QCAQP (Sorted by the grade of the preparation, FY2021)

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	/	/	/	3	3,720	298
	Nosiheptide	—	—	—	—	—	—
Phosphoglycolipid	Flavophospholipol	/	/	/	2	18,000	1,440
Polyether	Salinomycin sodium	—	—	—	33	315,220	42,322
	Semduramicin sodium	—	—	—	/	/	/
	Narasin	/	/	/	13	142,300	14,230
	Monensin sodium	—	—	—	/	/	/
	Lasalocid sodium	—	—	—	/	/	/
Orthosomycin	Avilamycin	/	/	/	17	62,550	12,510
Others	Bicozamycin	—	—	—	/	/	/
Total		0	0	0	68	541,790	70,800
Proportion (%)		0.0	0.0	0.0	100.0	100.0	100.0

— : No application

/ : No standard

Table 4: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2020 and 2021)

Category	Type of the specified feed additives	FY 2020		FY 2021	
		Manufactured quantity* (kg)	Quantity converted into potency (kg(potency))	Manufactured quantity* (kg)	Quantity converted into potency (kg(potency))
Polypeptide	Enramycin	44,920	3,594	83,560	6,685
	Nosiheptide	80,940	3,238	84,720	3,389
	Subtotal	125,860	6,831	168,280	10,074
Polyether	Salinomycin sodium	146,380	14,638	153,580	15,358
	Monensin sodium	351,520	70,304	379,760	75,952
	Lasalocid sodium	188,840	28,326	145,860	21,879
	Subtotal	686,740	113,268	679,200	113,189
Total		812,600	120,099	847,480	123,263
Ratio to the previous fiscal year (%)		89.5	95.4	104.3	102.6

* Heard from registered manufacturer of specified feed

Table 5: Total manufactured quantity of the specified feed additives (FY 2021)

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	87,280	6.3	6,982	3.6
	Nosiheptide	84,720	6.1	3,389	1.7
	Subtotal	172,000	12.4	10,371	5.3
Phosphoglycolipid	Flavophospholipol	18,000	1.3	1,440	0.7
Polyether	Salinomycin sodium	468,800	33.7	57,680	29.7
	Semduramycin sodium	—	—	—	—
	Narasin	142,300	10.2	14,230	7.3
	Monensin sodium	379,760	27.3	75,952	39.1
	Lasalocid sodium	145,860	10.5	21,879	11.3
	Subtotal	1,136,720	81.8	169,741	87.5
Orthosomycin	Avilamycin	62,550	4.5	12,510	6.4
Others	Bicozamycin	—	—	—	—
Total		1,389,270	100.0	194,062	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

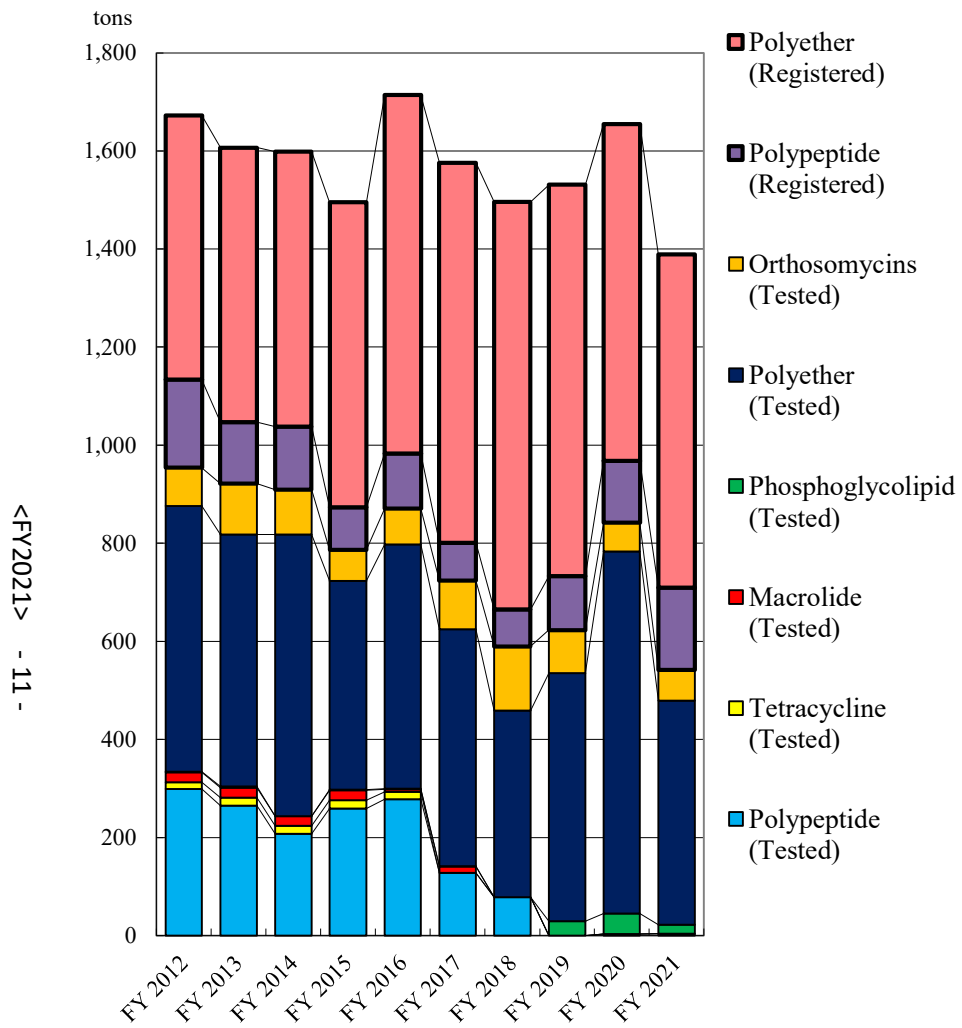


Figure 1: Changes in OTPQ and the QMRM of the specified feed additives (Sorted by category of antibiotics)

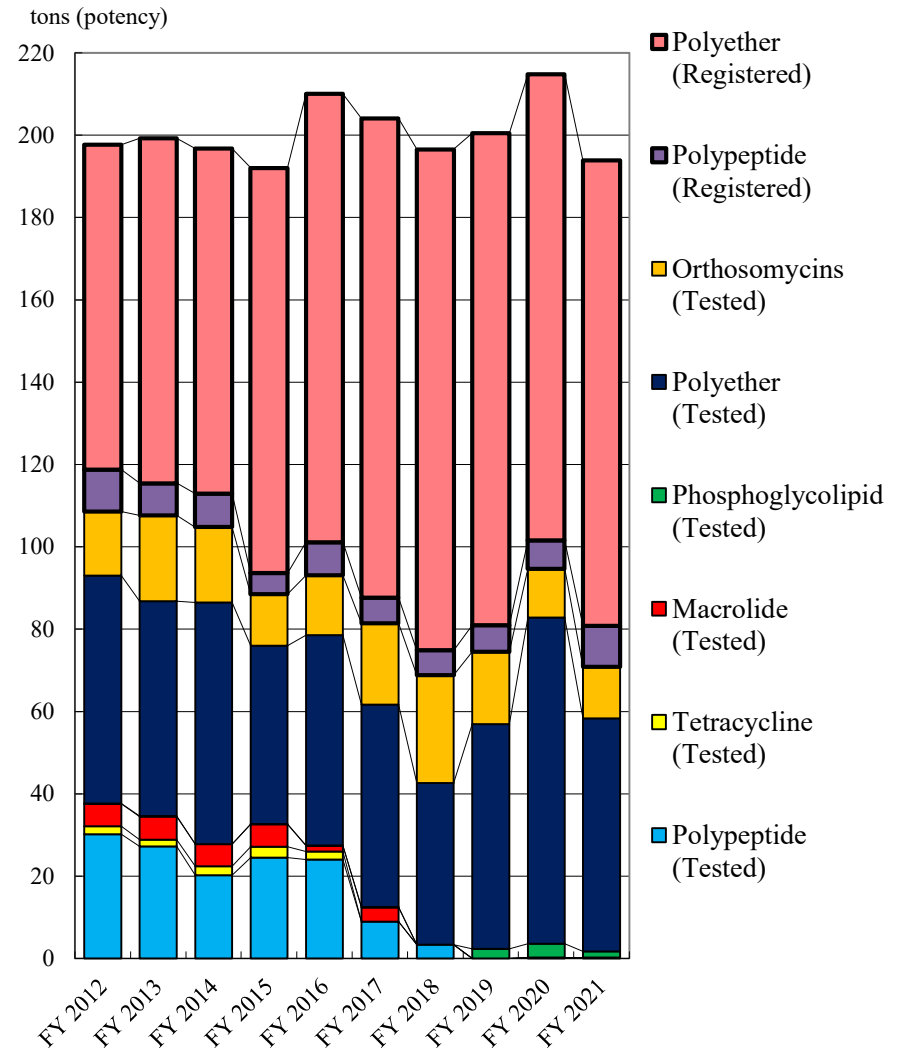


Figure 2: Changes in OTPQ and the QMRM of the specified feed additives converted into potency (Sorted by category of antibiotics)