Results of Official Testing of Specified Feed Additives in Japan (fiscal year 2023)

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 antimicrobial agents 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, for which the official testing are conducted by the Food and Agricultural Materials Inspection Center (hereinafter referred to as "FAMIC") and the labels, which certify that they have passed the official testing are attached in accordance with the provisions of Article 5, paragraph (1) of the Feed Safety Act, may be sold. However, that shall not apply to 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"), and the labels referred to in Article 16, paragraph (1) of the same Act are affixed to and those manufactured by the foreign manufacturers of specified feed additives registered under Article 21, paragraph (1), and the labels referred to the paragraph (2) of the same Article are affixed to.

The following report is the summary of the results of the specified feed additives which have been applied to FAMIC and passed the official testing in Japanese fiscal year (FY) 2023. The quantity and others of the specified feed additives, manufactured by the registered manufacturers of specified feed additives in FY 2023 are also included in the report. As of the end of March 2024, there has been no foreign registered manufacturer of the specified feed additives.

1. Applicants and others for the official testing of the specified feed additives

Table 1 shows the applicants, the types of the products and others, concerning the specified feed additives which passed the official testing in FY 2023.

There were 4 applicants for the official testing of the specified feed additives, the same number as the previous year. The business categories of these applicants were as follows: two of them were manufacturing preparation, and the other two applicants were importing preparations. The raw materials, domestically used for manufacturing antimicrobial agents were imported materials.

5 types, 8 brands of specified feed additives passed the official testing in FY 2023 (6 types and 9 brands in the previous FY).

The imported antimicrobial agents were from: the UK for avilamycin, Bulgaria for flavophospholipol and salinomycin sodium and the USA for narasin. The raw materials used for manufacturing the antimicrobial agents were imported from: China for enramycin and salinomycin sodium. The total number of the import source countries was 4 (4 in the previous FY).

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

Table 2 shows 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 2021, 2022 and 2023.

In FY 2023, the number of OTPC, OTPQ and QCAQP were 101 cases, 634 tons and 82 tons (potency), respectively. Compared with the previous FY, the number of OTPC, OTPQ and QCAQP showing no significant changes, and the ratios to the previous FY were 104.1 %, 100.5 %, and 98.3 %, respectively.

Analyzing the percentage of OTPQ of the specified feed additives by type in FY 2023, the highest type was salinomycin sodium, which was 40.8 % (48.3 % in the previous FY), followed by narasin: 39.5 % (33.0 % in the previous FY), avilamycin: 13.4 % (9.5 % in the previous FY), flavophospholipol: 5.7 % (7.3 % in the previous FY) and enramycin: 0.6 % (0.7 % in the previous FY).

In terms of the percentage of QCAQP of the specified feed additives by type in FY 2023, the highest type was salinomycin, which was 44.8 % (53.8% in the previous FY), followed by narasin: 30.6 % (25.0 % in the previous FY), avilamycin: 20.7 % (14.4 % in the previous FY), flavophospholipol: 3.5 % (4.4 % in the previous FY) and enramycin: 0.4 % (0.4 % in the previous FY).

As for OTPQ of the specified feed additives by category, in FY 2023, the highest category was polyether antibiotics, accounted for 80.3 % (82.6 % in the previous FY), followed by orthosomycin antibiotics: 13.4 % (9.5 % in the previous FY), phosphoglycolipid antibiotics: 5.7 % (7.3 % in the previous FY), and polypeptide antibiotics: 0.6 % (0.7 % in the previous FY).

Compared with the previous FY, OTPQ and QCAQP of narasin and avilamycin in FY 2023 increased, while those of enramycin, flavophospholipol, monensin and salinomycin sodium decreased. There were no applications for the official testing of monensin sodium in FY 2023, for which there had been some applications in the previous FY.

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

There have been no applications for the official testing of zinc bacitracin since FY 2016, nosiheptide since FY 2019, lasalocid sodium since FY 2010, semduramicin sodium since FY 2007, and bicozamycin since FY 1999, and there were no application FY 2023 either. On the other hand, lasalocid sodium, monensin sodium and nosiheptide have been manufactured by the registered manufacturers of specified feed additives as shown in Table 4 below.

3. The number of OTPC and others of the specified feed additives by grade (refining grade / 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 only the 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 constituent of antibiotics, medium components and fungus compound used for manufacturing is dried.

Table 3 shows the number of OTPC, OTPQ, and QCAQP of the specified feed additives by grade (refining grade / feed grade) in FY 2023.

There were no applications of the official testing for the specified feed additives of the refining grade and only those of the feed grade were applied and passed the official testing in FY 2023.

Although both the feed grade and the refining grade standards have been established for nosiheptide and salinomycin sodium, there were no applications for the official testing of both grades of nosiheptide in FY 2023. Only the feed grade of salinomycin sodium was applied and passed the official testing in FY 2023.

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

As of the beginning of April in 2023, Tatsuno Factory, Scientific Feed Laboratory Co., Ltd., has been registered as a place of business of a registered manufacturer of specified feed additives concerning enramycin, lasalocid sodium, monensin sodium, nosiheptide and salinomycin sodium.

Table 4 shows the manufactured quantity and QCAQP of the specified feed additives by the registered manufacturers of specified feed additives in FY 2023. Moreover, lasalocid sodium and nosiheptide, which have not been applied for the official testing as the specified feed additives, as shown in Table 2, have been 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 2023 was 754 tons (95.1 % over the previous FY) and QCAQP was 114 tons (potency) (96.1 % over the previous FY), as shown in Table 4.

In the descending order of the manufactured quantity and QCAQP in FY 2023 were monensin sodium, lasalocid sodium, salinomycin sodium, enramycin and nosiheptide.

5. Total quantity of the specified feed additives

Table 5 shows the total quantity (OTPQ and the quantity manufactured by the registered manufacturers of specified feed additives (hereinafter referred to as QMRM)) and the total QCAQP (the total quantity of potency converted from OTPQ and QMRM) of the manufacturured or imported specified feed additives in FY 2023.

In FY 2023, there were 8 types of manufactured or imported specified feed additives, and looking at the quantities of each type, the highest type was monensin sodium (27.2 %), followed by salinomycin sodium (26.6 %) and narasin (18.0 %). As for the total quantity of the specified feed additives by category, the highest category was polyether antibiotics: 1,120 tons (OTPQ: 509 tons; QMRM: 611 tons), which accounted for 80.7 % of the total. In terms of the total QCAQP of the

specified feed additives by type, the highest type was monensin sodium (38.6 %), followed by salinomycin sodium (24.4 %), and narasin (12.8 %). When looking at the total QCAQP of the specified feed additives by category, the highest category was polyether antibiotics: 167 tons (potency) (OTPQ: 62 tons, QMRM: 105 tons), accounted for 85.1 % of the total.

Figure 1 and Figure 2 show the changes in the total quantity and the total QCAQP of the specified feed additives by category over the last decade, from FY 2014 to FY 2023, respectively.

Although the total quantity showed slight fluctuations, it followed a declining trend. Total QCAQP remained largely unchanged.

Although OTPQ showed slight fluctuations, it followed a declining trend. QCAQP of the specified feed additives that passed the official testing also showed the similar trend.

The manufacturing by registered maufacturer has been actually implemented since FY 2007, and QMRM exceeded OTPQ from FY 2017 to FY 2019, and from FY 2021 to FY 2023. In FY 2023, QMRM accounted for 54.3 % of the total quantity (55.7 % in the previous FY) and the quantity of potency converted from QMRM accounted for 58.2 % of the total QCAQP of the specified feed additives (58.8 % in the previous FY) in FY 2023.

6. Summary

A. The results of the official testing of the specified feed additives in FY 2023 were as follows.

(a) There were 5 types (8 brands) of the specified feed additives which passed the official testing, applied by 4 business entities.

(b) The number of OTPC, OTPQ, and QCAQP were 101 cases, 634 tons, and 82 tons (potency), respectively. Compared to the previous FY, the number of OTPC, OTPQ and QCAQP all increased.

(c) There were no applications for the specified feed additives of the refining grade and only those of the feed grade were applied and passed the official testing.

(d) Analyzing OTPQ of the specified feed additives by type, the highest type was salinomycin sodium, followed by narasin and avilamycin. The quantity of potency converted from OTPQ by type showed the same descending order.

(e) As for OTPQ of the specified feed additives by category, polyether antibiotics, polypeptide antibiotics, and phosphoglycolipid antibiotics decreased, while orthosomycin antibiotics increased in FY 2023 compared with the previous FY. QCAQP of the specified feed additives by category showed the similar trend.

B. The situations of the manufacturing of the specified feed additives by the registered manufacturers of specified feed additives in FY 2023 were as follows.

(a) There was 1 business entity (1 factory) that has been registered as the manufacturer of specified feed additives. That entity manufactured 5 types, 754 tons of the specified feed additives and QCAQP was 114 tons (potency). Compared with the previous FY, both the manufactured quantity and QCAQP of the specified feed additives by the registered manufacturers decreased in FY 2023.

(b) Looking at the manufactured quantity of the specified feed additives by type, the highest type

was monensin sodium, followed by lasalocid sodium and salinomycin sodium. QCAQP of the specified feed additives by type showed the same descending order.

C. The results of the total quantity and others of the specified feed additives in FY 2023 were as follows.

When looking at the total quantity (OTPQ and QMRM) of the specified feed additives by type, the highest type was monensin sodium, followed by salinomycin sodium and narasin. The total QCAQP showed the same descending order.

Table 1: Applicants and others for the official testing of the specified feed additives (FY 2023)

Contact office of FAMIC *1	Applicants	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
			Flavophospholipol	✓	80
Total	4 business entities	2 place	5 types (8 brands)		

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

*2 Importer

Table 2: The number of OTPC, OTPQ, and QCAQP of specified feed additives (Sorted by type, FYs 2021 to 2023)

Category	Type of the specified feed additives	FY 2021					FY 2022					FY 2023				
		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	3	3,720	0.7	298	0.4	2	4,120	0.7	330	0.4	3	3,960	0.6	317	0.4
	Nosiheptide	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	3	3,720	0.7	298	0.4	2	4,120	0.7	330	0.4	3	3,960	0.6	317	0.4
Phosphoglycolipid	Flavophospholipol	2	18,000	3.3	1,440	2.0	8	46,000	7.3	3,680	4.4	6	36,000	5.7	2,880	3.5
Polyether	Salinomycin sodium	33	315,220	58.2	42,322	59.8	48	304,685	48.3	44,841	53.8	45	259,020	40.8	36,702	44.8
	Semduramicin sodium	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Narasin	13	142,300	26.3	14,230	20.1	20	208,625	33.0	20,863	25.0	23	250,425	39.5	25,043	30.6
	Monensin sodium	—	—	—	—	—	2	8,000	1.3	1,600	1.9	—	—	—	—	—
	Lasalocid sodium	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Subtotal	46	457,520	84.4	56,552	79.9	70	521,310	82.6	67,304	80.8	68	509,445	80.3	61,745	75.4
Orthosomycin	Avilamycin	17	62,550	11.5	12,510	17.7	17	59,950	9.5	11,990	14.4	24	84,925	13.4	16,985	20.7
Others	Bicozamycin	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Total		68	541,790	100.0	70,800	100.0	97	631,380	100.0	83,303	100.0	101	634,330	100.0	81,926	100.0
Ratio to the previous fiscal year (%)		51.1	64.3		74.8		142.6	116.5		117.7		104.1	100.5		98.3	

- : No application

Table 3: The number of OTPC, OTPQ, and QCAQP (Sorted by grade, FY2023)

Category	Type of the specified feed additives	Refining grade			Feed grade		
		Passed cases	Passed quantity (kg)	Quantity convreted into potency (kg(potency))	Passed cases	Passed quantity (kg)	Quantity convreted into potency (kg(potency))
Polypeptide	Zinc bacitracin				—	—	—
	Enramycin				3	3,960	317
	Nosiheptide	—	—	—	—	—	—
Phosphoglycolipid	Flavophospholipol				6	36,000	2,880
Polyether	Salinomycin sodium	—	—	—	45	259,020	36,702
	Semduramicin sodium	—	—	—			
	Narasin				23	250,425	25,043
	Monensin sodium	—	—	—			
	Lasalocid sodium	—	—	—			
Orthosomycin	Avilamycin				24	84,925	16,985
Others	Bicozamycin	—	—	—			
Total		0	0	0	101	634,330	81,926
Proportion (%)		0.0	0.0	0.0	100.0	100.0	100.0

- : No application

/ : No standard has been set for the corresponding classification.

Table 4: Manufactured quantity by the registered manufacturers of specified feed additives (FY 2022 and 2023)

Category	Type of the specified feed additives	FY 2022		FY 2023	
		Manufactured quantity* (kg)	Quantity converted into potency (kg(potency))	Manufactured quantity* (kg)	Quantity converted into potency (kg(potency))
Polypeptide	Enramycin	64,340	5,147	81,840	6,547
	Nosiheptide	70,800	2,832	61,620	2,465
	Subtotal	135,140	7,979	143,460	9,012
Polyether	Salinomycin sodium	140,840	14,084	110,500	11,050
	Monensin sodium	380,560	76,112	378,360	75,672
	Lasalocid sodium	136,780	20,517	121,840	18,276
	Subtotal	658,180	110,713	610,700	104,998
Total		793,320	118,692	754,160	114,010
Ratio to the previous fiscal year (%)		93.6	96.3	95.1	96.1

* Reported from the registered manufacturers of specified feed additives.

Table 5: Total quantity of the specified feed additives (FY 2023)

Category	Type of specified feed additives	Total quantity *1 (kg)	Composition ratio (%)	Total quantity converted into potency *2 (kg(potency))	Composition ratio (%)
Polypeptide	Zinc bacitracin	—	—	—	—
	Enramycin	85,800	6.2	6,864	3.5
	Nosiheptide	61,620	4.4	2,465	1.3
	Subtotal	147,420	10.6	9,329	4.8
Phosphoglycolipid	Flavophospholipol	36,000	2.6	2,880	1.5
Polyether	Salinomycin sodium	369,520	26.6	47,752	24.4
	Semduramycin sodium	—	—	—	—
	Narasin	250,425	18.0	25,043	12.8
	Monensin sodium	378,360	27.2	75,672	38.6
	Lasalocid sodium	121,840	8.8	18,276	9.3
	Subtotal	1,120,145	80.7	166,743	85.1
Orthosomycin	Avilamycin	84,925	6.1	16,985	8.7
Others	Bicozamycin	—	—	—	—
Total		1,388,490	100.0	195,936	100.0

- : No application

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

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

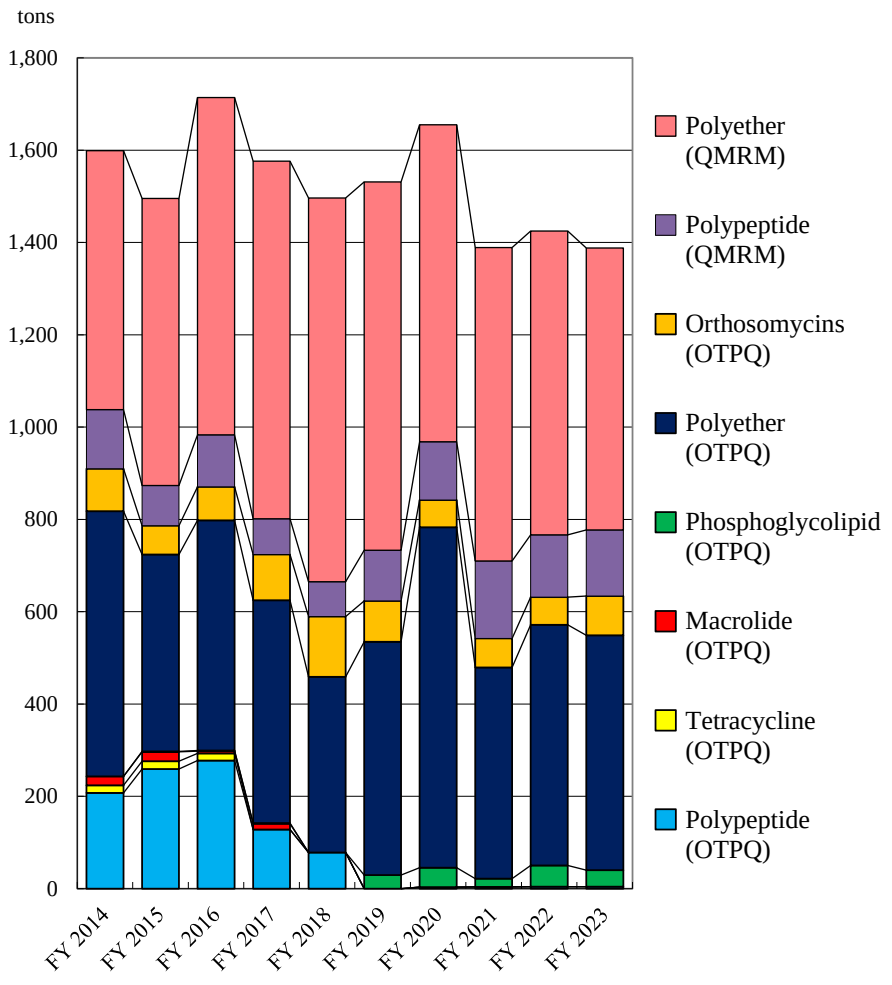

Figure 1: Changes in the total quantity (OTPQ and QMRM) of the specified feed additives (Sorted by category)

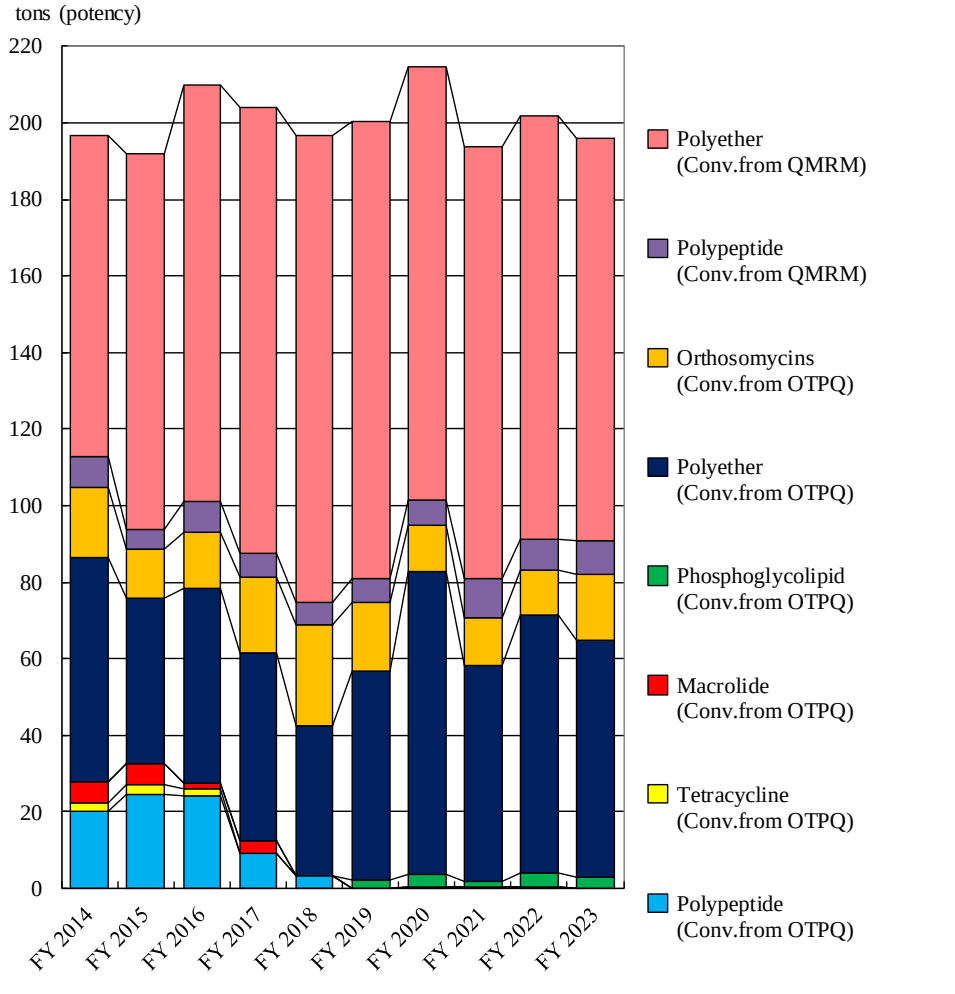

Figure 2: Changes in the total QCAQP (the total quantity of potency converted from OTPQ and the QMRM) of the specified feed additives (Sorted by category)