

2023/ND/EOD/65

List of feed additives could be considered for import with caution

Sl.No.	Name of Feed Additive	Comments
1.	Tiamulin Hydrogen Fumerate - 10% Feed grade	Withdrawal period of 72 hours should be followed for use in poultry before slaughter.
2.	Bamberomycin 4% and 8% - Feed Grade	Recommended at low dosages i.e. 1-2g/tonne of feed in poultry.
3.	Lincomycin 11%- Feed Premix	As per Codex Alimentarius Maximum residue limit (MRL) should not exceed 100µg/kg fat, 200 µg/kg in muscles, 500µg/kg in liver and kidney.
4.	Robenidine 10% premix (Feed Grade)	MRL (mg/kg wet tissue) should not exceed 0.80 for liver, 0.35 for kidney, 0.20 for muscle and 1.30 for skin/fat.
5.	Tiamulin 10% Feed Premix	Withdrawal period of 72 hours should be followed for use in poultry before slaughter.
6.	Enramycin 8% Feed grade	Withdrawal period of 7 days should be followed for use in poultry before slaughter. Avoid use in layers.
7.	Virginiamycin 50%	Withdrawal period of 5 days should be followed for use in poultry before slaughter.
8.	Kitasamycin 8% feed premix	Withdrawal period of 7 days should be followed for use in poultry before slaughter.
9.	Avilamycin 10% Feed Grade	As per Codex Alimentarius Maximum residue Limit (MRL) should not exceed 200µg/kg chicken, fat/skin and 300µg/kg for liver.
10.	Spectinomycin 2.2% feed premix	As per Codex Alimentarius Maximum residue limit (MRL) should not exceed 2000µg/kg in liver, egg, fat, 500 µg/kg in kidney and 500 µg/kg in muscles.
11.	Narasin 10%	As per Codex Alimentarius Maximum residue limit (MRL) should not exceed 50 µg/kg in liver, fat, 15 µg/kg in muscles
12.	Combination of Lincomycin 2.2% and Spectinomycin	Mentioned earlier.
13.	Kitamycin 15%	Withdrawal period of 7 days should be followed for use in poultry before slaughter.

List of Non-Antibiotics as feed additives

Sl.No.	Name of Feed Additive	Comments
1.	Bacteriophage	Recommended.
2.	Yusea-sehidigera	Recommended.
3.	Pellet binder	As the term is general, details need to be mentioned for recommendations.
4.	Aviguard	Strict Quality Control measure.
5.	Sodium diformate	Recommended.
6.	Potassium diformate	Recommended.

10/11/23
 Director
 Ministry of Agriculture
 Government of India
 New Delhi

No.102-50/2011-Trade
Government of India
Ministry of Agriculture
Department of Animal Husbandry, Dairying and Fisheries

Krishi Bhawan, New Delhi,
Dated, 18th June, 2012

To,
The Drug Controller General of India,
Directorate General of Health Services,
Office of the Drugs Controller General(India),
(Import Registration Div.),
FDA Bhavan,
Kotla Road, New Delhi.

Subject: Import of Feed Additives/Supplements.

Sir,

I am directed to refer to the representation submitted by CLFMA of India to this Department requesting declaration of the list of drugs used as feed additives/ supplements in addition to the list of drugs which were communicated vide letter of even number dated 8th July, 2011 for import clearance at the port. In this regard, CLFMA has submitted two list i.e. 2nd and 3rd list consisting of total 45 various items which are used as feed additives/ feed premixes/ supplements.

2. Both the lists submitted by CLFMA have been examined in the Department in consultation with Indian Council of Agricultural Research (ICAR). ICAR has recommended that the following items can be used as feed additives for animal feeding:

No.	Genetic name/contents
1.	Combination of fibre degrading enzymes (e.g. xylanase, beta-glucanase, cellulase, beta-mannanase, amylase, lipase, protease etc.
2.	Rumen buffers
3.	Salt licks -Mineral supplement for cattle
4.	Calcium salt of fatty acid.
5.	Mixture of essential oil with plant extracts
6.	Co-Enzyme Q 10 (Ubiquinone) 5% &10% Premix (Feed Grade)
7.	Calcium Butyrate (Feed Grade)
8.	Sodium Butyrate coated 30% (Feed grade)
9.	Bypass fats based on fatty acid FFA > 80%
10.	Molasses Dried Yeast - for animal feed
11.	Coated Amino Acids for dairy
12.	Selenium yeast Premix (Feed grade)
13.	Bacillus subtilis Feed Grade
14.	Algae based complimentary feed for fish
15.	Mixture of essential oil with plant extracts and spices
16.	Fumaric Acid

17.	Saponine 2-2.5%
18.	Calcium salts made from palm oil fatty acids, soya oil, sunflower oil and corn oil.
19.	Betaine Hcl 93-98%
20.	Deoiled Lecithin 90% on silicon Dioxide base
21.	Betaine Anhydrous 96%
22.	Bypass fat (fatty acid based)
23.	Conjugated linoleic acid 10% Coated with bypass fat

3. Further, in the list of items which was communicated earlier vide this Department's letter of even number dated 8th July, 2011 the following corrections in respect of the items described below may be made in the said communication:

Under the heading Amino acids, the name 'Methyl Hydroxy analogue' may be read as 'Methionine hydroxyl analogue'.


(Dr. S.K. Dutta)
Asstt. Commissioner

Copy to :
1. Chairman, CLFMA of India, 111, Mittal Chambers, 11th Floor, 228 Nariman Point, Mumbai-400 021. Fax: 022 2288 0128

F.No. 102-50/2010-Trade
Government of India
Ministry of Agriculture
Department of Animal Husbandry, Dairying and Fisheries
(Trade Unit)

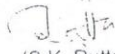
Krishi Bhawan, New Delhi
Dated 28.07.2014

To,
Drug Controller General of India,
FDA Bhawan,
Kotla Road,
New Delhi

Subject:- Submission of 4th List of feed additives - regarding
Sir,

I am directed to refer to CLFMA's letter no. 100/ Feed Additives dated 30.05.2014 on the subject cited above and to say that their request has been examined in consultation with ICAR and as per recommendation of ICAR, the following products are also used as feed supplement/ feed additives.

- a. HSCAS – Hydrogen Sodium Calcium Amino Silicate for feed use.
- b. Vitamins and chelated minerals.
- c. Rumen protected / bypass amino acids- feed grade
- d. Dried distillers grains with solubles (DDGS)
- e. Cocktail enzymes – combination of enzymes for use in feed
- f. Organic mineral mixtures – feed grade
- g. Dried Bacillus subtilis fermentation products
- h. Mould inhibitors feed grade
- i. Organic selenium feed grade.
- j. Organic trace minerals for feed.
- k. Dicalcium phosphate (feed grade)
- l. Tricalcium phosphate (feed grade)
- m. Nosiheptide 1% feed grade


(S.K. Dutta)
Asstt Commissioner

Copy to:

1. All Quarantine officers at AQCS Delhi, AQCS Mumbai, AQCS Kolkata, AQCS Hyderabad, AQCS Chennai, AQCS Bangalore
2. Chairman, CLFMA of India, 111 Mittal Chambers, 11th floor, 228, Nariman point, Mumbai-400.021.

No. 102-50/2011-Trade
 Government of India
 Ministry of Agriculture
 Department of Animal Husbandry, Dairying & Fisheries

Krishi Bhawan, New Delhi
 Dated, 8th July, 2011.

To,
 Dr. Arvind Kukrety,
 Asstt. Drug Controller (I),
 Directorate General of Health Services,
 Office of the Drugs Controller General (India),
 (Import & Registration Div.)
 FDA Bhavan,
 Kolla Road, New Delhi.

Subject: Import of Feed Additives/ Supplements.

Sir,
 I am directed to refer to the representation submitted by CLFMA of India to this Department requesting declaration of the list of drugs used as feed additives/ supplements.

2. The request of CLFMA has been examined in the Department in consultation with Indian Council of Agricultural Research (ICAR). It is mentioned that the following items can be used as feed additives/ feed supplements and included as ingredients in concentrate mixtures for optimum growth and milk production. Further, it is confirmed by ICAR that these items cannot be used as both drugs and feed additives/feed supplements.

Category of product	Name of the product
Amino Acids	L-Lysine Mono HCL 99% Feed Grade
	L-Lysine Sulphate 65% Feed Grade
	DL-Methionine 99% Feed Grade
	Methyl Hydroxy Analog 88% Feed Grade
	Methyl Hydroxy Analog Calcium salt 84% Feed Grade
	L-Threonine 98.5% Feed Grade
	L-lysine Sulphate 65% Feed Grade
	L-Tryptophan 98% Feed Grade
Vitamin Premix	Vitamin A/D3 Feed Grade 1000:200
	Vitamin A Acetate 1000 Feed Grade
	Vitamin E 50% Feed Grade
	Vitamin C coated 35% Feed Grade
	Vitamin D3 0.5miu/gm Feed Grade
	Vitamin B2-80% Feed Grade
	Biotin 2% & 10% Feed Grade
	Vitamin Premix Feed Grade (as per formula)
	Vitamin Mineral Premix Feed Grade (As per formula)
	Choline Chloride 50% & 60% on Corn Cob courier
Phosphates	Mono Calcium Phosphate (MCP) 22% P Feed Grade
	Di Calcium Phosphate (DCP) 18% Feed Grade
	Sodium Hydrogen Phosphate 17% Feed Grade
	Mono Potassium Phosphate 26% Feed Grade
	Di Potassium Phosphate 17% Feed Grade
	Cholesterol 95% Feed Grade

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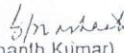
Enzymes	Phytase:5000 & 10000 FTU per gram Feed Grade
Other products	Anli oxidant Premix – Mixture of BHA, BHT & Etoxyquin
	Toxin Binders Feed Grade
	Acidifiers Feed Grade – Mixture of organic acids
	Inactivated Dry yeast (37-40% Protein) Feed Grade
	Active Dry Yeast – Feed Grade
	Yeast Cell Wall – for use in feed
	MOS & FOS

3. It is also clarified by ICAR that antibiotics/ antibacterials and anticoccidials mentioned below can only be used as feed premix but not as feed supplements/ drugs. The medicines listed below may not be allowed for therapeutic use.

Antibiotic/Antibacterial	ChlorTetra Cycline(CTC) 15% Feed Grade
	Colistin Sulphate - 10% Premix Feed Grade
	Clopidol 25% Feed Grade
	Dichhlozuril 1% Feed Grade
	Zinc Bacitracin 10% Feed Grade
	BMD – Bacitracin Methyl Disalicylate 15% Feed Grade
	Tylosyn Phosphate 10% premix Feed Grade
Anticoccidials	Maduramycin 1% Feed Grade
	Salinomycin 12% Feed Grade
	Nicarbazine - 8% Feed Grade
	Monancin Sodium 20% Premix Feed Grade
	Losolacid Sodium 15% Premix Feed Grade


4. However, Drugs Controller General of India may take a considered view in line with the Rules and Guidelines under Drugs and Cosmetic Act.

Yours sincerely,


(B. Prashanth Kumar)
Director

Copy to :

Chairman, CLFMA of India, 111, Mittal Chambers, 11th Floor, 22B Narlman Point, Mumbai-400 021, Fax: 022 2288 0128.


(B. Prashanth Kumar)
Director

No. 111-327/2012-Trade
Government of India
Ministry of Agriculture
Department of Animal Husbandry, Dairying and Fisheries

Krishhi Bhawan, New Delhi
Dated 14.09.2015

To,
Drug Controller General of India,
FDA Bhawan,
Kolla Road,
New Delhi.

Subject: Inclusion of Propionic Acid 47% in 4th list of feed additives -
regarding

Sir,

I am directed to refer to the letter received from M/s Skylark Feeds Pvt Ltd., Haryana, dated 17.08.2015, wherein the firm has requested to permit import of DMX-7, Mold Inhibitor, which contains 47% Propionic Acid.

The matter has been examined in consultation with Indian Council of Agricultural Research (ICAR) for which ICAR has recommended that, Propionic Acid 47% the main ingredient of DMX-7 that inhibits mold growth in feed and grains. This Department did not list the product in the existing list of feed supplement. The product cannot be listed in the brand name. Therefore, only Propionic Acid 47% may be included in the list of feed additives as mold inhibitor.

However the import clearance of this product is subjected to a certificate issued by the competent authority of the exporting country with the effect that the product is of non antibiotic and non animal origin category.

(S.K. Dutta)
Asstt. Commissioner

Copy to:

M/s Skylark Feeds Pvt. Ltd., Vill Khara Khemawati, Teh- Safidon, Dist- Jind,
Haryana- 126112

Certified copy

(Dr. SANJEET KUMAR)
Assistant Commissioner
Govt. of India

Min. of Agriculture & Farmer's Welfare
D/o Animal Husbandry, Dairying & Fisheries
New Delhi

30/05/2016

No 102-SD/2011-Feed (M.H)
Government of India

Ministry of Agriculture and Farmers Welfare
Department of Animal Husbandry, Dairying and Fisheries
(Trade Unit)

Krishi Bhawan, New Delhi
Dated 17.05.2016

To,
Drug Controller General of India,
FDA Bhawan,
Kotla Road,
New Delhi.

Subject:- Submission of 4th List of feed additives – regarding

Sir,
This is in reference to CLFMA'S letter no. 100/ Feed Additives, dated 30.05.2014 on the subject cited above and to say that request to include the new products as submitted by CLFMA was examined in consultation with Indian Council of Agricultural Research (ICAR) and as per the recommendation of ICAR, the views of this Department on declaring the listed products as feed supplements and feed additives are as under:

1. Indian Council of Agricultural Research, has not recommended the use of antibiotics as feed additives/ feed supplement therefore the Department does not support the inclusion of following item in the 4th list of feed additives:
 - Tylvalosine Tartarate upto 15%
 - Combination of Maduramycin- 0.75% and Nicarbazine-8%
 - Nicarbazine upto 25 % - feed grade
 - Ethopabate upto 8 % feed grade
 - Florfenicol 10% feed grade
 - Tilmicosin phosphate upto 25 .5% feed grade
2. Ammonia Binders regarding the specifications of the product, their doses and species in which it is to be used.
- 3 List of silage additives and their safety studies
- 4 As regards to probiotics, following information may please be furnished
 - a Identification of substance
 - b Safety and efficacy of the product
- 5 However the Department has no objection to declare the following item as feed additives/ supplements.
 - a JISCAS – Hydrogen Sodium Calcium Amine Silicate for feed use

- b. Vitamins and chelated minerals.
- c. Rumen protected / bypass amino acids- feed grade
- d. Dried distillers grains with solubles (DDGS)
- e. Cocktail enzymes – combination of enzymes for use in feed
- f. Organic mineral mixtures – feed grade
- g. Dried Bacillus subtilis fermentation products
- h. Mould inhibitors feed grade
- i. Organic selenium feed grade.
- j. Organic trace minerals for feed.
- k. Dicalcium phosphate (feed grade)
- l. Tricalcium phosphate (feed grade)
- m. Nosiheptide 1% feed grade

The recommendation regarding inclusion of the above mentioned products was communicated to DCGI, vide the letter of even no dated 28.07.2014.

6. Yucca plant concentrate and Quillaja extract for feed are also not supported to be included in the list of feed additives because they are prime products and cannot be used as feed supplement/ additives.

It is also to be mentioned that Nicarbazine 8% which was included in the list issued in 2011 (copy enclosed) should be withdrawn due to emergence of antimicrobial resistance in animals and human beings, as the same is being imported by many firms.

(Lipi Sairiwal)
Livestock Officer

Copy to:

1. Dr. Dinesh Bhosale, Chairman, CLFMA of India, Maharashtra, Mumbai-400021 w r t letter no 100/feed additives, dated 30th May, 2014

2. All Quarantine officers at AQCS Delhi, AQCS Mumbai, AQCS Kolkata, AQCS Hyderabad, AQCS Chennai, AQCS Bangalore, for information

No. 102-50/2010-Trade
Government of India
Ministry of Agriculture and Farmers Welfare
Department of Animal Husbandry, Dairying and Fisheries

Krishi Bhawan, New Delhi
Dated 2nd June, 2016

To,

Drug Controller General of India,
FDA Bhawan,
Kotla Road,
New Delhi.

Subject:- NOC for import of feed additives- regarding

Sir,

This is in reference to the letter no APC/PER/009 dated 29th April, 2016 received from M/s APC Nutrients Pvt. Ltd., Secundrabad, wherein the firm has requested for the permission to import following feed additives:

- a) Butyric- Novel form of **Butyric Acid** (Prophorce SR 130[®])
- b) Sodium salt of formic acid to prevent heat stress (Prophorce AC 299[®])
- c) Mixture of Formic acid, Propionic acid, Butyric acid in the liquid form (Prophorce Exclusive[®])

The matter has been examined in the Department in consultation with the Indian Council of Agricultural Research. On perusal of the supportive documents and keeping in view the benefits of the feed additives to be imported, this Department has no objection to the import of Poultry feed containing Butyric Acid, sodium salt formic acid and Mixture of Formic acid, Propionic acid, Butyric acid in the liquid form subject to the condition that these compounds are not to be used as drugs/ medicinal use.


(Lipi Sairawal)
Livestock Officer

Copy to:

1. M/s APC Nutrients Pvt. Ltd., 507, 5th floor, Minerva House, S.D.Road, Secundrabad 500003, T.S.
2. Dr. Dinesh Bhosale, Chairman, CLFMA of India, Maharashtra, Mumbai-400021, for information
3. All Quarantine officers at AQCS Delhi, AQCS Mumbai, AQCS Kolkata, AQCS Hyderabad, AQCS Chennai, AQCS Bangalore, for information.

No. 102-50/2011-Trade
Government of India
Ministry of Agriculture and Farmers Welfare
Department of Animal Husbandry, Dairying and Fisheries

Krishi Bhawan, New Delhi
Dated 7th March, 2017

To,

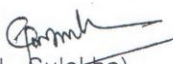
The Drug Controller General of India,
FDA Bhawan,
Kolla Road,
New Delhi.

Subject:- NOC for inclusion of L-Methionine in the list of feed additives to be imported- 90 %- regarding

Sir,

This is in reference to the application dated 14.11.2016 received from M/s CJ Cheiljedang Corporation, Mumbai regarding inclusion of L-Methionine 90% (L-Met Pro)-feed grade under the list of feed additives.

The matter has been examined in the Department in consultation with the Indian Council of Agricultural Research. On perusal of the supportive documents and keeping in view, the already enlisted DL-Methionine 99 % as feed additive vide letter No. 102-50/2010-Trade dated 8th July, 2011, this Department has no objection in inclusion of L-Methionine 90% as feed additive/ feed supplement subject to the condition that the source would be of non animal origin.

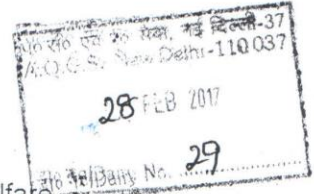

(S.L. Sulekha)

Assistant Commissioner (Trade)
Telephone no: 011-23097034

Copy to:

1. Dr Paran Sarma, Regional Head, CJ Cheiljedang Corporation, CJ Bio BU Mumbai office, B 304 Mahaveer Ikon , CBD -400614, Navi Mumbai, Maharashtra.
2. Mr. B.S. Yadav, Chairman, CLFMA of India, Mittal Chamber, 11th floor, Nariman Point, Maharashtra, Mumbai-400021, for information.
3. All Quarantine officers at AQCS Delhi, AQCS Mumbai, AQCS Kolkata, AQCS Hyderabad, AQCS Chennai, AQCS Bangalore, for information.

No. 102-50/2010-Trade
Government of India
Ministry of Agriculture and Farmers Welfare
Department of Animal Husbandry, Dairying and Fisheries



Krishi Bhawan, New Delhi
Dated 23rd February, 2017

To,

The Drug Controller General of India,
FDA Bhawan,
Kotla Road,
New Delhi.

Subject:- NOC for import of probiotics- regarding

Sir,

This is in reference to the letter dated 26.09.2016 regarding approval of Multistrain probiotic received from M/s EW nutrition India Pvt ltd.

The matter has been examined in the Department in consultation with the Indian Council of Agricultural Research. On perusal of the supportive documents and keeping in view the benefits of the probiotic, this Department has no objection to the import of Multistrain probiotic containing **Dried Lactobacillus casei fermentation product, dried Lactobacillus acidophilus fermentation product, dried Bacillus licheniformis fermentation product, dried Bacillus subtilis fermentation product, dried Enterococcus faecium fermentation product, dried Bacillus subtilis fermentation product, dried Enterococcus faecium fermentation product, dried lactobacillus plantarum fermentation product** subject to the condition that these compounds are not to be used as drugs/ medicinal use. Further, Dried Bacillus subtilis fermentation products has already been included in the list as per the letter vide F. No 102-50/2011- Trade dated 17.05.2016.


(S. Sulekha)

Assistant Commissioner (Trade)
Telephone no: 011-23097034

Copy to:

1. EW Nutrition, India Pvt Ltd, Regus Business Centre Delhi, Level 2, Elegance Tower, Old Mathura Road, Jasola, Delhi 110025.
2. Mr. B.S. Yadav, Chairman, CLFMA of India, Mittal Chamber, 11th floor, Nariman Point, Maharashtra, Mumbai-400021, for information
3. All Quarantine officers at AQCS Delhi, AQCS Mumbai, AQCS Kolkata, AQCS Hyderabad, AQCS Chennai, AQCS Bangalore, for information.

By Speed Post

No. L-110102/3/2017-Trade
Government of India
Ministry of Agriculture
Department of Animal Husbandry, Dairying & Fisheries

Krishi Bhavan, New Delhi
Dated 10.04.2017

To

The Drug Controller General of India,
Directorate General of Health Services,
Office of the Drug Controller General (India),
(Import Registration division)
FDA Bhavan
Kotla road,
New Delhi.

Subject: Inclusion of Nicarbazine and its formulation with ionophore as feed additive/supplement.

Sir,

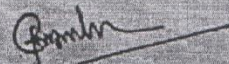
The undersigned is directed to refer to the letter No. Nil dated 22.08.2016 submitted by the CLFMA of India regarding the subject mentioned above and to say that the request has been examined in the department expert committee meeting held under the chairmanship of JS (LH). As per the recommendation of the committee, the Department has no objection to the import of Nicarbazine 8% with non ionophore coccidiostat for another one year from the date of issue of the this letter, with the condition that the manufacturer will put a label on the final pack about its ingredients and mandatory requirement of withdrawal period as under:

Nicarbazine (8%)

- a) Egg: 300 MRLs ($\mu\text{g}/\text{kg}$) or PPB
- b) Liver: 300 MRLs ($\mu\text{g}/\text{kg}$) or PPB
- c) Kidney: 100 MRLs ($\mu\text{g}/\text{kg}$) or PPB
- d) Other Food: 50 MRLs ($\mu\text{g}/\text{kg}$) or PPB

Maduramycin

- a) Egg: 12 300 MRLs ($\mu\text{g}/\text{kg}$) or PPB
- b) Other Food: 2 MRLs ($\mu\text{g}/\text{kg}$) or PPB.


(Dr. Sulekha SL)

Assistant Commissioner (Trade)

Copy to: CLFMA of India, 111, Mittal Chambers, 228, Nariman point, Mumbai-400021.