Overview on Feed additives

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Tentative Translation
What are feed additives?

( Law Concerning Safety Assurance and Quality Improvement of Feeds )

① Added to feed for the purposes specified by MAFF Ordinance
② Designated by the MAFF Minister after consultation with the Agricultural Materials Council
(purposes specified by MAFF Ordinance)

① to prevent deterioration of quality of feeds
② to supply nutrient ingredients and other effective ingredients of feed
③ to promote efficient use of feed nutrient ingredients
Designated Feed Additives (1)

1. Prevent deterioration of quality of feeds (17)
   - Antioxidants (3): Dibutylhydroxytoluene etc…
   - Mold Inhibitors (3): Propionic Acid etc…
   - Thickeners (5): Propylene Glycol etc…
   - Emulsifiers (5): Glycerin Fatty Acid Ester etc…
   - Adjusters (1): Formic Acid
O Designated Feed Additives (2)

2 Supply of nutrient ingredients and other effective ingredients of feed (87)

- Amino Acids (13): L-Arginine etc…
- Vitamins (33): L-Ascorbic Acid etc…
- Minerals (38): Copper Sulfate etc…
- Pigmenters (3): Astaxanthin etc…
3 Promote efficient use of feed nutrient ingredients (53)
   - Synthetic Antimicrobials (6): Morantel Citrate etc...
   - Antibiotics (18): Salinomycin Sodium etc...
   - Sweeteners (1): Saccharin Sodium
   - Enzymes (12): Amylase etc...
   - Probiotics (11): *Enterococcus faecalis* etc...
   - Others (5): Flavours, Fumaric Acid etc...
Designation of feed additives

1. Manufacturers apply for designation to MAFF
2. Pre-consultation between applicants and MAFF
3. Submission of relevant data from applicants to MAFF
4. Evaluation by the Agricultural Materials Council (Assessment by the Food Safety Commission)
5. Designation of feed additives, establishment of specification/standards
Agricultural Materials Council (Feed Subcouncil)

- Consists of 39 academics
- Impartial and scientific discussion / judgement

1. Feed Safety WG
   - Designation of feed additives
   - Establishment of specifications of feed additives

2. GM feed WG
   - Safety evaluation of GM feed, GM derived feed additives

3. Feed Nutrients WG
   - Setting of official specification of feeds
   - Setting of quality labelling standards of feeds
Procedures for designating feed additives

Applicant

MAFF

Agricultural Materials Council

MHLW

Food Safety Commission

1. Apply
2. Request
3. Request
4. MRLs
5. Assessment result (animal health), approval of designation
6. Designation of feed additive, Amendment of specification etc…
Assessment standards for feed additives

(basic conditions for feed additives)

• Evaluation standards stipulate effect, residue and safety matters
Effect

• Feed additives shall possess effect for purposes stipulated by the ordinance.

• A new feed additive shall possess more than equivalent effect in case it has similar effect to already designated one.
In case of giving feed with antibacterial additives, concerned additives should not be detected from livestock products by quantitative methods with certain level of sensitivity.
OSafety

• Feed additives shall not result in producing harmful livestock products.
• In case a new feed additive has similar structure/effect to already designated one, it shall possess more than equivalent safety.
• Feed additives shall have certain level of safety margin for livestock.
• In principal, feed additives shall not be poisonous or deleterious substances.
• Giving feed with concerned additives shall not impose bad effect in medical area.
Standards for implementation of animal testing for feed additives (GLP)

Based on the GLP of OECD, points of compliance concerning conducting safety and residual test are stipulated.

→ Implement at testing establishments which are confirmed that they are complying with international standards is needed.

Safety and residual tests should be conducted in accordance with feed additives GLP
Data to be submitted (1)

1. Data on specification

   (a) history of origin or discovery. Situation of approval and usage abroad

   (b) data for specification

       ① name  ② chemical structure  ③ manufacture method  ④ biological, physical and chemical characteristics  ⑤ quantitative analytical method in feeds  ⑥ temporal change  ⑦ other items on specification

   (c) residual data
Data to be submitted (2)

2. Data on effect and safety
   (a) items on effect
   (b) items on residue
   (c) items on safety
      ① toxicity test data
      ② feeding performance to target livestock
      ③ test on resistance of micro-organisms