

行政院及所屬各機關出國報告

(出國類別：開會)

## 參加「世界動物衛生組織 飼料安全區域研討會」出國報告

服務機關：行政院農業委員會動植物防疫檢疫局

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派赴國家：日本

出國期間：108年1月14日至1月17日

報告日期：108年4月8日

## 摘要

本次研討會由世界動物衛生組織（OIE）亞太區域辦公室於 108 年 1 月 15 日至 16 日假日本東京大學彌生校區舉辦，此次參與國家包括印度、孟加拉、不丹、汶萊、柬埔寨、斐濟、伊朗、日本、馬來西亞、馬爾地夫、密克羅尼西亞聯邦、蒙古、緬甸、尼泊爾、新喀里多尼亞、巴布亞紐幾內亞、新加坡、斯里蘭卡、泰國、東帝汶、越南及我國等 22 個國家。另聯合國糧食及農業組織（FAO）與歐洲食品安全局(EFSA)以專家身份與會。研討會重點在使各會員國瞭解世界動物衛生組織(OIE)之飼料安全管理政策，互相分享交流各國之飼料安全監控體系、飼料添加抗微生物藥品之管理與實驗室之動物飼料檢驗資訊網絡，讓各與會國成員對上開議題能有深度瞭解，以協助各國強化飼料安全體系，進而確保動物健康與福利、食品安全與人體健康。

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## 壹、緣由與目的

近年全球對於動物來源食品需求逐漸增加，特別是亞太地區開發中的國家需求增加最為顯著，進而增加動物飼料的需求與國際間的飼料流通。由於飼料安全直接影響動物健康與福利，進而影響食品安全與人體健康，故飼料安全至關重要。有鑒於此，OIE 邀請亞太區域會員國之飼料安全管理（包含飼料添加抗微生物藥品與細菌抗藥性議題）相關代表與會研討交流，使各會員國瞭解世界動物衛生組織(OIE)之飼料安全管理政策，互相分享交流各國之飼料安全監控體系、飼料添加抗微生物藥品之管理與實驗室之動物飼料檢驗資訊網絡，讓各與會國成員對上開議題能有深度瞭解，以協助各國強化飼料安全體系，進而確保動物健康與福利、食品安全與人體健康。

## 貳、議程

### OIE「動物飼料安全區域研討會」

第一天 (2019 年 1 月 15 日)

時間	議程	主講人
09:00-09:30	報到	
09:30-10:00	開幕式與介紹研討會目的	Akinobu Kawamura (OIE) Host Country FAMIC
10:00-10:30	茶敘時間	
Session 1: 背景介紹		
10:30-10:50	2010 年舉辦「預防飼料媒介性疾病」區域研討會後續追蹤辦理情形	Ms Chitose, Watanabe, FAMIC
10:50-11:10	動物飼料之 OIE 國際標準	Dr Jeremy Ho, OIE

11:10-11:30	2010 年舉辦「預防飼料媒介性疾病」區域研討會後續追蹤辦理情形與聯合國糧農組織亞太區動物生產及健康委員會(FAO, APHCA)之飼料安全	Dr Carolyn Benigno, FAO
Session 2: 確保飼料安全		
11:30-11:50	日本飼料安全體系	Dr. Natsuko Kitaguchi, Japan
11:50-12:10	歐盟飼料安全體系	Dr Rosella Brozzi, European Food Safety Authority
12:10-12:30	日本飼料製造業者之 製造管理與品質控管	Mr Shuichi Tanaka, Nosan Corporation
12:30-12:50	提問與回應 (Q&A)	所有與會人員
12:50-14:00	午餐	
14:00-14:50	簡報飼料安全現況，包含動物飼料之法 規體系、製造管理與品質控管	挑選特定會員國代表 (斯里蘭卡、泰國與我 國)
分組討論		
14:50-16:10	<ul style="list-style-type: none"> <li>● 確保飼料安全之法規體系</li> <li>● 飼料安全製造管理與品質控管</li> </ul>	所有與會人員
16:10-16:30	茶敘時間	
16:30-17:00	小組報告討論重點	所有與會人員

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17:00-17:10

第一天會議總結

FAMIC  
OIE

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## OIE「動物飼料安全區域研討會」

第二天 (2019 年 1 月 16 日)

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### Session 3: 飼料使用抗微生物藥品

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9:00-9:15

飼料使用抗微生物藥品之 OIE 標準與建議

Dr Jing Wang, OIE

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9:15-9:30

全球使用抗微生物藥品於動物生產之概要

Prof. Katsuaki Sugiura,  
The University of Tokyo

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9:30-9:45

日本抗微生物藥品  
作為飼料添加物之風險評估

Dr Hisako Okura,  
Food Safety  
Commission of  
Japan

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9:45-10:00

歐盟使用抗微生物藥品  
於飼料之法規與現況

Dr Rosella Brozzi,  
European Food  
Safety Authority

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10:00-10:15

畜牧場端抗微生物使用量紀錄與特性之  
國家案例研究

Dr Carolyn Benigno,  
FAO

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10:15-11:10

第一部份：所有會員國進行 3 分鐘簡報：  
抗微生物藥品作為生長促進用之現況

所有會員國

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11:10-11:35	茶敘時間	
11:35-12:20	第二部份：所有會員國進行3分鐘簡報： 抗微生物藥品作為生長促進用之現況	所有會員國
12:20-13:00	OIE、FAO、EFSA、日本食品安全委員會與 日本食品安全研究中心共同組成專家小組 並針對飼料使用抗微生物藥品給予建議： ● 飼料使用抗微生物藥品之進展與缺口 ● 如何符合國際標準與建議	
13:00-14:00	午餐	
Session 4: 動物飼料實驗室聯繫網		
14:00-14:20	實驗室聯繫網於動物飼料領域之重要性	Dr Yoshihiro Sekiguchi, FAMIC
14:20-15:20	分組討論 ● 飼料實驗室聯繫網的好處與必要性 ● 確認飼料實驗室聯繫網特定目標的優先順序 ● 確認重要工作與運作機制	所有與會人員
15:20-15:50	每組報告討論結果	所有與會人員
15:50-16:20	全體討論	所有與會人員
16:20-16:40	茶敘時間	

## 閉幕式：摘要與結論

16:40-17:20

會議總結

FAMIC, OIE

17:20-17:30

閉幕致詞

備註

1. FAMIC：Food and Agricultural Materials Inspection Center
2. FAO：Food and Agriculture Organization of the United Nations

## 參、研討會摘要

一、1月15日

(一) 開幕式

本次研討會主要出席之國家與組織分別為 OIE、印度、孟加拉、不丹、汶萊、柬埔寨、斐濟、伊朗、日本、馬來西亞、馬爾地夫、密克羅尼西亞聯邦、蒙古、緬甸、尼泊爾、新喀里多尼亞、巴布亞紐幾內亞、新加坡、斯里蘭卡、泰國、東帝汶、越南及我國等。另聯合國糧食及農業組織（下稱 FAO）與歐洲食品安全局（下稱 EFSA）以專家身份與會。首先由日本農林水產消費安全技術中心（FAMIC）與 OIE 代表共同擔任主席，向與會人員說明會議背景與議程，並請各與會代表自我介紹後，全體與會人員合影留念。

(二) 2010 年舉辦之「預防飼料媒介性疾病」區域研討會重要事項及其後續辦理情形

日本農林水產消費技術中心（Food and Agricultural Materials Inspection Center, FAMIC）於 2009 年被指派擔任第一個 OIE 飼料安全與檢驗合作中心，並已協助會員國改善其技術能力。追蹤 2010 年舉辦「預防飼料媒介性疾病」之飼料安全區域研討會辦理情形，該研討會係由 OIE 亞太區域代表處（OIE Regional Representation for Asia and the Pacific,

RRAP)、FAO 之亞太區動物生產及健康委員會 (Animal Production and Health Commission for Asia and Pacific, FAO-APHCA) 與 FAMIC 聯合辦理, OIE、FAO 與 FAMIC 已依據該次研討會建議, 完成相關工作。

### (三) 動物飼料之 OIE 國際標準

飼料安全為食品安全之源頭, 與飼料安全有關的 OIE 規範或指引分別為 OIE 陸生動物衛生法典 (OIE Terrestrial Animal Health Code)、OIE 陸生動物診斷試驗與疫苗手冊 (OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 包含狂犬病、新城病、牛海綿狀腦病、Campylobacter jejuni 與 Campylobacter coli 感染症、Listeria monocytogenes 感染症與沙門氏菌感染症章節)、OIE 水生動物衛生法典 (OIE Aquatic Animal Health Code) 與 OIE-FAO 良好農業作業指引 (OIE-FAO Guide to Good Farming Practice)。與飼料安全有關之獸醫服務體系績效 (Performance of Veterinary Services, PVS) 為動物飼料安全的 PVS 評估工具與動物飼料安全的 PVS 區域評估概述。各會員國可參考前揭規範或指引進行飼料安全管理, OIE 將安排其他飼料安全研討會, 並將持續與 FAO 合作發展與推廣國際標準與指引。

### (四) 追蹤 2010 年舉辦之研討會與 FAO-APHCA (Animal Production and Health Commission for Asia and the Pacific, APHCA) 之飼料安全

FAO 舉辦與飼料安全有關之活動包含 2013 年於泰國曼谷舉辦 FAO-APHCA (Animal Production and Health Commission for Asia and the Pacific, APHCA) 動物飼料資源區域研討會、2015 年於曼谷舉辦反芻動物飼料策略與國家飼料評估以維護乳業發展之亞洲區域會議。FAO 建立飼料安全多方(飼料業與食品業)夥伴關係, 以發展飼料安全技術能力。其飼料安全平台可促進利害關係者的交流與合作、促進資訊與知識的分享、取得下列相關資料, 包含專家與專業知識、組織與機構、及發展技術能力。

### (五) 日本飼料安全體系

飼料安全法規標準係透過農林水產省(The Ministry of Agriculture, Forestry and Fisheries, MAFF)諮詢食品安全委員會、厚生勞動省 (Ministry of Health, Labour and Welfare,

MHLW)與農業材料委員會(Agricultural Materials Council)而建立，包含飼料中有害物質的最大容許量，即飼料安全相關法規係透過衛生單位與農政單位共同研議制定而成，以符合飼料安全與食品安全之需求。日本於 2015 年已建立良好製造飼料作業規範(GMP)，而我國目前尚無飼料國際標準 GMP 或 HACCP。日本係由 MAFF 每年成立飼料監測計畫，檢驗飼料有害物質，一旦檢出有問題，該飼料將被禁止銷售，以維護食品安全。日本於 2009 年經 OIE 認定為 BSE 風險可控制國家，另於 2013 年經 OIE 認定為 BSE 風險可忽略國家。日本透過風險管理，飼料安全違規案件已從 1994 年之將進 60 件違規，降至 2016 年不到 5 件違規。

#### (六) 歐盟飼料安全體系

EFSA 主要工作為提供獨立的科學建議、支援歐盟食品及飼料安全風險管理與政策制定；提供獨立、及時的風險溝通；促進科學上的合作。科學專家委員會包含植物健康、植物保護、基因改良有機物、動物飼料、動物健康與福利、生物性危害、化學性污染物、食品添加物、食品包裝與營養等 10 大領域。主要法規為供給動物營養之飼料添加物法規(1831/2003)與歐盟委員會指引(2002/32/EC)，後者規範飼料與飼料添加物污染物最大容許量。歐盟係將飼料視為食品鏈之一環。一旦食品與飼料有公共衛生風險問題，即緊急通報歐盟會員國食品安全單位，並進行相關反應處理。歐盟參考實驗室目標係確保歐盟的檢驗具高品質與一致性，歐盟參考實驗室會提供參考方法、標準品、良好的檢驗計畫與實驗室訓練。

#### (七) 日本飼料製造業者之製造管理與品質控管

日本大部分的飼料成分依賴進口。於品質管控方面，1953 年制訂飼料安全法、1998 年制訂配方飼料場預防沙門氏桿菌指引、2007 年制訂抗微生物藥品飼料添加物管理指引。透過良好的衛生管理，飼料成分沙門氏菌陽性比率已由 1988~1989 年的 14.6%，降至 2015 年的 1.3%。2001 年日本發生 BSE(牛海綿狀腦病 或稱狂牛症)首例，2010 年已無 BSE 案例。2008 年建立預防有害飼料化學污染物指引。2015 年建立飼料 GMP。未來挑戰包含推廣 HACCP、抗生素是否持續作為飼料添加物、微生物抗藥性、生物安全與零風險管理等。

## (八) 斯里蘭卡、泰國與我國飼料安全現況報告

斯里蘭卡目前已有法律規範動物飼料製造、進口、批發與零售。該國面臨困難包含於飼料產業無適當之監測系統、沒有足夠之實驗室設備以確保飼料品質並分析飼料中的殘留物、缺乏認證之實驗室等。而未來將針對以上困難進行強化與改善。泰國於飼料安全已有完善之法規，包含有飼料 GMP/HACCP 驗證制度，並提供業者 GMP/HACCP 訓練計畫，而我國目前尚無 GMP/HACCP 制度。

## (九)分組討論

### 1. 討論題目：

(1) 飼料安全之法規體係：須納入飼料安全法規體係的危害物質與對象(例如進口業者、製造業者、經銷商、使用者、法規主管機關與參考實驗室)為何？建立飼料安全法規的挑戰為何？

(2)飼料安全的製造管理與品質管控：簡述飼料製造情形及其相對應之法規、用於飼料製造品質控管的標準或指引為何？實施前揭標準面臨的挑戰為何？

### 2.討論結果：

會員國飼料法規或指引的建立狀態差異甚大，有些國家已有完善的法規，有些國家尚無。飼料安全的危害物質應考量物理性、化學性與生物性危害物質、汙染物與攙雜物。亞太區域會員會使用的飼料安全標準包含 GMP、HACCP、ISO、Codex、OIE 標準或國內制訂的國家標準。面臨挑戰包含法規不完備、缺乏專業技能、缺乏政策支持、缺乏風險評估與涉及的對象甚廣等。

二、1月16日

### (一) 管控微生物抗藥性之 OIE 國際標準

管控微生物抗藥性之 OIE 國際標準包含 OIE 陸生動物衛生法典第 6.7 章節管控微生物抗藥性之建議簡介、第 6.8 章節國家微生物抗藥性調查與監測計畫之整合、第 6.9 章節監測產食動物之抗微生物藥品使用量與方式、第 6.10 章節於獸醫學領域使用抗微生物藥品之責任並謹慎使用、第 6.11 章節針對動物使用抗微生物藥品進行抗藥性之風險分析。上述相同主題亦分別列於 OIE 水生動物衛生法典第

6.1 章節至 6.5 章節。OIE 其他微生物抗藥性管控資料包含陸生動物診斷試驗與疫苗手冊第 3.1 章節細菌抗藥性敏感試驗之實驗室方法學。

動物醫療使用抗微生物藥品之情形包含動物傳染病之治療、控制與預防。若作為「生長促進用」則「非」屬動物醫療用。WHO(衛生組織)列為最高優先重要之抗微生物藥品者(Highest Priority Critically Important Antimicrobials)，應優先停止作為生長促進用。Cephalosporins、Fluoroquinolones 與 Colistin 為人醫與獸醫至關重要的抗生素，因此不應再被作為生長促進使用。經 2017 年全球調查，目前將抗微生物藥品作為生長促進劑的國家僅有 29% (45/155)，非洲為 22%(10/44)、美洲為 60%(18/30)、亞太區域 46%(14/30)、歐洲有 4%(2/44)、中東為 14%(1/7)。2017 年調查 31 國家，被最多國家使用作為生長促進使用第一名為 Bacitracin、其次為 Tylosin 與 Flavomycin 並列第二，再次之為 Avilamycin。

## (二) 全球使用抗微生物藥品於動物生產之概要

抗微生物使用量調查已可區分動物別的國家為美國、法國、日本，其資料係向藥品上市許可證持有者調查。加拿大與大部分歐盟國家無法區別抗微生物使用量的動物別，其資料亦係向藥品上市許可證持有者調查，此與我國情況相同。而丹麥、德國、荷蘭與比利時可自飼養農戶調查抗微生物使用量，並區分動物別。歐盟、比利時、丹麥、德國、法國與荷蘭尚有記錄平均家畜數量、平均體重(kg)、劑量(mg/kg/day)與有效成分重量，可換算出每公斤家畜體重所使用的藥品重量。2016 年調查 30 個國家抗微生物藥品銷售量，其中銷售量最多的國家為賽普勒斯、義大利與西班牙，其銷售最多的種類均為 Tetracyclines 與 Penicillins。

## (三) 日本抗微生物藥品作為飼料添加物之風險評估 (食媒性抗藥性細菌)

有關產食動物使用抗微生物藥品而篩選出抗藥性細菌方面，日本食品安全委員會於 2004 年已針對此方面，制訂食品對人體健康影響之評估指引。截至 2017 年 8 月風險評估結果，具微生物抗藥性中度風險品項為供豬、牛與雞作為動物醫療用 (Veterinary Medical Product, VMP)之 Fluoroquinolone；供豬作為 VMP 之 Tulathlomycin 與 Gamithlomycin、供豬、牛作為 VMP 之 Ceftiofur、Cefquinome；供豬、雞作為飼料添加物(Feed additives, FA)之 Virginiamycin；供家畜作為 VMP 或 FA 之 Colistin。

具微生物抗藥性低度風險品項為供乳房內灌流作為 VMP 之 Pirlimycin；供牛作為 VMP 之 Gamitholomycin 與 Tulathlomycin。具微生物抗藥性風險可忽略品項包含作為 FA 之 Monencin、Seduramycin、Lasalocid、Salinomycin、Narasin、Nosiheptide、Enramycin、Flavophospholipol、Avilamycin；以及作為 VMP 之 Florfenicol、用於蜜蜂之 Tylosin。無微生物抗藥性證據品項包含作為 FA 之 Amprolium、Ethopabate、Morantel 與 Nicarbazine。

日本農林水產省(MAFF)將依據風險評估結果採取微生物抗藥性(AMR)之管理措施，若 VMP 經日本食品安全委員會評估結果為具高度風險，則 MAFF 將撤銷許可證(Revocation of approval)，並暫時禁止使用。若 VMP 經食品安全委員會評估為具中度風險，則 MAFF 將限制其使用、縮短許可證有效期間、列為二線用藥、加強監測 (例如增加樣本數)。若 VMP 經評估為具低度風險或風險可忽略，則 MAFF 持續監測。而針對 FA，若經評估為高度至低度風險者，則撤銷其 FA 使用(Revocation of designation)，僅有經評估為風險可忽略者，MAFF 則採取持續監測之措施。

#### (四) 歐盟使用抗微生物藥品於飼料之法規與現況

抗微生物藥品(Antimicrobial)的定義不包含抗病毒藥、抗寄生蟲藥(例如抗球蟲藥)與消毒劑。歐盟對抗細菌抗藥性之作為：(1) 禁止群體動物預防性使用抗生素。(2) 盡可能保留特定抗生素，僅供人類使用。(3) 強制歐盟成員須蒐集抗微生物藥品之販賣與使用資料。

製造混合動物用藥之飼料係受到管制，已禁止抗微生物藥品作為生長促進使用，並限定須透過獸醫師處方使用抗微生物藥品，但飼料添加可使用具抗球蟲劑(Coccidiostats)或抗黑頭病原蟲劑 (Histomonostats) 效果之物質。

#### (五) FAO 於畜牧場端抗微生物使用量紀錄與特性之國家案例研究

FAO 於越南等國進行牧場端抗微生物藥品的使用量調查研究，納入抗微生物藥品使用量調查的越南畜牧場數量僅 20 家，針對畜牧場端的抗微生物藥品使用量調查目前僅能進行小範圍調查。

#### (六) 每個會員國針對抗微生物藥品作為生長促進用之現況，進行 3 分鐘簡報

日本目前有 20 項抗微生物藥品作為飼料添加劑，經該國評估，其中 13 項抗微生物藥品列為風險可忽略或不須進行風險評估，分別為 Amprolium、Avilamycin、Enramycin、Ethopabate、Flavophospholipol (Flavomycin)、Lasalocid、Monensin、Morantel、Narasin、Nicarbazine、Nosiheptide、Salinomycin 與 Sempduramicin。Avilamycin、Enramycin、Flavomycin 與 Nosiheptide 為抗菌劑，其餘皆為抗寄生蟲劑。另 7 項抗微生物藥品為 Bacitracin、Bicozamycin、Chlortetracycline、Halofuginone、Oxytetracycline、Sulfaquinoxaline 與 Tylosin，日本正在進行風險評估，而此 7 項藥品均為抗菌劑。Colistin 與 Virginiamycin 因具有細菌抗藥性可能的風險，故其飼料添加許可證已被日本撤銷。會員國間依據法規差異，可分為三類，第一類為缺乏相關法規管理，包含缺乏資源與缺乏專業技能等。第二類為抗微生物藥品於飼料無規範，因為抗微生物藥品的管理已納入其他相關法規，例如生物安全或進出口管制與檢疫法規。第三類為抗微生物藥品於飼料有規範，包含嚴格禁止使用抗微生物藥品作為生長促進劑、或規範特定抗微生物藥品須於特定條件下使用。各國之未來展望包含建立專業技能、提高對抗藥性議題的重視、與不同領域合作以達防疫一體(One Health)、資訊分享、實施飼料使用抗微生物藥品之標準、AMR 國家行動方案、逐步淘汰抗微生物藥品的使用並尋求替代藥品、強化抗微生物藥品的監測、法規與管控。泰國已禁止抗微生物藥品作為生長促進劑。

(七) 由 OIE、FAO、EFSA、日本食品安全委員會與日本食品安全研究中心共同組成專家小組，針對飼料使用抗微生物藥品方面給予建議如下：

- 目前仍有許多國家尚無法提供抗微生物藥品使用量(Antimicrobial Use, AMU)的資料，建議可逐步分階段進行並盡可能納入相關利害關係人。
- 建議可參考國際規範以補足該國缺口。
- 實施相關法律：發展國際指標以監測與評估，確認 AMR 國家行動方案之進度。逐步並持續進行
- 改善風險管理的態度：邀請所有利害關係人分享資訊、參考 OIE/Codex 規範。
- AMU 管控涉及不同對象

1. 各國有其特殊情況與考量
2. 教育 (例如飼養農戶、獸醫師等)
3. 提高對抗微生物藥品議題的重視
- EFSA 專家分享抗微生物藥品管理的歐洲經驗，有 2 項重要秘訣
  1. 禁止對飼養農戶有抗微生物藥品廣告之行為
  2. 獸醫師不准因銷售抗微生物藥品而獲取經濟利益
- AMR 調查方面
  1. OIE 參考實驗室已開發調查 AMR 的基礎技術能力，建議此基本方法用於 AMR 調查試驗
  2. 籌組訓練計畫
  3. 制訂符合目標的資料表
  4. FAO-OIE 區域合作中心網絡於 AMR 調查方面建立良好之技術能力
  5. 製訂調查指引
  6. 鼓勵 AMU 監測與 AMR 風險分析，同時確認技術能力與資源需求

#### (八) 實驗室聯繫網於動物飼料領域之重要性

目標為資訊分享，技術訓練與提供研討會討論議題。參與飼料安全實驗室分 4 步驟：第一、登記該國實驗室聯絡人。第二、FAMIC 寄送提供所有聯絡人的電郵清單。第三、填報資料表給 FAMIC，FAMIC 將彙整各國資訊並回饋給各國。第四、持續分享資訊，各國將飼料安全檢驗資訊提供給 FAMIC，FAMIC 將彙整各國資訊並回饋給各國。

#### (九) 針對飼料實驗室聯繫網議題進行分組討論：

1. 討論題目：
  - (1) 飼料實驗室聯繫網的好處與必要性
    - A. 每個國家是否有檢驗飼料的實驗室？若有，是否有該國的實驗室代表作為聯繫窗口？
    - B. 每個國家動物產品食品安全業務窗口(focal point for animal production food safety) 是否熟悉該國動物飼料安全的狀況？

(2) 確定飼料實驗室聯繫網特定目標的優先順序

A. 於飼料實驗室聯繫網，什麼類型的資訊應分享或交流？

B. 是否有其他的議題應處理？

(3) 確定關鍵工作項目與運作機制

A. 試想出 1~2 個您期望未來聯繫網提供之工作服務（例如動物飼料檢驗訓練）。

B. 飼料實驗室聯繫網如何運作？（方法、規定、統籌單位(FAMIC)、推動者、參與者(會員國動物飼料的國家實驗室？或其他單位？) 是否需要職權範圍規約 (terms of reference) ？)

2.討論結果：

大部分會員國有國家實驗室，且可建立實驗室聯繫窗口代表。由 FAMIC 統籌飼料實驗室聯繫網。會員國對於該聯繫網的建議如下：資訊分享、整合實驗室方法或系統、技術支援、訓練（例如檢驗與資料分析)與制訂指引。

## 肆、OIE 結論與建議

**關注事項：**

1. 動物飼料為全球食品業之主角，將動物飼料視為食品生產鏈之一環，並透過該生產鏈各領域利害關係人之參與，以確保動物性蛋白可持續性生產、符合食品安全且價格平易近人。
2. 動物飼料方面之挑戰除須符合與日俱增的需求量外，尚須確保其安全。飼料安全為食品安全、人體健康、動物健康與動物福利之必要先決條件。
3. 由 OIE 與國際食品法典委員會 (Codex) 建立國際標準與指引，協助會員國優化飼料安全議題之處理。
4. 日本農林水產消費技術中心 (Food and Agricultural Materials Inspection Center, FAMIC) 於 2009 年被委派擔任第一個 OIE 飼料安全與檢驗合作中心，並已協助會員國改善其技術能力。

5. 追蹤 2010 年舉辦「預防飼料媒介性疾病」之飼料安全區域研討會辦理情形，該研討會係由 OIE 亞太區域代表處 (OIE Regional Representation for Asia and the Pacific, RRAP)、FAO 之亞太區動物生產及健康委員會 (Animal Production and Health Commission for Asia and Pacific, FAO-APHCA) 與 FAMIC 聯合辦理，OIE、FAO 與 FAMIC 已依據該次研討會建議，完成相關工作，另 OIE 已於 2019 年 1 月 15~16 日與 FAMIC 共同舉辦飼料安全區域研討會。
6. 動物飼料安全包含法規體系、製造管理、飼料添加抗微生物藥品作為生長促進劑之品質管制與監控機制，各會員國差異甚大，並已於本次研討會瞭解各會員國缺口與未來展望。
7. 亞太區域國家飼料檢驗實驗室之間的聯繫很重要，包含資訊分享與建立技術能力。另本次研討會已討論此聯繫網建立之目標與期望。
8. 自 2013 年起，飼料安全之重要技術能力已制訂於 OIE PVS 工具中，許多亞太地區的會員國尚未辦理 PVS 的此項評估。

#### 研討會建議：

##### 一、 建議 OIE 會員國

1. 實施 OIE 與 Codex 國際標準，並熟悉其他單位所設定的標準，如歐盟食品安全局(European Food Safety Authority, EFSA)所設定的標準，以管控動物飼料的危害物質，並更加積極參與標準設定的程序。
2. 若該國已有動物飼料法規體系，則考慮將「依據 OIE 與 Codex 國際標準，審視、更新與強化該法規體系(包含法規執行)」乙事視為必要性。
3. 若該國無動物飼料法規體系，則考慮依據 OIE 與 Codex 國際標準，制訂動物飼料法規體系。
4. 使相關利害關係人提高對於飼料安全議題的重視，此不僅係教育飼料安全的重要性，尚包含強調每個關鍵角色的責任與處理飼料使用抗微生物藥品之議題。
5. 確保農業飼養戶優良農業規範(good agricultural practices)的國家指引與飼料製造業者的優良製造規範 (good manufacturing practices, GMP)符合相關國際標準，

並編輯成冊。

6. 推廣動物飼料謹慎使用抗微生物藥品之 OIE 標準與建議。
7. 指派飼料安全國家實驗室聯繫網的聯絡人，該聯繫網將由 FAMIC 統籌。於該會員國尚未正式指派聯絡人的期間，應考慮將參加本次研討會的人員作為飼料安全國家實驗室之初期聯絡人。
8. 強化飼料法規機關與動物飼料國家實驗室之間的合作，以及強化國家動物來源食品業務窗口(focal point for animal production food safety)與飼料安全聯絡人之間的合作。
9. 各會員國審視與實施 OIE 獸醫服務體系效能評鑑 (Performance of Veterinary Services, PVS)評估後的調查結果，且必須追蹤後續辦理情形。

## 二、 建議 FAMIC

10. 持續制訂與分享危害物質資料(hazard cards)，另針對優先重要的動物飼料危害物質，核准符合目標之檢驗方法。
11. 透過籌組實作技術訓練計畫，持續提供技術支援給亞太區域會員國，訓練計畫包含優先重要的動物飼料危害物質檢驗與其他飼料安全實驗室技術能力的建立計畫，而不僅限於法規體系方面。
12. 作為 OIE 動物飼料安全與檢驗的合作中心，制訂與統籌亞太區域飼料安全實驗室聯繫網。為此，FAMIC 將草擬職權範圍規約 (Terms of Reference, ToR)給會員國，供會員國參考並於適當時機核定。

## 三、 建議 OIE

13. 持續與 FAO 合作，以推廣實施動物飼料安全國際標準與指引。
14. 考慮鼓勵 OIE 動物飼料安全與檢驗合作中心與 OIE 食品安全合作中心互相合作，以優化動物飼料安全議題的處理。
15. 持續協助會員國制訂或審視其動物飼料法規體系，例如鼓勵會員國參加 OIE 獸醫立法工作。
16. 持續與夥伴組織合作，對抗細菌抗藥性 (Antimicrobial resistant, AMR)，協助會

員國強化實驗室 AMR 檢測技術與減少 AMR。

17. 協助 FAMIC 辦理亞太區域飼料安全實驗室聯繫網與技術訓練。

18. 考慮須舉辦追蹤後續辦理情形之動物飼料安全研討會，與/或須定期舉辦相關研討會，以及須與其他夥伴組織合作。

## 伍、心得與建議

FAMIC 目前已有「建立飼料 GMP 指引」英文版草案(如附件 1)，另 FAMIC 網站有公布飼料安全法規供參(如附件 2)。FAMIC 已草擬飼料實驗室聯繫網職權範圍規約(terms of reference)草案(如附件 3)，並分享資訊。OIE 將再籌辦飼料安全研討會，並持續與相關組織(例如 FAO)合作，以制訂與推廣國際標準與準則。

OIE RRAP 區域代表獸醫官 Dr. Akinobu Kawamura 表示 OIE 目前有 8 個業務窗口(focal point)，無法再為飼料安全議題設置 1 個業務窗口，由於飼料安全屬於食品安全的一環，故飼料安全將歸屬於動物產品生產業務窗口(focal point for animal production food safety)，該國的動物產品生產業務窗口須與飼料安全部門合作與整合。此外，現場有進行問卷調查，調查每個國家的動物產品生產業務窗口是否熟悉該國飼料安全情況，許多國家的動物產品生產業務窗口並不熟悉，包含新加坡、印度、馬爾地夫、伊朗、緬甸與汶萊。日本為少數動物產品生產業務窗口係熟悉飼料安全情況的國家。

日本將 Avilamycin、Enramycin、Flavophospholipol (Flavomycin)與 Nosiheptide 等 5 項抗菌劑歸類為風險可忽略或不須進行風險評估，可作為飼料添加劑使用。而 Bicozamycin、Sulfaquinoxaline 與 Tylosin 仍在進行風險評估的階段。前揭 8 項抗微生物藥品於我國亦作為飼料添加劑使用，屬非處方用藥，惟未來將依據防疫一體科技計畫結果評估是否撤銷含藥物飼料添加物許可。

目前已有許多國家於飼料製造已具有 GMP/HACCP 制度，包含日本與泰國，可作為我國飼料主管機關未來政策參考，以提升我國飼料產業品質。提升我國飼料安全品質同時亦可提高食品安全，此為目前 OIE 關注之重要議題。

於 1 月 15 日會議中場休息時間，日本農林水產省消費安全局動物衛生課課長輔佐近藤園子向我國提醒，近期針對動物福利部分有修正相關規範，並已將此資訊傳送給我國動物福利業務窗口，期望我國給予回應表示支持或給予修正意見。

陸、附圖



圖 1. 與會國代表於東京大學彌生校區會場前合影



圖 2. 本局動物防疫組黃怡銘技士於研討會中進行專題演說



圖 3. OIE、FAO、EFSA、日本食品安全委員會與日本食品安全研究中心共同組成專家小組，針對飼料使用抗微生物藥品方面給予建議



圖 4. 分組討論

## 柒、附錄

附件一、日本「建立飼料 GMP 指引」英文版草案

附件二、日本飼料安全法規目錄

附件三、FAMIC 飼料實驗室聯繫網職權範圍規約(terms of reference)草案

附件四、與會者名單

## Establishment of the Guidelines for Feed Good Manufacturing Practice (GMP)

(June 17, 2015, Shoan 27 No. 1853, Notice of the Director-General of Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan)

(Partial amendment: April 8, 2016, Shoan 27 No. 6399)

To ensure the safety of feed, the Ministry of Agriculture, Forestry and Fisheries of Japan (hereinafter referred to as “MAFF”) has established the standards and specifications based on “[Law concerning Safety Assurance and Quality Improvement of Feeds](#)” (Act No. 35 of 1953), and business operators involved in importing, manufacturing and distribution (hereinafter referred to as “business operator”) have taken necessary measures, recognizing that they themselves have the primary responsibility to act on the food safety assurance, based on “[Food Safety Basic Act](#)” (Act No. 48 of 2003).

Recently, the approach to ensure the safety of food has been shifting from the conventional one relying on testing final products to the one putting emphasis on the process control system such as HACCP. For feed, as part of the food chain, it is important that business operators themselves introduce such a process control method in all steps from ingredients to final products to ensure feed safety more effectively and efficiently.

Therefore, the existing guidelines addressing feed safety issues in feed manufacturing have been integrated and the Guidelines of Good Manufacturing Practice (GMP) for Feed, as shown in [Attachment 1](#), has been established as a guide so that business operators themselves can introduce the basic safety control (GMP) in order to provide safe feed. Please notify the parties concerned about it.

## Attachment 1

### Guidelines for Feed Good Manufacturing Practice (GMP)

#### I. Purpose

In terms of the preventive measures against adverse effects on the health of citizens, the fundamental principle in Article 5 of the [Food Safety Basic Act \(Act No. 48 of 2003\)](#), MAFF has taken measures for feed safety based on “[Law concerning Safety Assurance and Quality Improvement of Feeds](#)” (Law No. 35 of 1953, hereinafter referred to as “Feed Safety Law”). Such measures include establishing standards and specifications for feed. At the same time, business operators, which manufacture, import, distribute, and conduct business activities, have taken necessary measures in order to assure the feed safety, recognizing that they themselves have the primary responsibility to act on the food safety assurance, based on Article 8 of the Food Safety Basic Act.

Recently, the international approach to ensure the safety of food has been shifting from the conventional method relying on testing final products to that focusing on the process control. Introduction of the HACCP system, built upon the basic hygiene practices for the production of safe food such as Good Manufacturing Practices (GMP), analyzing hazard at each process, monitoring and recording control points in manufacturing process, has now become mainstream.

In light of this stream, it is also important that business operators of feed, as a part of the food chain, introduce such a method and more effectively and efficiently ensure the safety in the entire processes from the ingredients to final products. Specifically, business operators are required to implement hygiene measures and manage facility properly based on the GMP, as well as controlling various hazards through proper control of manufacturing process and quality control activities. More specifically, preventing contamination of harmful microorganisms, including salmonella, preventing contamination of foreign matters such as metal fragments, preventing contamination of harmful chemical substances such as mycotoxins, and physical separation of animal derived proteins as a measure against bovine spongiform encephalopathy (BSE) Moreover, with feed containing antibacterial feed additives, establishing a system to ensure accurate weighing of additives and homogeneous blending is required.

The Good Manufacturing Practice (GMP) guidelines for feed, etc. (hereinafter referred to as “GMP guidelines”) is a guide so that business operators themselves can appropriately control the hazards, introduce GMP which is the basic safety control for providing safe feed, and, furthermore, introduce higher safety control based on the concepts of HACCP depending on their own actual business conditions.

#### II. Definitions

The definitions of the terms used in the GMP guidelines are as follows, including those specified in the [Feed Safety Law](#).

##### 1. Ingredients

Ingredients and materials to manufacture feed and feed additives

##### 2. Feed, etc.

Feeds, feed additives, ingredients, etc.

##### 3. Product

Feed and feed additives manufactured, including intermediate products

##### 4. Business operator

Those who manufacture, import, and distribute feed, etc.

**5. Business site**

Place handling feed, etc. out of the places where the business operator conducts its business.

**6. Type A feed**

Feed, etc. which is handled not to be contaminated with animal-derived protein, etc. because they are or may be fed to ruminants (cattle, sheep, goats, and deer; the same applies hereinafter) in a farm.

**7. Type B feed**

Feed other than Feed-A and Feed for fish.

**8. Exclusive feed for fish**

Feed manufactured in the manufacturing process, which is approved by the Minister of Agriculture, Forestry and Fisheries that meets the manufacturing standards for the feed for aquaculture which contain bovine blood meal or bovine meat and bone meal.

**9. Animal-derived protein, etc.**

The following substances and materials containing them, excluding milk, dairy products, eggs, and egg products; gelatin, collagen, and fat not derived from ruminants confirmed by the Minister of Agriculture, Forestry and Fisheries based on "[Ministerial Ordinance on the Specification and Standards of Feed and Feed additives](#)" (Ministry of Agriculture and Forestry Ordinance No. 35 of 1976, hereinafter referred to as "Ministerial Ordinance"); and special animal fat specified in the Ministerial Ordinance Appendix 1-5-(1).

- 1) Mammal derived protein
- 2) Poultry derived protein
- 3) Fish derived protein
- 4) Animal fat
- 5) Animal derived protein in food scraps
- 6) Feed additive containing substances corresponding substances 1) to 5)

**10. Antimicrobial feed additives**

Feed additives specified in the table in the [Ministerial Ordinance](#) Appendix 1-1-(1)-c

**11. Antimicrobial formulation for feed additives**

Single or combined formulation of antimicrobial substances to be incorporated in antimicrobial feed additives

**12. Manufacturing instructions**

Giving instructions to manufacturing section for manufacturing products, including the name of product to be manufactured, amount of manufacture, manufacturing sequence

**13. Lot**

A batch of products or ingredients, etc. manufactured to have homogeneity in a series of manufacturing processes in a certain manufacturing period

**14. Non-conforming products**

Products or ingredients, etc. which do not meet the specifications and standards specified in the [Ministerial Ordinance](#), etc.

**15. Cleaning**

Removal, and cleaning, as appropriate, or cleansing of residues attached to the facilities and equipment (including instruments; the same applies hereinafter) (cleansing indicates washing using detergents or other cleansing methods which are equally effective.

**16. Transportation**

Movement of feed, etc. within the facility or between facilities using aconveyer

## 17. Hazard

Substances in feed, etc. or state of feed etc. which may cause adverse effects on human or livestock health (for example, microbiological factors such as harmful microorganisms, etc., chemical factors such as pesticide residues, mycotoxins, etc., physical factors such as foreign matter contamination)

## 18. Process control standard code

Documents specifying the control method to be taken on the hazards which are evaluated as important by the hazard analysis in order to ensure the safety of feed, etc..

### III. Good manufacturing practices (GMP)

The business operator shall ensure the safety of feed, etc. by conducting the following management activities as appropriate according to the individual condition of the plant.

#### 1. Organization and employees

##### (1) Establishment of the management system

- 1) The manufacturer shall designate both process control manager and quality control manager for each business site. For the business sites appointing the feed manufacturing manager specified in Article 25, paragraph 1 of the [Feed Safety Law](#), the feed manufacturing manager can concurrently serve as the process control manager.
- 2) The manufacturing and quality control managers shall not concurrently serve as either of the two.
- 3) The manufacturer shall establish the quality control section independent of the manufacturing section.
- 4) The importer and distributor shall designate the operation control manager to develop the plan for implementation of the following items and conduct verification of the implementation status and effectiveness.

##### (2) Education and training of employees

The business operator shall set up the procedure manual on education and training and direct the previously designated person to carry out followings concerning education and training.

- 1) Providing systematic training and education, including trainings provided by FAMIC, on hygiene control, process control, or quality control for the employees.
- 2) Creating the education and training record and store the record for at least two years from the date created.

#### 2. Establishment and maintenance of facilities, etc.

The business operator shall establish the premises of the business sites, facilities, and equipment so that they meet the following standards, and direct the previously designated person to conduct the periodic inspection and maintenance so that they are maintained in the appropriate state. Also, the business operator shall create a record concerning inspection and maintenance and store the record for at least two years from the date created.

When the business operator outsources the transportation or storage operation, it shall confirm in writing that the facilities and equipment which the outsourcee use, including ships, vehicles, tanks, and carrying machines, meet the following standards (limited to those corresponding to such facilities and equipment).

##### (1) Premises and facilities

- 1) Premises including pave and shall be maintained appropriately so that habitats of pests are removed.
- 2) The structures and materials of the floors, interior walls, ceilings, etc. of the facilities shall be easy for hygiene control and maintenance.
- 3) The structure of the premises shall allow for adequate control of the entry of people to the facilities by,

for example, placing defined borders on the premises.

- 4) The premises and facilities concerning manufacturing, import, distribution, or storage of feed, etc. shall be designed to prevent cross-contamination among type A feed, type B feed and the dedicated aquaculture feed according to “[Guidelines for Prevention on cross-contamination of Animal Derived Proteins in Ruminant Feeds](#)” (Notification 15 Sho-an No.1570 of September 10, 2003 by the Director-General of Food Safety and Consumer Affairs Bureau, MAFF; hereinafter referred to as “Guidelines on ruminant feed”).
- 5) The structure shall be designed to prevent environment-origin contamination in the area for the operation process exposed to the open air, such as receiving of ingredients and filling containers. (i.e. install a ceiling over such area)
- 6) The facility shall have a separated area for eating and drinking by employees, as well as a restroom, and washroom.

## **(2) Equipment and instruments**

- 1) Equipment shall have adequate performance for the intended purpose and production volume. The structure and materials of the equipment shall be easy for hygiene control and maintenance.
- 2) Facility shall be equipped for appropriate control of lighting, ventilation, temperature and humidity.
- 3) Water used in the facility shall be microbiologically and chemically suitable for the purpose. Systems for supply and discharge such water shall be installed.
- 4) Systems to appropriately dispose drainage water and waste shall be in place.
- 5) Measures to prevent cross-contamination among type A feed, type B feed, and dedicated aquaculture feed shall be implemented according to the Guidelines on ruminant feed.
- 6) The equipment in which antibacterial feed additives or feed containing antibacterial feed additives, etc. directly contact the feed not containing antimicrobial feed additives, etc. shall be exclusively used in principle. When both feeds containing and not containing antibacterial feed additives, etc. are handled in the same equipment, the equipment shall be cleaned before handling the feed not containing antimicrobial feed additives. Effectiveness of the cleaning method in terms of removal of antimicrobial feed additives, etc. shall be validated in advance.
- 7) Measuring and dosing instruments with the appropriate measurement range shall be calibrated periodically confirmed. The accuracy and effectiveness of the mixers with regard to homogeneity shall be checked periodically.

## **3. Management of incoming ingredients, etc.**

The business operator shall implement, or direct the designated person to implement, the following measures regarding management of incoming ingredients, etc. or direct the

- (1) The business operator shall prepare clear specifications necessary to ensure the safety of feed for each incoming ingredient, etc. Contract to supply ingredients, etc. meeting such specifications shall be signed with the suppliers.
- (2) The business operator shall verify the safety of incoming ingredients, etc. and record the result of verification. The verification activities include assessing the compliance of suppliers with the GMP guidelines or the Good Agricultural Practices, etc. assessing the test results submitted by suppliers, conducting the survey or hearing on supplier’s management, or conducting tests on incoming ingredients as appropriate. When the business operator outsources the manufacturing of products and supplies ingredients, etc. to the outsourcee, the business operator shall confirm the safety of such ingredients, etc. and record the results.

#### 4. Hygiene management

The business operator shall set up the procedure manual on the following items necessary to facilitate appropriate hygiene management (hereinafter referred to as “hygiene management manual”). The process control manager, the operation control manager or the designated person shall implement hygiene management activities based on hygiene management manual. Routine check-ups on those activities shall be carried out.

When the business operator outsources the transportation or storage operation, it shall ensure in writing to the outsourcee conducting the operations that the items corresponding to such operation in the hygiene management manual are satisfied.

- 1) Employees' health status shall be recognized and routine hand washing, wearing of clean working clothes, disinfection of shoes, etc. shall be enforced among employees.
- 2) Regular cleaning and maintenance of facilities and equipment shall be carried out to maintain cleanliness. Disinfection shall be implemented as appropriate. Especially for the process in which condensation may occur, a clean and dry state shall be maintained.
- 3) Storage of ingredients, etc. and products shall be kept clean and dry state.
- 4) Items directly contacting the ingredients, etc. and products during transportation, carrying, and storage such as tanks, truck cargos, containers, wrappings and conveyers shall be dry and clean. Immersion of water or contamination of foreign matters shall be avoided.
- 5) Pest control measures such as setting traps or fumigation shall be implemented. Measures to prevent birds from entering from the opening of the facility shall be taken. (i.e. installing a bird net)
- 6) Agent to be used in cleaning, disinfection, and pest control shall be used and stored in order not to remain in the equipment for handling feed, etc.
- 7) Waste and waste water shall be managed appropriately in order not to contaminate equipment for handling feed, etc. or becoming habitats for pests.

#### 5. Process and quality controls

- (1) The business operator shall direct the process control manager of the business site (the operation control manager for an importer and a distributor) to prepare the process control procedure manual including necessary items out of the following items necessary to facilitate appropriate process control (hereinafter referred to as “process control manual”). The process control manager, the operation control manager, or the designated person shall implement process control activities based on the process control manual.

When the business operator outsources the transportation or storage operation, it shall confirm in writing that the outsourcee conducting the operations will conduct importation or storage based on the process control procedure.

- 1) When receiving ingredients, the incoming ingredients, shall be checked the conformity with the specification which have previously been contracted with the suppliers. Especially, ingredients for type A feed shall be confirmed to be managed in an appropriate manner. When receiving animal derived protein etc., it shall be confirmed to be managed in an appropriate manner by checking the label or the manifest.
- 2) Manufacturing plan, along with the manufacturing instructions and product formulation specifications shall be prepared and products shall be manufactured according to the plan. For the manufacturing process of formula feed containing antimicrobial feed additives and antimicrobial feed additives premixtures, appropriate manufacturing sequence shall be specified in the manufacturing instructions.

- 3) In all the processes from receiving of ingredients to transport of finished products, the measures against cross-contamination, including identification of ingredients and finished products using lot numbers, cleaning of the manufacturing line, air-cleaning of clothes, hands of workers, and appropriate disposal of residues shall be taken.
  - 4) Quantity of stored antibacterial feed additive premixtures shall be checked and recorded.
  - 5) Rework of products with defects shall be carried out using the method for which the safety has been validated. Information on rework including lot numbers of reworked product shall be recorded.
  - 6) The products shall be appropriately labelled. Measures against contamination during transport of type A Feed, type B feed and exclusive feed for fish shall be taken, according to the Contamination Prevention Guidelines.
  - 7) The records on manufacture shall be provided based on Article 52 of the [Feed Safety Law](#), and kept for eight years based on Article 72 of “[Ministerial Ordinance for Enforcement of the Law concerning Safety Assurance and Quality Improvement of Feeds](#)” (Ministry of Agriculture and Forestry Ordinance No. 36 of 1976).  
Moreover, the record on storage, receipt and shipments, and manufacturing control shall be kept for at least two years.
- (2) The manufacturers and importers shall develop the procedure manual on the tests, laboratory analysis and other operations on quality control which are required to confirm that the operations according to the GMP guidelines are appropriately conducted and the safety of the products is sufficiently ensured (hereinafter referred to as “quality control procedure”). The quality and operation control managers or the designated person shall conduct activities on quality control based on the quality control procedure manual.

## 6. Tests and laboratory analysis

The business operator shall develop the procedure manual on sampling methods, testing methods, interpretation of the results, and other necessary items including the following items (hereinafter referred to as “test and laboratory procedure manual”) in order to ensure safety of ingredients and the quality control operations specified in 5 (2). In case the business operator outsources the test and laboratory analysis, the business operator shall request the outsourcee to develop such manual. The designated person appointed by either the business operator or the outsourcee shall conduct activities on tests and laboratory analysis.

- 1) Collecting samples of ingredients or final products at defined intervals set by the business operator or outsourcer in line with the method stated in “[Operation Guide for Inspection of Feed, etc.](#)” (Notification 52-Chiku-B No.793 of May 10, 1977, by the Director General of Livestock Industry Bureau, Ministry of Agriculture and Forestry) and creating records of sampling. As for products containing antimicrobial feed additives, in principle, the samples shall be collected by a manufacturing lot.
- 2) Testing collected samples at business sit or external laboratories. As for feeds containing antimicrobial feed additives, including salinomycin sodium and monensin sodium, etc. described in Article 2, 2 (3) (a), a, (b) of “[Concerning the administration of the Law concerning Safety Assurance and Quality Improvement of Feeds](#)” (12 Seichiku No.1826 of March 30, 2001), the samples shall be tested and analyzed by a manufacturing lot.
- 3) A record of the results of the tests and laboratory analysis shall be provided and kept for at least two years in principle.
- 4) For manufactures, the results of the test and laboratory analysis shall be informed to the person in charge of the feed manufacturing or the manufacturing control manager in writing.

- 5) When non-conforming products are detected in the tests and laboratory analysis, or when deviations from the usual state are observed, the causes shall be investigated and the necessary measures for preventing recurrence shall be taken.
- 6) The manufacturer shall store the samples collected for the certain period which the manufacturer itself has specified in the test and inspection procedure under the appropriate storage conditions after the tests and inspections. As for the final products containing antibacterial feed additives, twice the amount of the samples required for the prescribed tests and inspections shall be stored.
- 7) The facilities and instruments to be used for the tests and inspections shall be periodically inspected and maintained and a record of the inspection and maintenance shall be created.

#### 7. Self-inspection (Internal audits)

- (1) The business operator shall develop the procedure manual concerning the self-inspection for each business site in principle, in order to check that the process and quality control are implemented steadily and effectively. The business operator shall make designated person to periodically perform the self-inspection based on such procedure. The results shall be recorded and the record for at least two years in principle.
- (2) The business operator, based on the results of the self-inspection in (1), shall take the remedial measures, when the control method is required to be improved, Activities for remedy shall be recorded and the record shall be stored for at least two years in principle.

#### 8. Actions to be taken in response to irregularity

The business operator shall develop the procedure manual concerning actions to be taken in response to irregularities including the following items, in principle, for each plant. Such irregularities include manufacture of non-conforming products and products which may cause health hazards to humans and/or livestock or the case such products may be manufactured caused by equipment troubles in the manufacturing process. The business operator shall make the manufacturing, quality, or operation control manager to take actions in accordance with the manual.

- 1) The causes of occurrence of irregularity shall be investigated and the countermeasures shall be taken.
- 2) When required, measures to improve hygiene, process control or quality management shall be taken.
- 3) Information shall be shared with the relevant business operators, including suppliers of ingredients and distributors as appropriate.
- 4) Products and ingredients with abnormality shall be appropriately handled.
- 5) Irregularity incidents shall be recorded with a summary of the incident, results of investigation and the measures for improvement, as appropriate. The record shall be kept for at least two years in principle.

#### 9. Management of customer complaints

The business operator shall develop the procedure manual concerning actions to be taken in response to customer complaints on products safety including the following items, in principle, for each plant. The business operator shall make the manufacturing, quality, or operation control manager to take actions in accordance with the manual.

- 1) The causes of complaints shall be investigated and the countermeasures shall be taken.
- 2) When required, measures to improve hygiene, process control or quality management shall be taken.
- 3) Information shall be shared with the relevant business operators, including suppliers of ingredients and distributors as appropriate.
- 4) Management of complaints shall be recorded with a summary of complaints, the results of investigation and the measures for improvement. The record shall be kept for at least two years in

principle.

## 10. Recall operation

The business operator shall develop the procedure manual for recall operation including the following item in case non-conforming products were manufactured or products might cause health hazards to humans or livestock. The business operator shall make the manufacturing, quality, or operation control manager to take actions regarding recall in accordance with the manual.

- 1) The causes of the recall shall be investigated and the countermeasures shall be taken.
- 2) When required, measures to improve hygiene, process control, or quality control shall be taken.
- 3) Information shall be shared with the relevant business operators, including suppliers of ingredients and distributors as appropriate.
- 4) Recalled product shall be appropriately handled.
- 5) Recall incidents shall be recorded with a summary of the recall, the results of investigation and the measures for improvement. The record shall be kept for at least two years in principle.
- 6) Recall incidents shall be reported to the Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, MAFF (hereinafter referred to as “Animal Products Safety Division”), in principle, through the Center.

## 11. Cooperation with government administrations and the relevant organizations

In order to ensure feed safety or respond to the incidents in which feed may compromise food safety, the business operator shall cooperate with MAFF and the relevant organizations including the Center as follows.

### (1) Registration of business operators

The business operator shall register its e-mail address with the Center in order to receive the information on the safety assurance of feed, etc. which the Center will send.

### (2) Reporting of the quantity of feed imported or manufactured

The importers and manufacturers shall report the previous year's quantity of feed imported or manufactured in the [appended form 1](#) or [2](#) to the Animal Products Safety Division by July 31 every year by e-mail, fax, etc.

When the report of such fiscal year has been already submitted to MAFF in some way, the above report shall not be required.

### (3) Collection of information on production areas

The importer shall collect and organize the relevant information which may affect the feed safety.

Such information includes extreme weather (for example, drought) in the production area, occurrence of mycotoxins during the storage or usage of pesticide for massive insect pests. Information considered to be of special importance shall be reported to the Animal Products Safety Division through the Center.

### (4) Cooperation for surveillance and monitoring

When the Center performs surveillance and monitoring based on the “annual plan of surveillance and monitoring of hazardous chemicals concerning the food safety,” etc., the business operator shall cooperate with it for those activities, including providing samples.

### (5) Providing the information on the results of tests and laboratory analysis.

When the results of the tests and laboratory analysis indicates a trend that feed safety issue might arise such as the problem might affect large area, the business operator shall provide the information to the Animal Products Safety Division or the Center.

### (6) Use the shared information

The business operator shall use the results of surveillance and monitoring and other information, etc. provided by the Animal Products Safety Division, ingredient suppliers to know the latest information

which may affect the safety of feed. If necessary, ingredient suppliers, variety of ingredients, frequency and targets of tests, etc. shall be reviewed.

#### IV. Process control based on the hazard analysis

The business operator is recommended to develop a control method base on the HACCP principle in order to effectively and efficiently reduce risks by the following procedures 1 and 2 in addition to the implementation of GMP. Control method might be selected corresponding to the manufacturing conditions including variety of ingredients, source of ingredients, variety of products, settings of establishments. This procedure can be replaced by the procedure for HACCP introduction specified in the Codex Alimentarius or the procedure specified by the food safety management systems which requires HACCP procedures.

##### 1. Hazard analysis

The business operator should prepare the list including the specifications of ingredients and the table describing the results of hazard assessment for each site.

##### 2. Process control in the critical control points

- (1) Based on the assessments provided in 1, the business operator should determine the major processes which are significant for controlling hazards and specify the control method in the process control standard code.
- (2) The business operator should establish the procedure so that the manufacture or operation control manager of such business site appropriately and smoothly perform the process control procedure specified in the process standard code and shall reflect such procedure in both the process and quality control procedure manuals specified in III. 5.
- (3) The business operator validates the appropriateness of the control method specified in (1) at sufficient frequencies.

#### V. Verification by center

If a center confirmed regarding implementing a management based on the third of GMP guideline by an application from a manufacturer or an importer in accordance with [Attachment 2](#), a certificate of verification shall be issued.

#### VI. Manufacturing process control concerning formula feed containing antibacterial feed additives and premixture of antimicrobial feed additives

The manufacturers manufacturing formula feed containing antimicrobial feed additives and premixture of antibacterial feed additives are exempted from the analysis of every manufacturing lot specified in III. 6. 2), when the Center confirms the control status, etc. of antimicrobial feed additives, according to [“Establishing the guidelines for manufacturing and quality control of formula feed containing antibacterial feed additives and compound preparation of antibacterial feed additives”](#) (Notification 18 Shoan No. 13845 of April 10, 2007, by Notice of the Director-General of Food Safety and Consumer Affairs Bureau, MAFF) or when the Center confirms the control status, etc. in accordance with GMP guideline by the fifth.

(Appended form 1)

## Report of manufacturing quantity of feed, etc. (Fiscal Year YYYY)

Date: YYYY/MM/DD

To Person in Charge of Feed Inspection Instruction Group, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan (FAX: 03-3502-8275)

Name of Company: \_\_\_\_\_  
 Person in charge : \_\_\_\_\_  
 Zip code : \_\_\_\_\_  
 Contact Address : \_\_\_\_\_  
 Phone : \_\_\_\_\_  
 E-mail address : \_\_\_\_\_

Table 1 Feed

Category		Name of kind of feed	Manufacturing quantity (ton) <sup>1)</sup>
Single feed	Feed A <sup>2)</sup>		
	Other than Feed A		
Mixed feed	Feed A <sup>2)</sup>		
	Other than Feed A		
Formula feed	Feed A <sup>2)</sup>		
	Other than Feed A		

Table 2 Feed Additives

Category	Name of kind of feed additives	Manufacturing quantity (ton) <sup>1)</sup>
Feed A <sup>2)</sup>		
Other than Feed A		

&lt;&lt; Instructions for filling out the above &gt;&gt;

- 1) For manufacturing quantity, round off the figure if the accurate total figure has not been obtained.
- 2) “Feed A” means feed used for ruminant (cattle, sheep, goats, and deer) (including those shared for other livestock).
- 3) If the space for entry is not large enough, use an additional paper.

DRAFT

(Appended form 2)

Report of import quantity of feed, etc. (Fiscal Year YYYY)

Date: YYYY/MM/DD

To Person in Charge of Feed Inspection Instruction Group, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries of Japan (FAX: 03-3502-8275)

Name of Company : \_\_\_\_\_  
 Person in charge : \_\_\_\_\_  
 Zip code : \_\_\_\_\_  
 Contact Address : \_\_\_\_\_  
 Phone : \_\_\_\_\_  
 E-mail address : \_\_\_\_\_

Table 1 Feed (grass hay and main grain)

Category	Name of exporting country	Number imported	Import Quantity (ton) <sup>1)</sup>
Grass hay			
Corn			
Milo			
Rye			
Oats			
Other wheat and barley			

Table 2 Feed (Excluding those reported in Table 1)

Category		Item	Number imported	Name of exporting country	Import Quantity (ton) <sup>1)</sup>
Single feed	Feed A <sup>2)</sup>				
	Other than Feed A				
Mixed feed	Feed A <sup>2)</sup>				
	Other than Feed A				
Formula feed	Feed A <sup>2)</sup>				
	Other than Feed A				

Table 3 Feed Additives

Category	Item	Number imported	Name of exporting country	Import Quantity (ton) <sup>1)</sup>
Feed A <sup>2)</sup>				
Other than Feed A				

<< Instructions for filling out the above >>

- 1) For import quantity, round off the figure if the accurate total figure has not been obtained.
- 2) "Feed A" means feed used for ruminant (cattle, sheep, goats, and deer) (including those shared for other livestock).
- 3) If the space for entry is not large enough, use an additional paper.

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## Attachment 2

### Verification procedure based on guideline for Feed Good Manufacturing Practice (GMP)

#### I. Verification procedure

- 1 An importer and manufacturer (hereafter referred to as “applicant”) whose feeds or feeds additives (hereafter referred to as “feeds, etc.”) are to be confirmed that a management is implemented in accordance with the guideline for Feed Good Manufacturing Practice (GMP) (Hereinafter referred to as “guideline”) shall apply to Food and Agricultural Materials Inspection Center (FAMIC) Director (hereafter referred to as “center”) for the confirmation. The manufacturer shall apply to every manufacturing sites.
- 2 As for the application of the first (1), an applicant shall pay a necessary expense to the center in accordance with a rule defined by the center.
- 3 When there is an application of the first (1) from an applicant, the director of the center shall determine if the applicant meets the criteria by carrying out a field inspection and shall provide the applicant with a notice of the result of the determination. If it meets the criteria of the third (3), a certificate of the verification shall be issued.  
As for a manufacturer, a field inspection shall be carried out in every manufacturing sites and shall be a notice of the determination result and a certificate of the confirmation.  
Also, if the center confirmed that it clearly meets the part of criteria of the third (3) such as an applicant obtains a private certification with respect to Food Safety Management System (FSMS), etc., a part of the field inspection related to the verification can be omitted.
- 4 When it no longer comply with the verification criteria, an operator who received the verification of the director of the center with respect to meeting the verification criteria shall notify that effect to the director of the center with the 3 certificates of the verification. If an operator didn't renew and the effective period was expired, the same shall apply.
- 5 When an operator who received a verification no longer meet a verification criteria, the director of the center shall be able to cancel the verification.
- 6 An effective period of a verification shall be 3 years.

#### II. Intermediate verification

- 1 An operator who received a verification by the first (1) must apply for an intermediate verification by the center every year or shorter period during a new verification or from a renewal to next renewal.  
When there was an application of the first (1), the director of the center shall carry out a field inspection and determine if the conformity status is maintained by confirming, etc. a description content of a book and a record, and shall notify the applicant of the result.
- 2 When there was an application of the first (1), the director of the center shall carry out a field inspection and determine if the conformity status is maintained by confirming, etc. a description content of a book and a record, and shall notify the applicant of the result.
- 3 As for a verification of an operator who didn't apply for an intermediate verification based on a rule of the first (1), it shall be deemed to be expired the effective period without 5 of the first (1).

#### III. Criterion of verification

##### 1 Matter to Organization and employees

Meeting III. 6 (1) and (2) of the guideline and following points

**(1) Matter to establishment of management system**

- 1) An organization chart, etc. described belongings, positions, names and work contents is prepared and a role and an authority of a manufacturing control manager, a quality control manager or a business management officer is specified.
- 2) A manufacturing control manager, a quality control manager or a business management officer carries out with respect to a hygiene control, a process control, and a quality control for his/her self in accordance with the guideline or let a person who was designated in advance carry out the work.

**(2) Matter to Education and training of employees**

- 1) In the procedure manual of education and training, a purpose, a content, a method of implementation and record, etc. are described. Also, a plan document which specifies object persons, etc. concretely is prepared.
- 2) A manufacturing control manager, a quality control manager, a business management, or its designated person takes the training of [Feed Safety Law](#), etc. which is held outside more than once per year as a general rule.

**2 Matter to Establishment and maintenance of facilities, etc.**

Meeting 2 of the third (3) of the guideline and following points

**(1) Premises and facility**

- 1) A subject of inspection and maintenance of a facility, a method of inspection and maintenance, a frequency, a person in charge, and a method of record are specified.
- 2) From a perspective of a pollution control of a facility, a site boundary line, a restricted area for vehicles, and an off-limits are designated as needed. Also, in order to prevent microbial contamination, the controlled area and the other areas are designated separately as needed and a maintenance of cleanliness in a clean area is confirmed by a periodical testing and inspection, etc.
- 3) Types of feeds (type A feed, type B feed, or dedicated aquaculture feed) which are used in a site and each area in facilities are identified.
- 4) From a perspective of a pollution control derived from an environment, an operation process and a place which feeds, etc. are to be exposed to the outside air are identified.

**(2) Matter to facilities and devices**

- 1) A subject of inspection and maintenance of a facility, a method of inspection and maintenance, a frequency, a person in charge, and a method of record are specified.
- 2) If a clean area is designated, a facility which is required a management in facilities and devices in the clean area from a perspective of preventing prevent microbial contamination.
- 3) A feed-water and drainage equipment and its place are identified. Also, if a water source other than water supply and sewerage systems is used, check if the water (which is used) is suitable for the use. A facility and a place for disposing waste water and waste are identified.
- 5) Types of feeds (type A feed, type B feed, or dedicated aquaculture feed ) which are used in each facility are identified.
- 6) A facility (including a combined facility) which directly touches an antimicrobial feed additive or a feed, etc. which includes the additive is identified. Also, check if a facility (equipment) which adds and mixes an antimicrobial feed additive is operated normally.
- 7) Types, numbers, installation locations, weighing ranges, and weighting accuracy of the installed weighing instruments are clarified and a method of inspection and maintenance is specified.  
Types, numbers, installation locations, of the installed a compounding mixer are clarified and a method of inspection and maintenance is specified.

An inspection of a mixed precision of a compounding mixer which mixes an antimicrobial feed additive is implemented more than once per year.

### 3 Matter to management of incoming ingredients, etc.

Meeting 3 of the third (3) of the guideline and following points

- (1) A validity of the standards, etc. of incoming ingredients, etc is confirmed and the standard, etc. is reviewed as needed, and the contract is re-signed.
- (2) A method of a safety confirmation by each incoming ingredients, etc is specified. Also, a method of confirmation of management conditions with respect to a supplier of materials, etc. is specified in advance.

A compliance status of the standard, etc. of materials, etc. which is to acquire is periodically checked by a test verification, etc.

### 4 Matter to hygiene management

(1) Meeting 4 of the third (3) of the guideline and following points

- 1) In the procedure hygienic management manual, a concrete control method, a person in charge, and a method of records, etc. are described.
- 2) A control method of entrance and exit of gowning and disinfection of shoes, etc. is specified according to hygienic conditions which is required by each work area.
- 3) A process and a place which are required disinfections are identified and a method of a disinfection and an applied drug are specified. In the process, measures against condensation and points where measures against consolidation/retention are heavily implemented are specified, and a control method and a preventive measures against commingling of a deterioration by consolidation/retention with a product are specified.

No occurrence of microbial contamination at the points is checked by a periodical testing and inspection.

- 4) A place which tends to occur pollution by harmful birds and mammals and pests is identified and a control method, a person in charge, a method of record, a confirmation method of effectiveness of measures.
- 5) From a perspective of prevention of commingling of harmful materials with feeds, etc., drugs which are used for measuring against cleaning, disinfection, harmful birds and mammals and pests are identified, how to use drugs, etc., a method of storage, a person who is in charge, and a method of record of use are specified.

These drugs, etc. are stored by a designated method in a designated place.

- 6) In a facility where feeds, etc. related to wastes and discharged water are dealt, measures to prevention of commingling, storage area and method of wastes are specified.
- Wastes and dirty water are not allowed to be disposed in other than places such as designated area and a facility.

(2) A method of verification is specified in advance, reviews, etc. of the procedure manual are conducted an improvement based on the verification result as needed.

### 5 Matter to process control and quality control

(1) Meeting 5-1 of the third (3) of the guideline and following points.

- 1) In the process control manual, a concrete control method, a person in charge, and a method of records, etc. are described.
- 2) A confirmation procedure when receiving materials is specified.
- 3) A confirmation method whether a manufacturing instruction, a preparation method of a combination

ratio table, etc., a person in charge, a method of determination of a manufacturing order of feeds, etc. including antibacterial feed additive, and a combination table, etc. meet the criteria/standard specified by law is specified. The prepared combination ratio table, etc. meet the criteria/standard specified by law is specified.

- 4) Measures to a cross-contamination of type A feed, type B feed, and dedicated aquaculture feed , measures to a cross-contamination when feeds which includes and don't include antimicrobial feed additive are dealt, and measures to cross-contamination with respect to materials and products are specified.
  - 5) A confirmation method of quantity of stock, etc. of antimicrobial feed additive, a person responsible, a person in charge, and a method of records, etc. are specified. A confirmation of quantity of stock, etc. of antimicrobial feed additive is implemented every day.
  - 6) A confirmation method of safety when reprocessing is specified in advance.
  - 7) A preparation procedure of a display sheet, a confirmation method of a person in charge, a confirmation method that a proper display is implemented and a handling method, etc. of a display sheet which is no longer needed.
  - 8) As for a book based on Article 52 of the [Feed Safety Law](#), a stock of materials, a manufacture of product, a status of shipment are described in association with each other by lot numbers, etc.
- (2) Meeting 5-2 of the third (3) of the guideline and following points.
- 1) In the procedure manual of a quality control, work contents, a person in charge, and a method of records are described.
  - 2) Preparation procedure of a quality control planning which is set out a timing of implementation, a frequency, a subject, and a method, etc. with respect to a quality control including a test and inspection is specified.
  - 3) Check that a content of antibacterial feed additive in feeds which include antibacterial feed additive meets the criteria/standard specified by law by a periodical test and inspection, etc.
  - 4) Check that measures to a cross-contamination of type A feed, type B feed, and dedicated aquaculture feed and measures to a cross-contamination when feeds which includes and don't include antimicrobial feed additive are dealt, and measures to a cross contamination of materials and products, etc. function effectively by a periodical test and inspection, etc.  
In the manufacturing of feeds, etc. which include antimicrobial feed additive, if a process of a pressurized heating treatment is included, check the effect on antimicrobialfeed additives in products in advance.
- (3) A verification method of process control and quality control are specified in advance, reviews, etc. of the procedure manual are conducted improvement based on the verification result as needed.

#### 6 Matter to test and laboratory analysis

Meeting 6 of the third (3) of the guideline and following points.

- (1) In the procedure manual of a test and an inspection, including a case of an outsourcing, a specimen collection, a method of implementation of the test and the inspection, a practitioner, a person in charge, a judging method of the result, a corresponding method based on the result, a storage method of a specimen, a method of a record, etc. are described.
- (2) As for a test and an inspection which to be implemented, a validity of their methods is confirmed.

#### 7 Matter to a self-inspection

Meeting 7 of the third (3) of the guideline and following points.

- (1) In the procedure manual of the self-inspection, a person in charge for the self-inspection, a

practitioner, an inspection content, an implementation time, a method of a record, etc. are described.

- (2) Based on the self-inspection, reviews, etc. of the procedure manual are conducted an improvement based on the verification result as needed.

#### 8 Matter to actions to be taken in response to irregularity

Meeting 8 of the third (3) of the guideline and following points.

- (1) In the procedure manual of response to abnormal situations, a situation and an evaluation criteria which are applied the procedure manual of response to abnormal situations, a contact and information sharing system, a handling method for products, etc which are found abnormality, a system of investigation to the cause, a method of a record, etc. are described.

- (2) As a remedy based on the result of the investigation to the cause, a review of the procedure manual, etc is implemented as needed.

#### 9 Matter to management of customer complaints

Meeting 8 of the third (3) of the guideline and following points. In the procedure manual of response to claim handling, a response procedure, a contact system, a handling method for products, etc. which are subjects of claims, a system of investigation to the cause, a method of a record, etc. are described.

#### 10 Matter to recall operation

Meeting 10 of the third (3) of the guideline and following points.

In the procedure manual of handling of recall, a procedure for handling of recall, a contact system, a storage method of recalled items, an identifying method, a method of a record, etc. are described.

#### 11 Matter to cooperation with the government and related institutes

Meeting 11 of the third (3) of the guideline and following points.

Email address which is registered on the center is updated.

### IV. Exemption from control method of antimicrobial feed additives

In a business site where a formula feed containing antimicrobial feed additives or a antimicrobial feed additives premixtures is produced, if it was confirmed by the director of the center based on the first (1), analysis by a production lot of feeds including salinomycin- sodium monensin sodium, lasalocid sodium, calcium halofuginone polystyrene sulfonate, semduramicin sodium, or narasin which are implemented by methods specified in “Regarding enforcement of ministerial ordinance, etc. revising a part of ministerial ordinance on the specification and standards of feed and feed additives (on September 5, 1978 53 Livestock B No. 2173, 53 Promotion of the fisheries No. 464 collective note of the Ministry of Agriculture, Forestry and Fisheries, the Director of Livestock/ the Secretary of Fisheries Ministry”, “Regarding enforcement of ministerial ordinance, etc. revising a part of ministerial ordinance on the specification and standards of feed and feed additives (on July 6, 1983 58 Livestock B No. 1676, note of the Ministry of Agriculture, Forestry and Fisheries, the Director of Livestock”, “Regarding enforcement of ministerial ordinance, etc. revising a part of ministerial ordinance on the specification and standards of feed and feed additives (on October 15, 1985 60 Livestock B No. 2928, collective note of the Ministry of Agriculture, Forestry and Fisheries, the Director of Livestock/ the Secretary of Fisheries Ministry”, “Regarding enforcement of ministerial ordinance, etc. revising a part of ministerial ordinance on the specification and standards of feed and feed additives (on December 25, 1987 62 Livestock B No. 3099, collective note of the Ministry of Agriculture, Forestry and Fisheries, the Director of Livestock/ the Secretary of Fisheries Ministry”, “Regarding enforcement of ministerial ordinance, etc. revising a part of ministerial ordinance on the specification and standards of feed and feed additives (on June 3, 1991 3 Livestock B No. 1113, collective note of the Ministry of Agriculture, Forestry and Fisheries, the Director of Livestock/ the Secretary of Fisheries Ministry”, “Regarding enforcement of ministerial ordinance,

etc. revising a part of ministerial ordinance on the specification and standards of feed and feed additives (on July 18, 1994 6 Livestock B No. 1012, note of the Ministry of Agriculture, Forestry and Fisheries, the Director of Livestock/”, and “Regarding enforcement of ministerial ordinance, etc. of revising a part of ministerial ordinance on the specification and standards of feed and feed additives (on December 19, 2001 13 Livestock B No. 4573, collective note of the Ministry of Agriculture, Forestry and Fisheries, the Director of Livestock/ the Secretary of Fisheries Ministry” shall be exempted.

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[Note]

This English translation of this guideline has been prepared up to the revisions of Notice 27 Shoan No. 6399 of 2016.

This is an unofficial translation. This is to be used solely as a reference to aid in the understanding of Japanese guideline. Food and Agricultural Materials Inspection Center is not responsible for the accuracy, reliability, or currency of the legislative material provided on this website, or for any consequence resulting from use of the information on this website. For all purposes of interpreting and applying the law to any legal issue or dispute, users are advised to consult the original Japanese texts.

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## Regulatory Frameworks to ensure Feeds Safety in Japan

### 1. "Law Concerning Safety Assurance and Quality Improvement of Feeds"

– Provisional translation

[Law](#)

[Ministerial Ordinance on the Specifications and Standards of Feeds and Feed additives](#)

### 2. Regulation on chemicals in feed

– [Pesticides residues](#)

[Application for Import tolerance](#)

– Contaminants

[Heavy metals](#)

[Mycotoxins](#)

[others](#)

### 3. Regulation on GM feed

– [Outline of regulation on GM feed](#)

– [Approval procedure for GM feed in Japan](#)

– [The list of approved GM feeds and GM feed additives](#)

### 4. Feed regulation on BSE prevention

### 5. Others

– Provisional Translation

[Guideline for Ensuring Safety of Feeds Using Food Residues, etc.](#)

[Establishment of Evaluation Criteria for Feed Additives](#)(External Link)

July 6<sup>th</sup>, 2015

MAFF (Ministry of Agriculture, Forestry and Fisheries)

Food Safety and Consumer affairs Bureau,

Animal Products Safety Division

FAMIC (Food and Agricultural Materials Inspection Center)

- Regulation on feed safety in Japan is regularly revised on scientific knowledge

- See [the FAMIC web site](#) for the latest regulation.

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## Information

### Harmful Chemical Substances in Feed

[Abstract](#)

[Results](#)

### Research Report of Animal Feed (links to PDF files)

[No.43 \(2018\)](#) **NEW**

[No.42 \(2017\)](#)

[No.41 \(2016\)](#)

[No.40 \(2015\)](#)

[No.39 \(2014\)](#)

[No.38 \(2013\)](#)

[No.37 \(2012\)](#)

[No.36 \(2011\)](#)

[No.35 \(2010\)](#)

[No.34 \(2009\)](#)

[No.33 \(2008\)](#)

[No.32 \(2007\)](#)

### Hazard Card

[Introduction](#)

[Livestock Poisoning Diagnostic Manual Online Version](#)

[Mycotoxins](#)

[Endophyte toxins](#)

### Analytical Standards of Feeds, etc.

Notice : These English versions of the Analytical Standard of Feeds and other documents are prepared to meet the needs of the non-Japanese speaking people.  
When and if any discrepancy arises between the latest Japanese original and its English translation, the former is authentic.

[Method for sampling](#)

[Sample preparation](#)

[Mycotoxins](#)

[Dioxins](#)

## 亞太區飼料安全實驗室聯繫網

### 職權範圍規約草案 (Draft Terms of Reference)

#### 背景說明：

動物飼料為全球食品業之主角且為食品生產鏈之一環，透過該生產鏈各領域利害關係人之參與，以確保動物性蛋白可持續性生產、符合食品安全且價格平易近人。動物飼料方面之挑戰除須符合與日俱增的需求量外，尚須確保其安全。確保飼料安全之品質為食品安全、人體健康、動物健康與動物福利之必要先決條件。因此，動物飼料實驗室區域聯繫網之資訊分享與技術能力之建立顯得相當重要。飼料實驗室聯繫網案已於 OIE 之 2019 年 1 月飼料安全區域研討會提出並討論。

#### 聯繫網之角色與責任：

- 定期交流動物飼料安全資訊
- 針對亞太區域影響動物飼料安全之議題或挑戰，定期分享與審視
- 提供飼料分析之技術支援

#### 聯繫網之組織結構：

- 組織管理單位 (Secretariat)：農林水產消費安全技術中心 (Food and Agricultural Materials Inspection Center，簡稱 FAMIC)

#### 一、會員：

- 動物來源食品安全之業務窗口 (Focal point for animal production food safety) 向組織管理單位表達有興趣參與者。
- 由 OIE 代表(OIE Delegate)或業務窗口(Focal point)提名之動物飼料國家實驗室。

#### 二、觀察員：

- 一旦其他的會員同意，聯繫網會考慮新增納入其他的實驗室或專家。

#### 聯繫網機制：

- 一旦亞太區域超過 7 個 OIE 會員國同意加入此聯繫網，則啟動聯繫網機制。
- 組織管理單位(FAMIC)將為聯繫網設立專門的網站，並管理其內容，網址為 <http://www.famic.go.jp/english/index.html>。
- 組織管理單位將促進會員、OIE、FAO 及其他成員之動物飼料安全議題交流。
- 當組織管理單位請求提供資料時，會員將定期提供報告。
- 鼓勵會員透過聯繫網，分享任何相關之技術文件。
- 若須審視聯繫網之職權範圍規約 (Terms of Reference)時，則會進行審視。

**OIE Regional Workshop on Animal Feed Safety  
Tokyo, Japan, 15-16 January 2019**

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