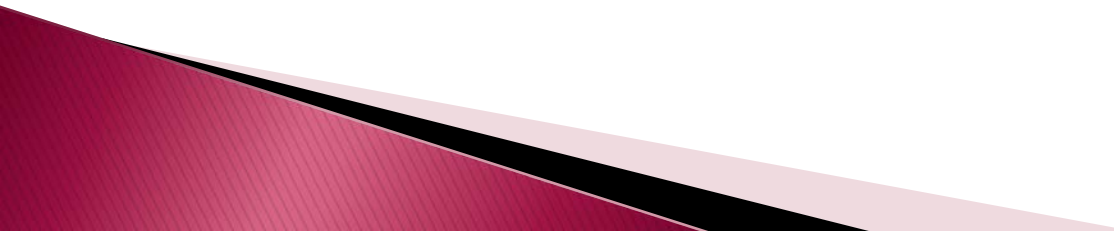


Actions taken by JMAFF related to risk management of AMR

2016.6.22

NVAL: National Veterinary Assay Laboratory

Contents

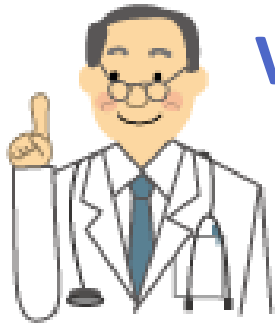
1. Antimicrobials for Livestock
 2. Risk management Measures based on Risk Assessments
 3. National Action Plan on AMR of Japan (2016–2020)
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1. Antimicrobials for Livestock

Antimicrobial Veterinary Drugs for Livestock

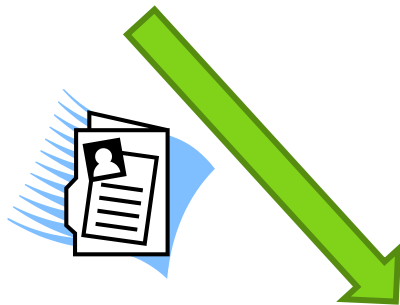
- Legal base : The Pharmaceuticals and Medical Devices Law
 - ⇒ regulates approval, marketing, distribution and usage of the drugs to improve public health and hygiene.
- Main points :
 - Approved only after deliberation on quality, efficacy and safety by Pharmaceutical Affairs Council
 - Require diagnosis by a veterinarian before prescribing antimicrobials
 - Licensed retailers sell only to farmers with a prescription by a veterinarian
 - Should be used in accordance with regulations on the use based on the Law
 - e.g.) appropriate dosages, withdrawal periods, target animals, etc.

Antimicrobial Veterinary Drugs for Livestock



Veterinarian

Issue the prescription
based on the result of
diagnosis



Livestock Farmer

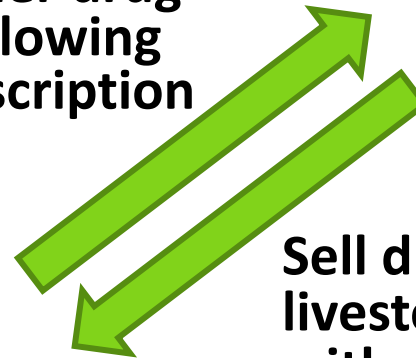


Use in accordance with
regulations on usage of drugs

Licensed Retailer



Order drug
following
prescription



Sell drugs only to
livestock farmers
with prescriptions
by veterinarians

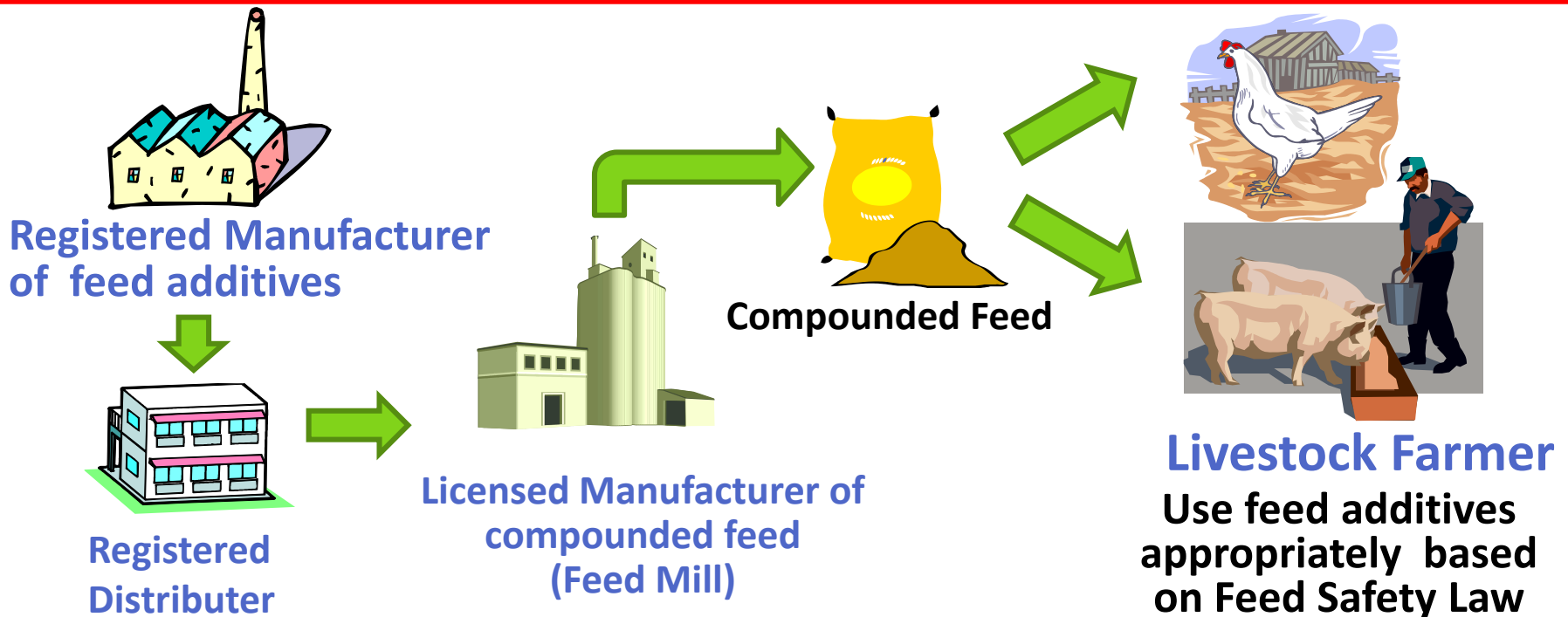


Antimicrobial Feed Additives for Livestock

- Legal base : The Law Concerning Safety Assurance and Quality Improvement of Feeds
 - ⇒ promotes healthy development of livestock animals through the efficient use of nutritional ingredients in feed.
- Main points :
 - Antimicrobial feed additives are designated after deliberation on effectiveness and safety for livestock animals by the Feed Council
 - A substance should not be designated as a feed additive if it could compromise the effectiveness of antimicrobial medicines to treat infectious diseases in humans
 - Should be used in accordance with the standards set by the Law (e.g.) amount added, animal species, growth stage, etc.
 - Current status
 - 24 antimicrobial feed additives designated
 - 23 revoked due to the possibility of resistant bacteria or no sales prospect, etc.
e.g.) Avoparcin (similar to Vancomycin in chemical structure)

Antimicrobial Feed Additives for Livestock

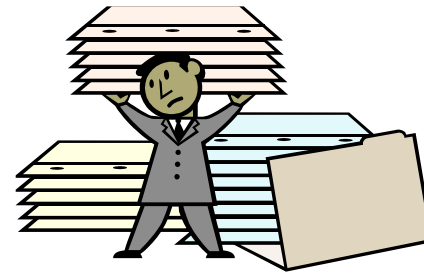
- Antimicrobial feed additives are used in a limited way under the MAFF regulation on amount in feed, target livestock species and growth stages etc., based on the Feed Safety Law.
- MAFF has revoked the designation of some antimicrobial feed additives due to possible risk of resistant bacteria or no sales prospect, etc.
e.g.) Avoparcin (Antibiotics similar to Vancomycin in chemical structure)



2. Risk management Measures based on Risk Assessments

Risk assessment by FSC for antimicrobials

- MAFF requests FSC (Food Safety Commission) for risk assessment on the effect of food on **human health** regarding antimicrobial-resistant bacteria selected by antimicrobial use in livestock animals



- FSC established the assessment guideline for AMR http://www.fsc.go.jp/senmon/hisiryuu/taiseikin_hyoukasisin_english.pdf
- FSC conducts risk assessment based on scientific findings in line with the guideline

Risk assessment by FSC for antimicrobials

- The result of risk assessment is described in qualitative terms, e.g.) “high”, “medium”, “low” or “negligible”

【Veterinary Drugs】

As of April 2016

- Estimated as Medium (4 items)
e.g.) Fluoroquinolones for cattle and swine
- Estimated as Low (3 items)
e.g.) Pirlimycin for daily cow
- No need of risk assessments because those items are considered not to select resistant bacteria (1 item)
- Estimated to be negligible (1 items)
- In process (9 items)



【Feed additives】

- Estimated to be negligible (9 items)
Monensin, Nosiheptide, Semduramisin, Lasalocid, Salinomycin, Narasin, Flavophospholipol, Avilamycin, Enramycin
- No need of risk assessments because those items are considered not to select resistant bacteria (4 items)
Nicarbazin, Amprolium, Ethopabate, Morantel
- In process (11 items)

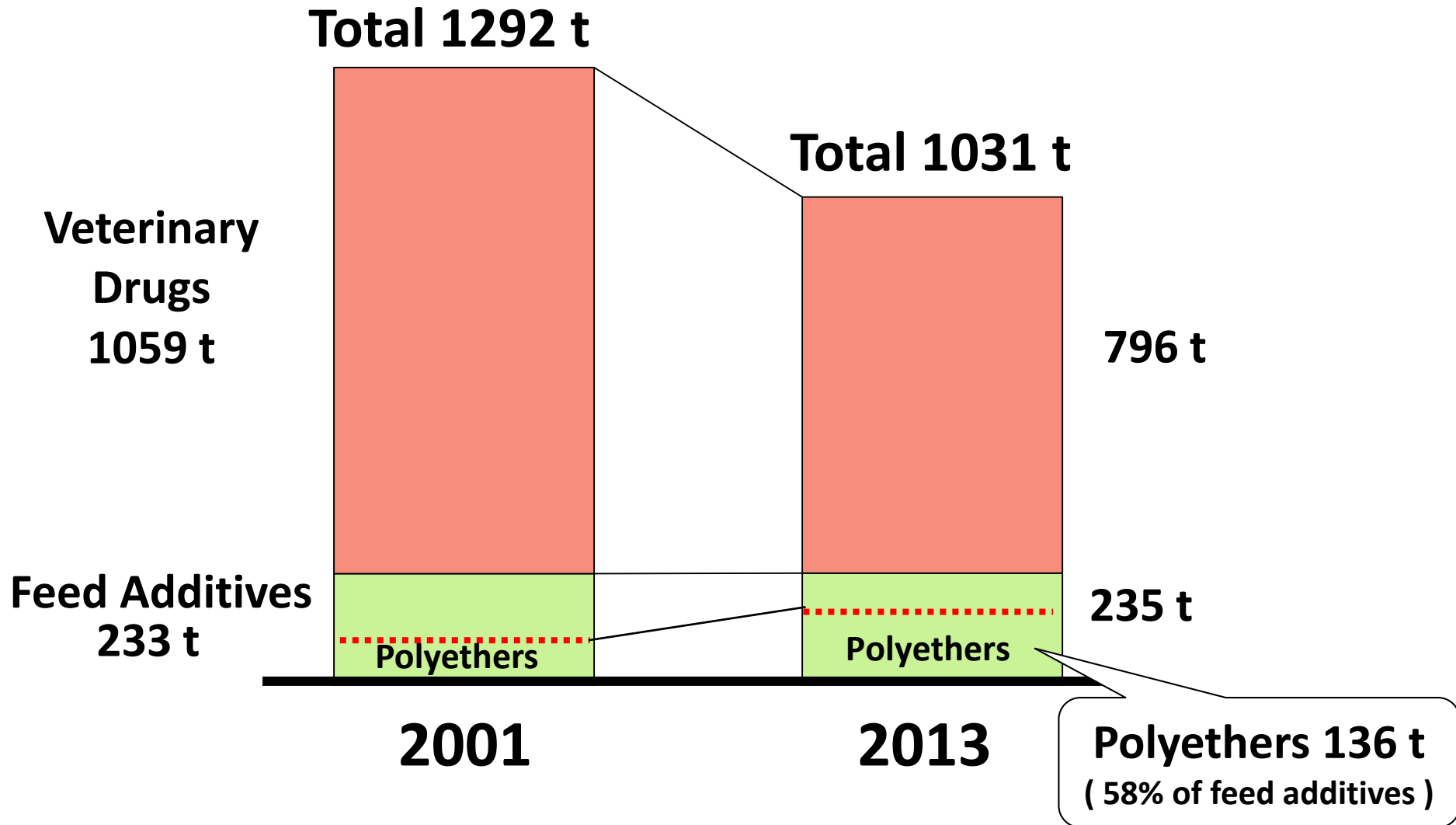
Risk management for antimicrobials

Risk management measures based on the result of risk assessment by FSC

Risk estimation	Examples of risk management	
	Veterinary drugs	Feed additives
High	Revocation of approval Temporary ban of use	Revocation of designation
	Restriction of the usage	Restriction of target animal species
Medium	Shortening of applicable periods	Shortening of applicable periods
	Strict use as a second choice drug Enhancing monitoring (e.g. increasing number of samples)	Enhancing monitoring (e.g. increasing number of samples)
Low	Continued monitoring	Continued monitoring
Negligible		

The Use of Antimicrobials for animals (including food producing animals and companion animals)

Monitoring of the quantities of antimicrobials used in animal husbandry estimated on a basis of sales/production quantities.



Monitoring System (JVARM)



Monitoring antimicrobial resistant bacteria since 1999 in the Japanese Veterinary Antimicrobial Resistance Monitoring System (JVARM)

- Target bacteria: Indicator (*Escherichia coli*, *Enterococcus spp.*), Zoonotic bacteria (*Salmonella spp.*, *Campylobacter spp.*)

➤ MAFF

- Design risk managements and provide the data for risk assessments to FSC



Report

➤ NVAL (National Veterinary Assay Laboratory)

➤ FAMIC (Food and Agricultural Materials Inspection Center)

- analyze and evaluate data
- Research into molecular epidemiology, resistance mechanism

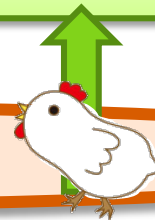
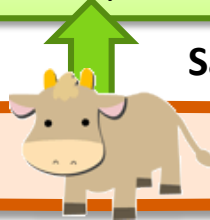
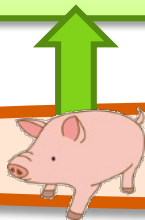


Isolated bacteria, Data

➤ Prefectural livestock Hygiene Service Center (170 centers)

- Collect feces on farms, isolate and identify bacteria, and measure MIC

➤ Farms (till 2015)



Samples

MAFF has added the monitoring of samples collected from slaughterhouses since 2012.



JVARM Report



A Report on the Japanese Veterinary
Antimicrobial Resistance Monitoring
System
-2008 to 2011-

National Veterinary Assay Laboratory
Ministry of Agriculture, Forestry and Fisheries
2013

JVARM has started collaboration with JANIS (Japan Nosocomial Infectious Surveillance: AMR surveillance for human health sector) in order to establish the integrated surveillance system recommended by WHO based on One Health Approach.

Prudent Use Guidelines for veterinary antimicrobials

Main Points

Established in 2013

i) Prevent infection

It is essential to prevent infection by appropriate management of feeding, sanitation and vaccines.



- The standards of Rearing Hygiene Management
- The guidelines on good hygienic practice

ii) Definite diagnosis

Identify the cause of infection and determine treatment measures based on definite diagnosis by a veterinarian



iii) Effective use of antimicrobials

- Choose effective antimicrobial drug with chemical sensitivity test.
- Fluoroquinolones, 3rd generation cephalosporins etc. should be used only as second choice drug, only if first choice drug has no effect



iv) Share information

Share info about AMR bacteria among the relevant parties

Summary

- AMR should be **considered comprehensively** with regard to human health, animal health, food hygiene, etc..
- It is important to decide the appropriate risk management strategy **based on the scientific risk assessments**.
- It is essential to **evaluate the efficacy of each risk management option** continuously after implementation and revise them if needed.

3. National Action Plan on AMR of Japan (2016–2020)

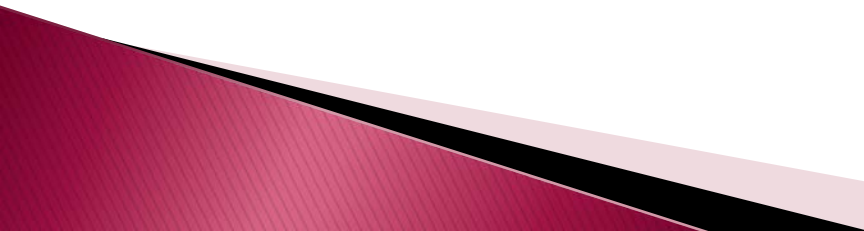
- ▶ **Global Action Plan on AMR (WHO, May 2015)**
(http://www.who.int/drugresistance/global_action_plan/en/)
- ▶ **National Action Plan on AMR of Japan (2016–2020) (April 2016)**
(<http://www.who.int/drugresistance/action-plans/library/en/>)
- ▶ **G7 Niigata Agriculture Ministers' Meeting Declaration (April 23 to 24, Japan)**
(http://www.japan.go.jp/g7/_userdata/common/data/g7_declaration.pdf)
- ▶ **G7 Ise-Shima Leaders' Declaration (G7 Ise-Shima Summit, 26–27 May 2016)**
(<http://www.japan.go.jp/g7/summit/documents/>)

Outline of National Action Plan on AMR (2016–2020) of Japan (Decision of the Ministerial Meeting)

- ▶ The national action plan sets goals, strategies and specific approaches in following 6 fields.

1. Public Awareness and Education
2. Surveillance and Monitoring
3. Infection Prevention and Control
4. Appropriate use of antimicrobials
5. Research and Development
6. International cooperation

Key Actions in animal sector

1. Strengthen risk management measures such as promoting prudent use of antimicrobials
 2. Strengthen surveillance and monitoring of AMR under one health approach including establishing a monitoring system for companion animals.
 3. Promote the expanded and strengthened involvement of experts in the use of veterinary antibiotics for farm-raised aquatic animals
 4. Promote international cooperation particularly in the Asia-Pacific region
- 

Role of NVAL in AMR management

- ▶ NVAL is the OIE Collaborating Center for Diagnosis and Control of Animal Diseases and Related Veterinary Product Assessment in Asia.
- ▶ NVAL is recognized as a core AMR laboratory of animal sector in Japan by the National Action Plan on AMR
- ▶ In collaboration with the OIE, NVAL will promote international cooperation by holding international seminars concerning surveillance and monitoring, as well as the VICH Outreach forum.

Thank you for your attention!



If you need more detailed information about JVARM, please refer to our website.

<http://www.maff.go.jp/nval/english/>

