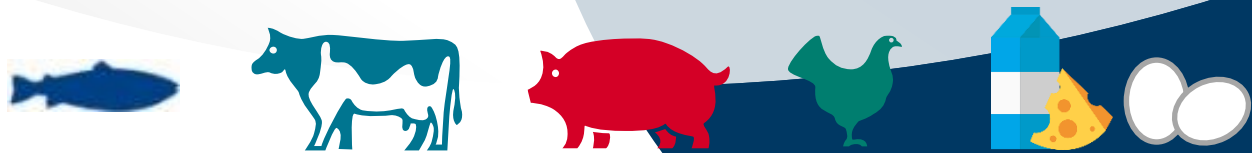


Safety Control Measures for Residues in Livestock and Fishery Products

Introduction of PLS for Residues for Livestock and Fisheries Products

September 15, 2021

**Ministry of Food and Drug Safety
Hazardous Substances Standard Division**



Contents

- 1 Rationale for Residue Safety Control**
- 2 Status of Veterinary Drugs Standard Setting and Future Plans**
- 3 Introduction of PLS for residues for livestock and fishery products**





1 Rationale for Residue Safety Control

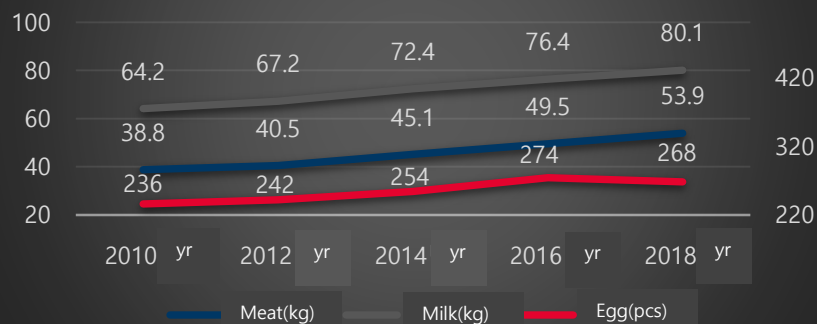


Increased Production and Imports of Livestock and Fishery Products Due to Increased Consumption



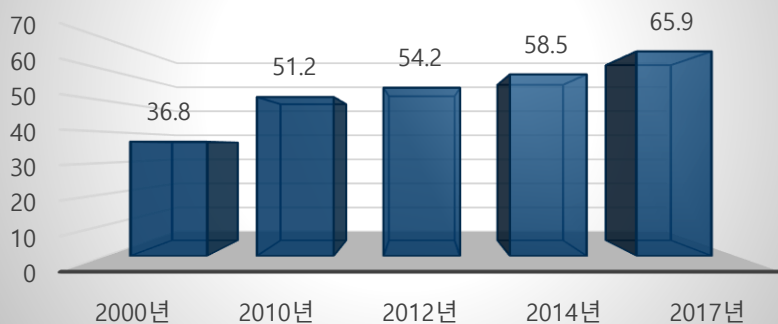
식품의약품안전처

Annual consumption of livestock products per person (Kg & pcs)



Source: Key Statistics on Agricultural, Forestry, and Livestock Products in 2009 released by Ministry for Food, Agriculture, Forestry and Fisheries

Annual consumption of fishery products per person (Kg)



Source: Statistics System by Ministry of Oceans and Fisheries

Consumption of fishery products per person per day by country



Source: Korea Economic Daily, Nov. 2015

뉴스 홈 > 경제 1,819 Posted : 2016-02-14

한국이 일본 제치고 수산물 소비 세계 1위



Korea ranks first in fishery products consumption.

More imports of livestock and fishery products due to increased trade (e.g., FTAs)

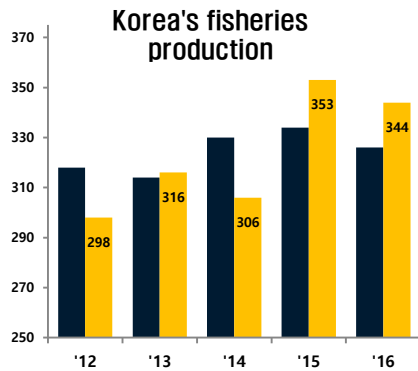
- (Livestock products) Imports: ('09) 2.7 trillion won → ('14) 6.2 trillion won → ('19) 8.7 trillion won
- (Fishery products) Imports: ('09) 3.2 trillion won → ('14) 5.0 trillion won → ('19) 5.5 trillion won

Increased Use of Veterinary Drugs

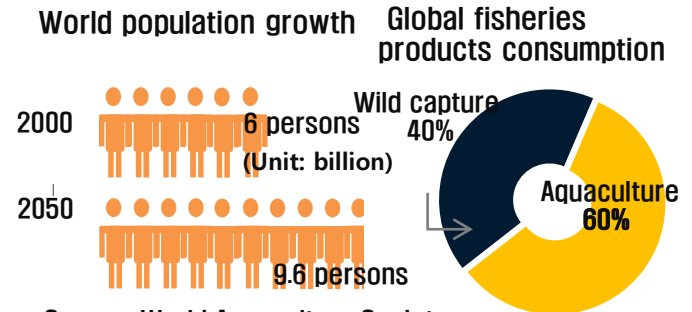
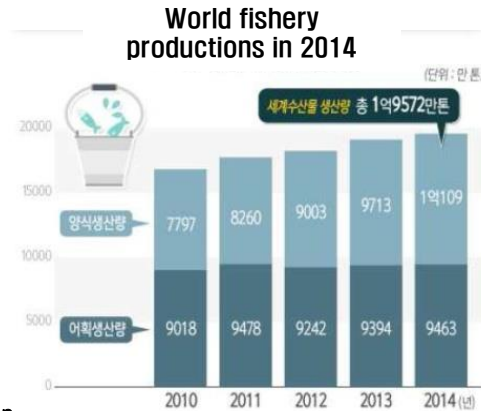


식품의약품안전처

Continuous increase in aquaculture (Source: Ministry of Oceans and Fisheries)



■ Capture production (1,000 tons) ■ Aquaculture production (million)



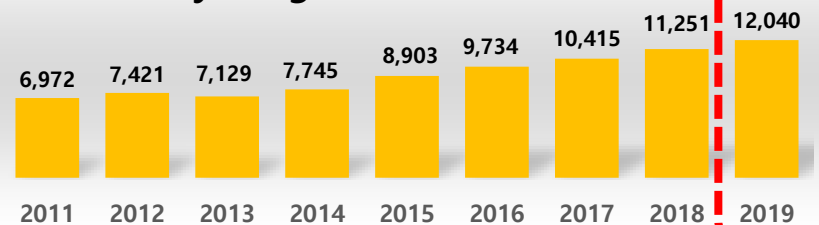
Source: World Aquaculture Society

Factors for industrial development (e.g., increased livestock and fisheries production)

- Breeding
- Improvement in husbandry
- Development of farming equipment
- Improved feed quality
- Vaccine development
- **Development of veterinary drugs**

Sales increase in Korean veterinary drugs

Veterinary drugs sales (KRW 100 million)



Veterinary Drug Safety Control System



식품의약품안전처

Managing Authorities

Licensing and production management

1. Article 85 of the Pharmaceutical Affairs Act and the Agricultural and Marine Products Quality Control Act

- Ministry of Agriculture, Food and Rural Affairs, Ministry of Oceans and Fisheries, and National Fishery Products Quality Management Service

2. Rules for handling veterinary drugs, etc.

- Animal Quarantine Agency and National Institute of Fisheries Science

Managing veterinary drug residues in food

1. The Food Sanitation Act, the Livestock Products Sanitary Control Act,

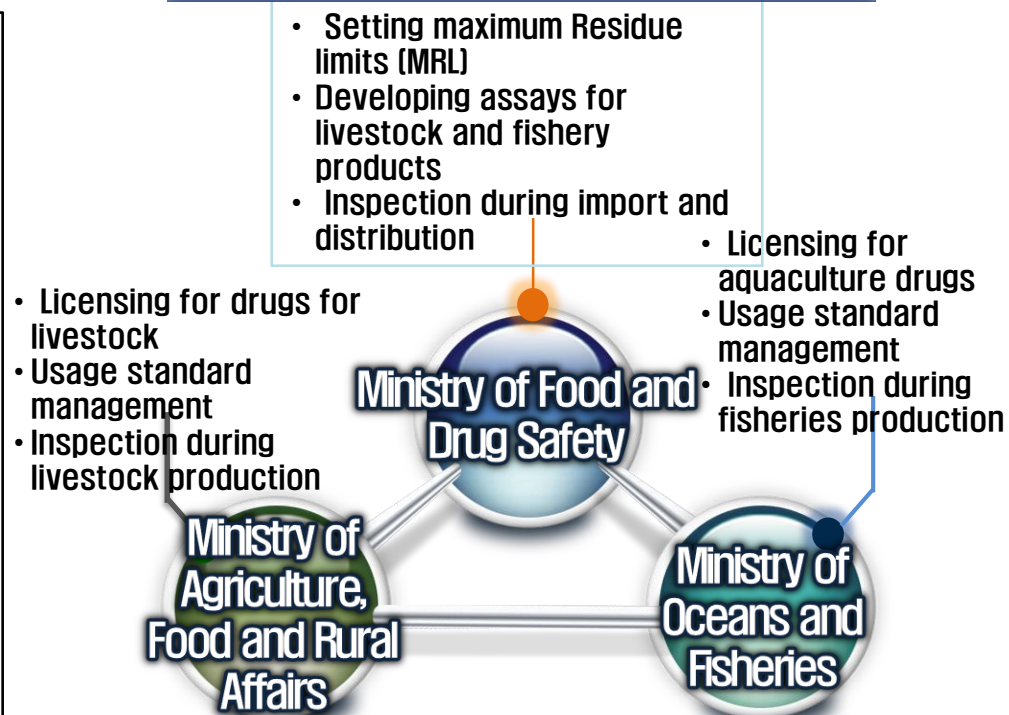
the Agricultural and Marine Products Quality Control Act

- Ministry of Food and Drug Safety (MFDS)

2. Food standards and specifications (Food Code)

- MFDS and National Institute of Food and Drug Safety Evaluation

Inter-agency coordination



Basis for Setting MRLs for Veterinary Drugs

◎ Licensing, manufacturing, importing, and marketing veterinary drugs

The Pharmaceutical Affairs Act (law)

Article 85 (Exceptions to Drugs, etc. for Animals)

(2) With respect to drugs for animals used for the treatment or prevention of animal's diseases, the Minister of Agriculture, Food and Rural Affairs or the Minister of Oceans and Fisheries may determine standards for use of animal drugs, such as animals for which such drugs are used, direction, dosage, and the period banning its use If the drugs falling under any of the following subparagraphs:

1. drug products designated as ones that may stay in an animal's body and inflict danger or injury to human health
2. drug products designated to be administered or used for the purpose of infectious disease control for livestock or aquatic animals

The Rules for Handling Veterinary Drugs, etc. (ordinance of the Ministry of Agriculture, Food and Rural Affairs)

Article 10-2 (Conditions for Product Approval)

The Director of the Animal and Plant Quarantine Agency or the National Institute of Fisheries Science ... must attach the condition for manufacture or import of veterinary drugs that they must be manufactured or imported for marketing after the MRLs have been set for the drugs and specify the condition in the statement of approval in Form 8.

Article 14 (Compliance Matters for the Manufacturers)

9. Veterinary drugs for which conditions have been attached pursuant to Article 10-2 shall be manufactured and marketed after MRL is established.

◎ Procedures for establishing MRLs for veterinary drugs

The Food Sanitation Act (law)

Article 7 (Standards and Specifications concerning Foods or Food Additives)

- (1) The Minister of Food and Drug Safety shall determine and **publicly announce** the following matters concerning foods or food additives for sale, if necessary **for public health**:

Article 7-3 (Request, etc. for Establishment of Maximum Residue Limits of Pesticides, etc.)

- (1) Any person who **needs the establishment of maximum residue limits** of pesticides under the Pesticide Control Act that remain on or in food, or veterinary drugs under the Pharmaceutical Affairs Act shall **file an application with the Minister of Food and Drug Safety**.

The Enforcement Rule of the Food Sanitation Act (ordinance of the Prime Minister)

Article 5-2 (Establishment of Maximum Residue Limits of Pesticides or Veterinary Drugs)

- (1) Any person who **wants to file an application for establishment of a maximum residue limit** for a pesticide or a veterinary drug in food (hereinafter referred to as “MRL”) pursuant to Article 7-3 (1) of the Act shall submit the **application for MRL establishment** (including electronic application) in Form 1 to **the Minister of Food and Drug Safety**.

Basis for Setting MRLs for Veterinary Drugs

『 Standards and Specifications for Foods 』 (Notice of the Ministry of Agriculture, Food and Rural Affairs)

[Annex 7] Guidelines on Establishing Maximum Residue Limits of Pesticides and Veterinary Drugs In Food

Article 3 (Scope of Application) Pesticides and veterinary drugs subject to establishment of maximum residue limits for food pursuant to Article 7 (1) of the Act are as follows:

(1) Domestic food

1. Domestically registered pesticides and veterinary drugs
2. [Pesticides and veterinary drugs for which an application for domestic registration has been filed](#)
3. Pesticides that require establishment of MRL as they have been used in the past or remain in the environment for a long time
4. [Other pesticides and veterinary drugs recognized as necessary by the Minister of Food and Drug Safety](#) (hereinafter referred to as “MFDS”)

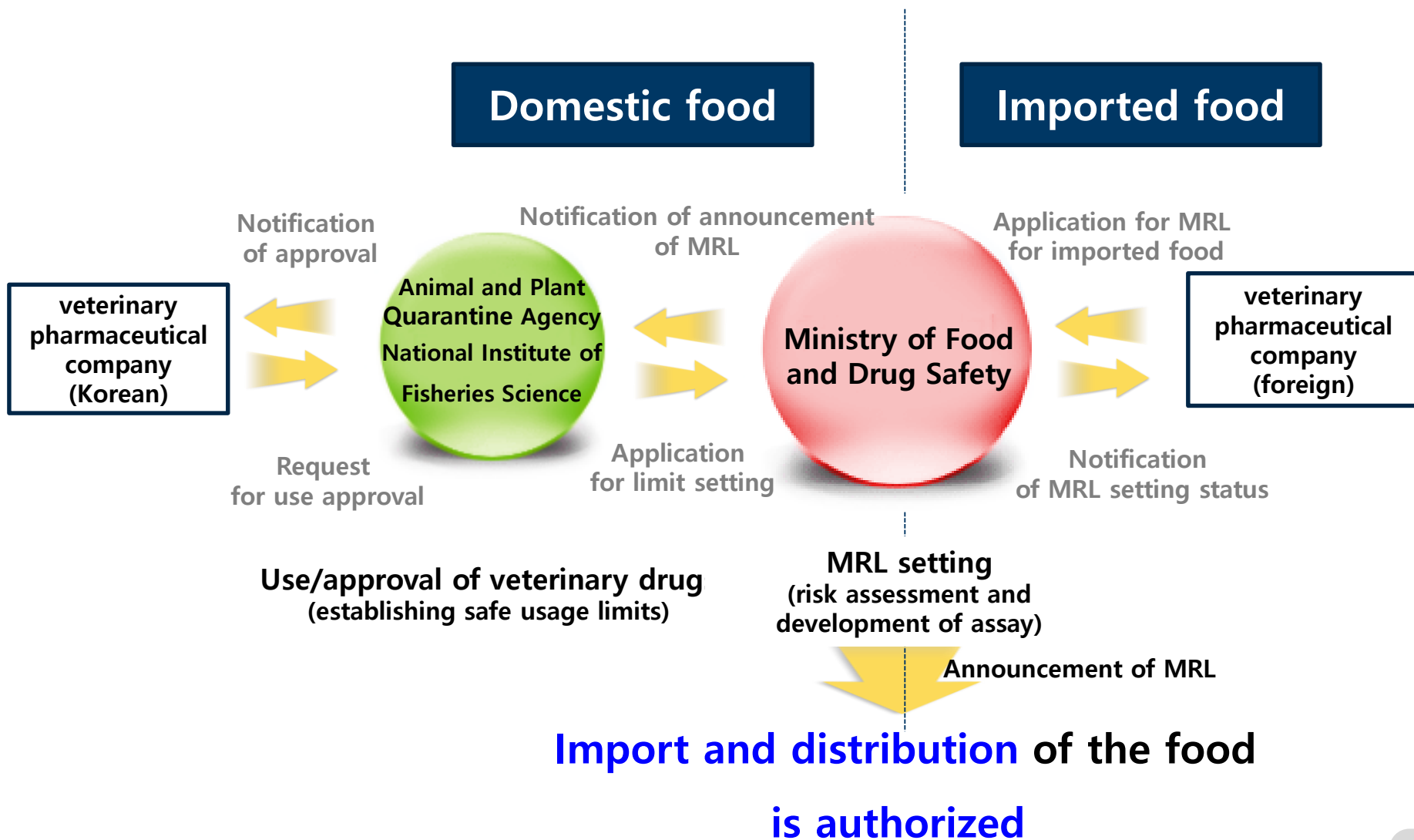
(2) Imported food

1. [Pesticides and veterinary drugs that have not been registered in Korea, but are registered and have their maximum residue limits established overseas](#)
2. Pesticides that require establishment of MRL as they have been used in the past or remain in the environment for a long time
3. [Other pesticides and veterinary drugs recognized as necessary by the Minister of Food and Drug Safety](#) (hereinafter referred to as “MFDS”)

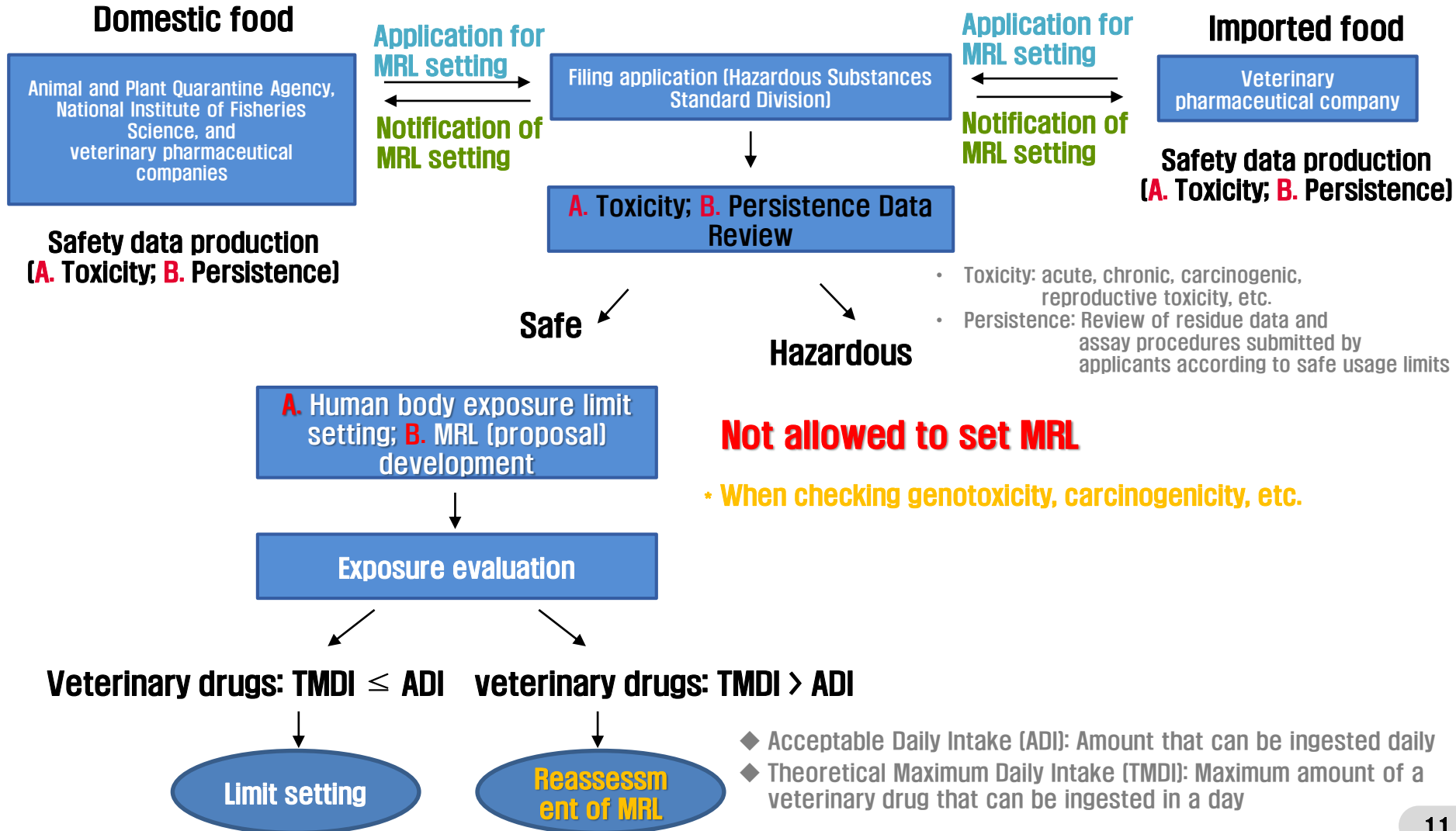
Procedures for Establishing MRLs for Veterinary Drugs



식품의약품안전처



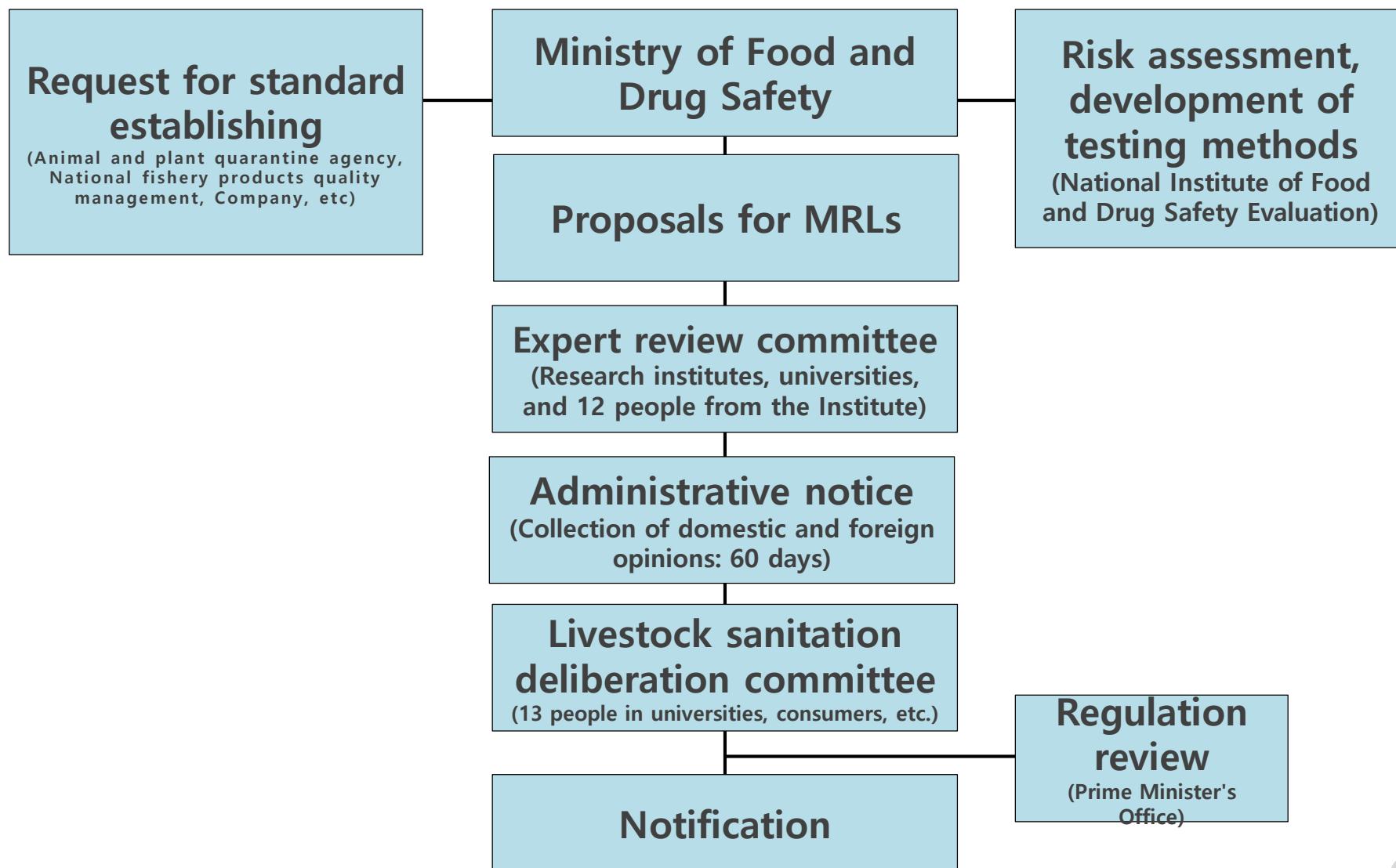
Flowchart on Veterinary Drug MRL Setting



Procedures for notification of MRLs for veterinary drugs



식품의약품안전처





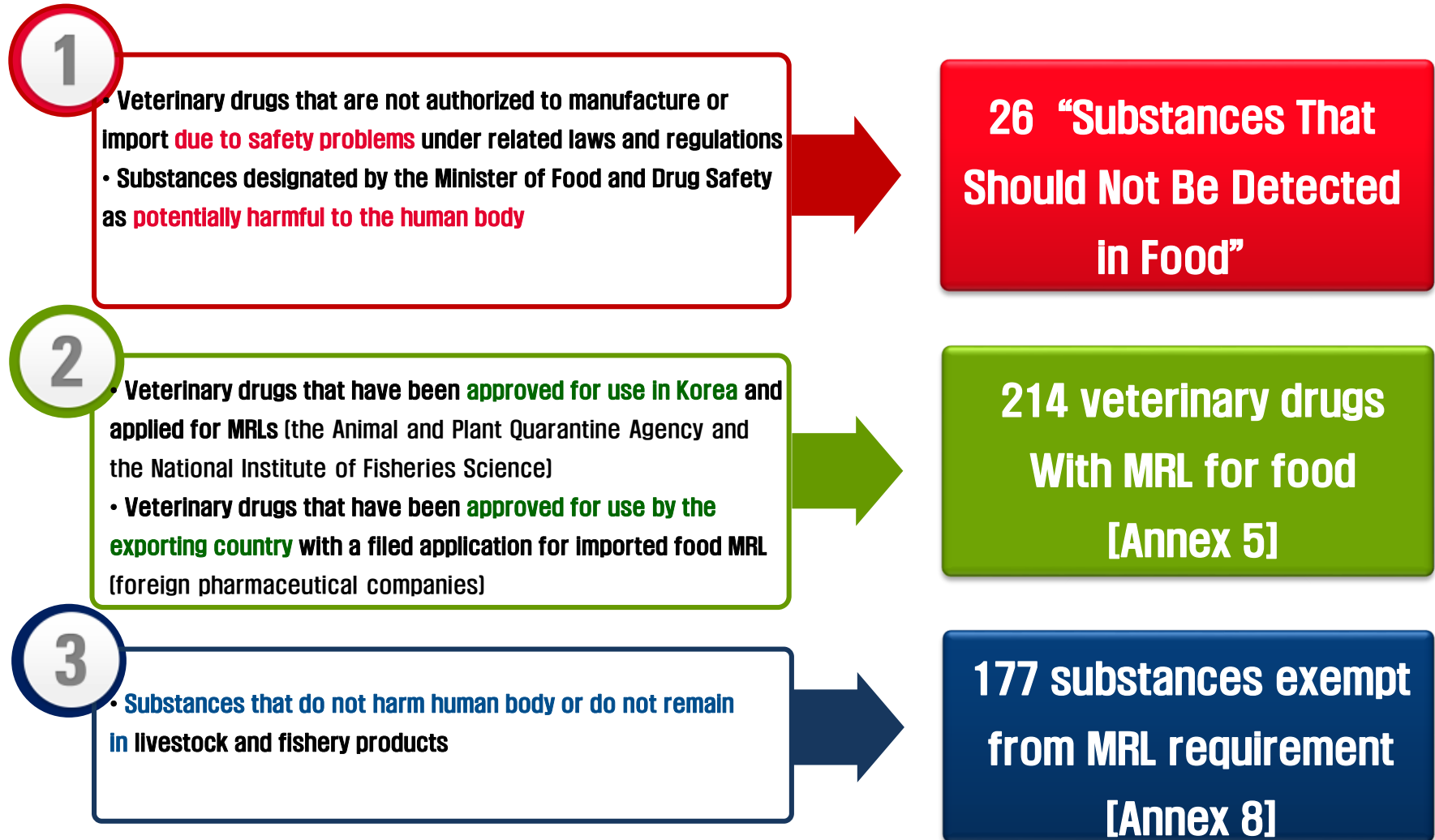
2

Status of Veterinary Drugs Standard Setting and Future Plans



Status of MRL Setting for Veterinary Drugs

Food standards and specifications (Food Code)



Food standards and specifications (Food Code 2021)

Food Code

2021



Ministry of Food and
Drug Safety



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Food standards and specifications (Food Code)

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Substances That Should Not Be Detected in Food

Food Code 8) MRLs for veterinary drugs

(1) Application of MRLs for veterinary drug residue in food

(1) **Veterinary drugs that are not authorized to manufacture or import because they are identified as having safety problems according to laws and regulations and the substances designated by the Minister of Food and Drug Safety as potentially harmful to the human body should not be detected.**

The key substances subject to this clause are as follows, and this clause can be applied to substances not specified below in accordance with applicable laws and regulations.

- Applicable regulations: Regulations on Drug Products Containing Substance with a Safety or Efficacy Problem (Notices of the Animal and Plant Quarantine Agency and the National Institute of Fisheries Science)

Substances That Should Not Be Detected in Food



식품의약품안전처

No	Substances That Should Not Be Detected in Food ¹	
	Substance Name	Definition of Residue
1	Nitrofurans	
	– Furazolidone	3-Amino-2-oxazolidinone(AOZ)
	– Furaltidone	3-Amino-5-morpholinomethyl-2-oxazolidinone (AMOZ)
	– Nitrofurazone	– Semicarbazide (SEM): Applicable only to the edible part of unheated livestock products and animal fishery products (including simple cutting, excluding crustaceans) – Nitrofurazone: Applicable only to crustaceans
	– Nitrofurantoin	1-Aminohydantoin(AHD)
	– Nitrovin	Nitrovin
2	Carbadox	Quinoxaline-2-carboxylic acid (QCA)
3	Olaquinox	3-methyl quinoxaline-2-carboxylic acid (MQCA)
4	Chloramphenicol	Chloramphenicol
5	Chlorpromazine	Chlorpromazine
6	Clenbuterol	Clenbuterol
7	Colchicine	Colchicine
8	Dapsone	Summed total of dapsone and monoacetyl dapson
9	Diethylstilbestrol (DES)	Diethylstilbestrol
10	Medroxyprogesterone acetate (MPA)	Medroxyprogesterone acetate
11	Thiouracil	Summed total of 2-thiouracil, 6-methyl-2-thiouracil, 6-propyl- 2-thiouracil and 6-phenyl- 2-thiouracil
12	GentianViolet (Crystal violet	Summed total of gentian violet and leuco -gentian violet
13	Malachite green	Summed total of malachite green and leuco-malachite green

Substances That Should Not Be Detected in Food



식품의약품안전처

No	Substances That Should Not Be Detected in Food ¹	
	Substance Name	Definition of Residue
14	Methylene Blue	Summed total of methylene blue and azure B
15	Dimetridazole	Summed total of dimetridazole and 2-hydroxymethyl-1-methyl-5-nitroimidazole(HMMNI)
16	Ipronidazole	Summed total of Ipronidazole and 1-methyl-2-[(2'-hydroxyisopropyl)-5-nitroimidazole (Ipronidazole-OH)]
17	Metronidazole	Summed total of metronidazole and 1-(2-hydroxyethyl)-2-hydroxymethyl-5-nitroimidazole(Metronidazole-OH)
18	Ronidazole	Summed total of ronidazole and 2-hydroxymethyl-1-methyl-5-nitroimidazole(HMMNI)
19	Norfloxacin	Norfloxacin
20	Ofloxacin	Ofloxacin
21	Pefloxacin	Pefloxacin
22	Pyrimethamine	Pyrimethamine
23	Vancomycin	Vancomycin
24	Roxarsone	Roxarsone
25	Arsanilic acid	Arsanilic acid
26	Salbutamol	Salbutamol ('effective on April 1, 2022)

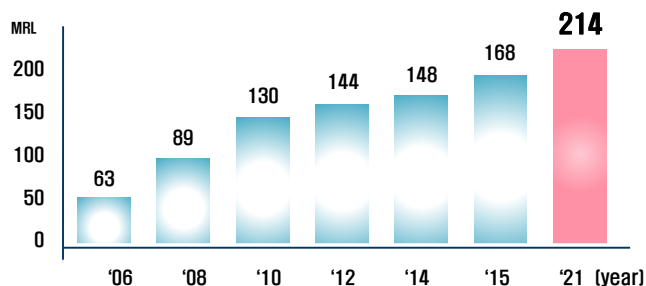
* Note 1. Applicable to livestock and animal fishery products and processed foods only.

MRLs for Veterinary Drug Residues in Food

Food Code 8) MRLs for veterinary drugs

(2) MRLs for veterinary drug residues in food are shown in [Annex5].

Status of Korean veterinary drug MRLs



Type of livestock	MRL	Total
Livestock products	Antimicrobial (90), anthelmintic (25), insecticide (20), growth supplement (9), sedative (6), nonsteroidal anti-inflammatory(12), steroid anti-inflammatory(4), antiprotozoal (22), antihistamine (2), antidiarrheal (3), other (12)	205
Fishery products (fish)	Antimicrobial (46), anthelmintic (2), insecticide (3), antiprotozoal (1), sedative (1), other (1)	54
Honey	Antimicrobial (4), anthelmintic (1), insecticide (5)	10

Status of foreign veterinary drug MRLs

	Korea	CODEX	Japan	EU	US
MRL	214	68	170	140	93

- Completion of MRL setting for **veterinary drugs authorized for use in Korea**
- MRL setting for **veterinary drugs that require MRLs based on information on risks available in Korea and overseas**

MRLs for Veterinary Drug Residues in Food



식품의약품안전처

MRLs for individual food items

● The food Standards and Specifications [Annex 5] are applied.

- ✓ For each veterinary drug, the MRL for **the specific item is applied**.

e.g., Gentamicin: beef muscle (0.1 mg/kg), beef liver (2.0 mg/kg), and carp, flounder, and trout (0.1 mg/kg)

Food items not listed in [Annex 5]

● By-products

- ✓ Edible parts such as internal organs, bones, head, tail, feet, skin, blood, fish roes and intestines of fishery products
- ✓ Livestock products: MRL for **the muscle** of the animal is applied.
- ✓ Fishery products: MRL for **fish** is applied.

● Processed food

- ✓ **MRL for the raw material** is applied according to its content (considering water content).

● Royal jelly and propolis

- ✓ MRL for **honey** is applied.

Food items with no listed MRL in Food Code

(1) Application of CODEX limits

- ✓ When CODEX limits have been established for the veterinary drugs for the same types of livestock and for the same drug item

(2) Application of the lower limit for the parts in the limits for similar edible animals

- ✓ Ruminant animals (e.g., cattle and sheep) and horses (non-ruminant animals): minimum levels for the pertaining parts of ruminant animals
- ✓ Non-ruminant animals (pigs): minimum levels for the pertaining parts of non-ruminant animals
- ✓ Poultry, fish, crustaceans: minimum levels for poultry, fish, and crustaceans
- ✓ (e.g., Gentamicin: mudfish → carp (0.1 mg/kg))

(3) Application of 0.03 mg/kg of antibacterial except (1) and (2)

- ✓ Livestock and fishery products (including milk, eggs, fish oil, and fish roes) and honey (including royal propolis)

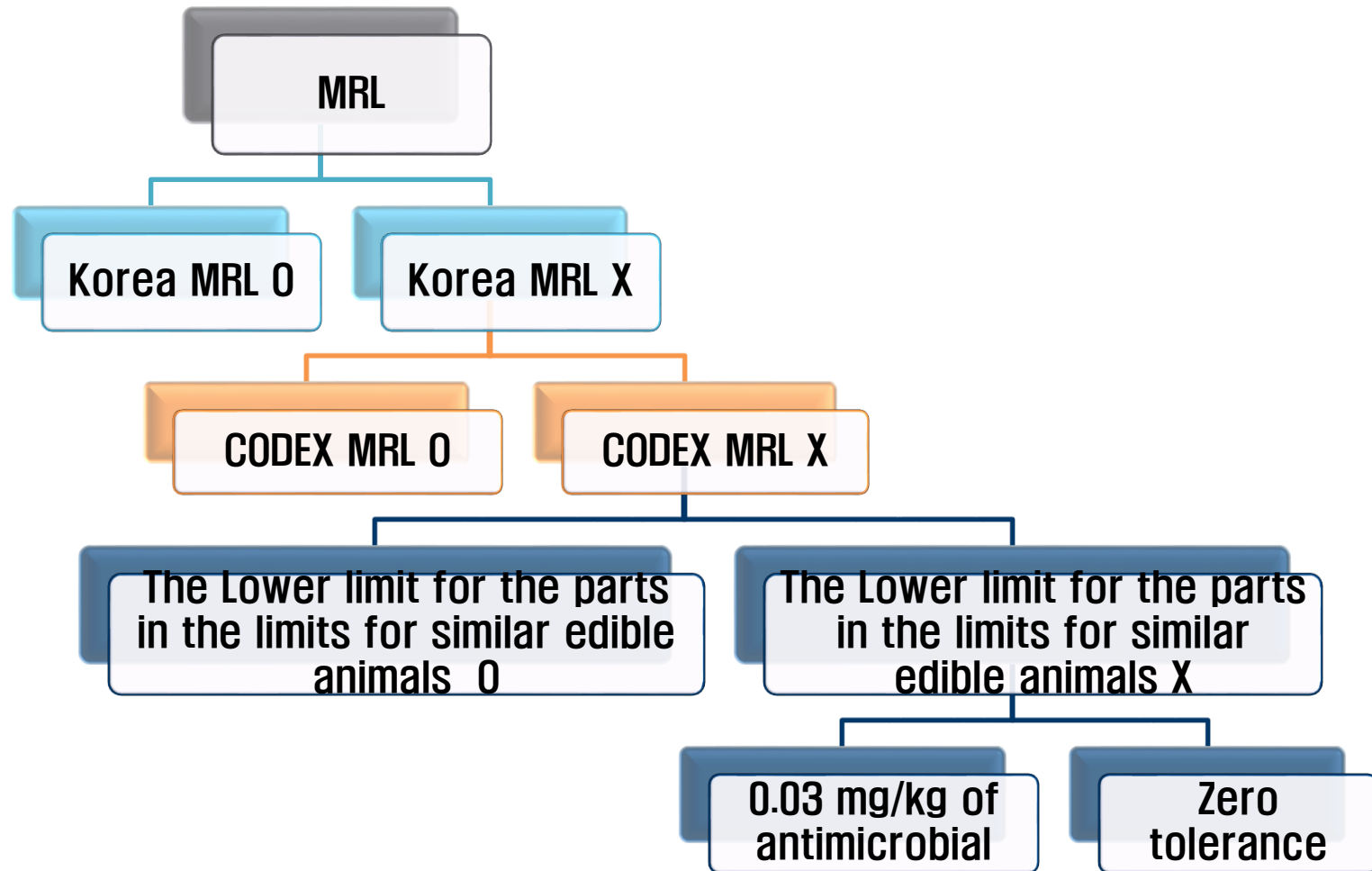
(4) Other veterinary drugs

- ✓ Zero tolerance

Application of MRLs for Veterinary Drugs



식품의약품안전처



Exemption from the veterinary drug MRLs in food

Food Code 8) Maximum Residual Limits (MRLs) for veterinary drugs

(3) Exemption from the veterinary drug MRLs in food

- ▶ In accordance with the laws of the relevant country with animal medicines and foreign countries permitted under the Pharmaceutical Affairs Act, the establishment of residual acceptance criteria may be exempted if any of the following reasons apply to the valid ingredients contained in legally used animal medicines, and components subject to exemption shall be as shown in [Annex 8].
 - ① Any of the following normal components, such as human-ingested food, food additives, or animal-ingested food
 - ② In case that it is a clear ingredient that does not normally harm the human body.

3

Introduction of PLS for residues for livestock and fishery products

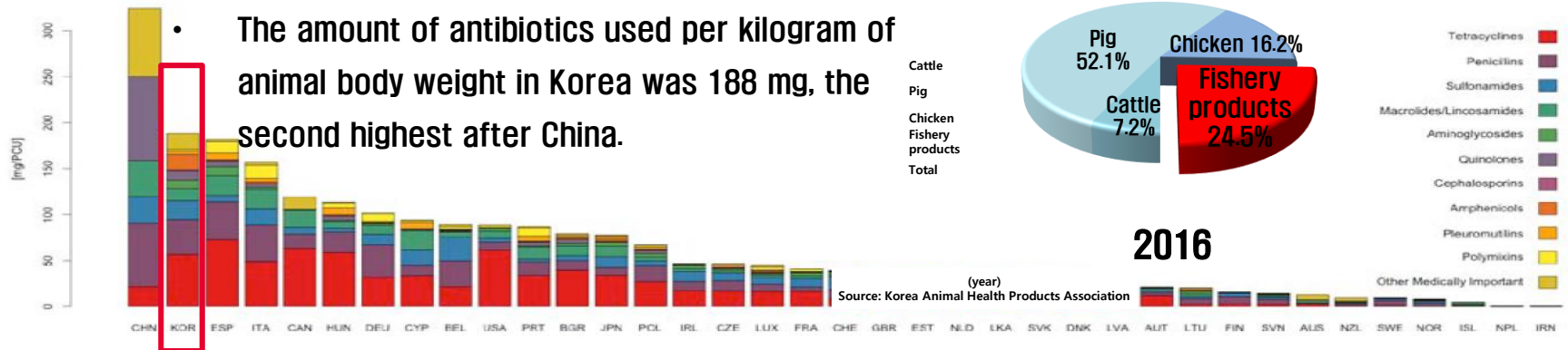


Veterinary Drug Residues Due to Drug Misuse/Abuse



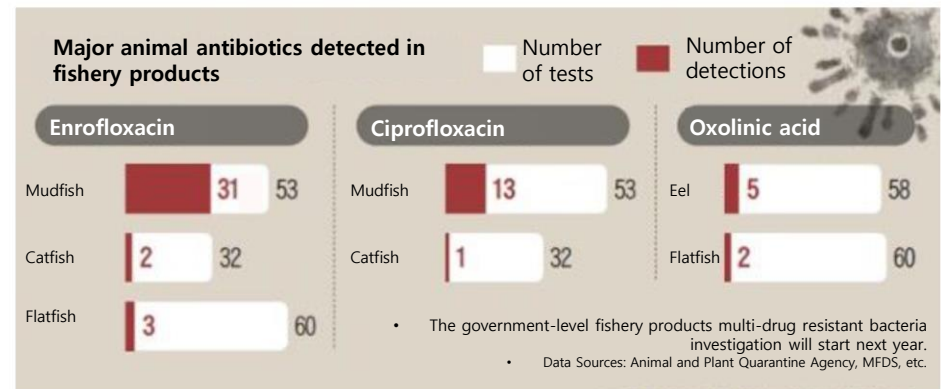
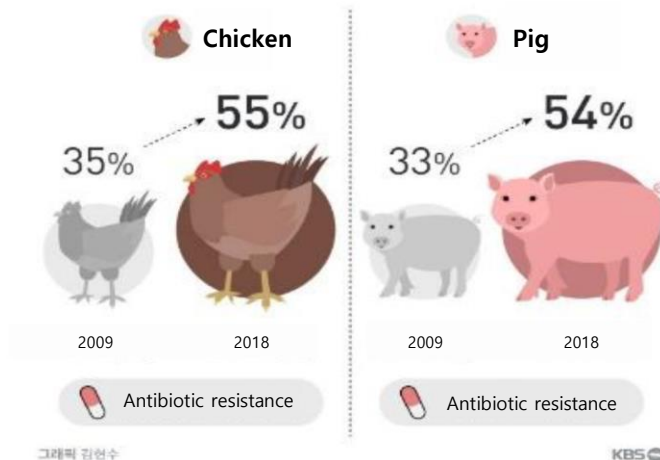
식품의약품안전처

< Comparison of use of antibiotics for animals by country (as of 2013) >



Source : Science 357(6358):1350, As of 2017/2013

Increased concerns about antibiotic resistance in livestock and fishery products



Revising the Uniform Limit Applied to Antimicrobials (antibiotic and synthetic antimicrobials) with No Established Limits



식품의약품안전처

1 Gravity of antibiotic resistance

YTN

2019.12.15

"항생제 오·남용 심각성, 국민인식부터 바꿔야"

[앵커]

지난 한 주간(9일~13일) 강원도 평창에서는 오메 산악 레저대성특별위원회가 열렸습니다.

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료 약도

무력화

시키는

심각

한 문

제를 일

으킵니

다.

[유상철 / 서울대 식품동물생명공학부 교수 : 식품에 잔류하는 항생제를 섭취하게 되면 장내 미생물의 균형을 깨게 돼서 여러 가지 다양한 질병의 원인이 될 수 있습니다.]

우리나라의 인체와 가축 항생제 사용량은 주요 국가들보다 높아 정부는 범부처 차원에서 항생제 줄이기 정책을 추진하고 있습니다.

또 의사 처방 약은 남지 않고 모두 먹기와 손 씻기 등 생활 속 항생제 줄이기 캠페인도 펼치고 있습니다.

항생제도 소용이 없는 세균 슈퍼박테리아에 감염이 돼서, 폐혈종과 폐렴으로 사망을 하는 사람이 우

...연 3600명 사망"



[앵커]

항생제도 소용이 없는 세균 슈퍼박테리아에 감염이 돼서, 폐혈종과 폐렴으로 사망을 하는 사람이 우리나라에서 한해 3600명이라는 연구조사 결과가 나왔습니다. 슈퍼박테리아가 전국 병원 곳곳에 퍼져있고 없앨 수 없는 상태가 됐다는 목소리가 나오고 있습니다.

먼저 배양진 기자입니다.

[기자]

슈퍼박테리아에 감염된 아버지의 일종을 딸은 지키지 못했습니다.

국민일보

2019년 12월 16일 월요일 H07면 기획

항생제 내성균 공포 알고도 계속 당하나

전 세계적으로 항생제 내성에 대한 문제의식이 고조되고 있다. 어떤 항생제도 듣지 않는 '슈퍼박테리아' (다제내성균) 출현으로 2050년에는 1000만명이 숨질 것으로 예측되고 있는 상황이다. 우리나라만 해도 매년 약 1만명의 환자가 다제내성균에 감염되는 것으로 추정된다.

김종민 분당서울대학교병원 감염내과 교수가 질병관리본부 정책연구용역사업(2017)의 일환으로 국내 10개 의료기관을 표본 추출해 조사한 결과에 따르면, 연간 발생하는 다제내성균 균혈증 환자는 2007년, 다제

내성균(ESBL) 31개국 평균(18.3DDD)보다 높다. 특히 광범위 항생제에 해당하는 세팔로스포린과 퀴놀론 항생제 처방량은 전체 항생제 처방량의 34.5%를 차지해 OECD 평균(18.8%)보다 높은 수준이다. 김 교수는 지난해 3월부터 1년간 국내 항생제 사용실태를 분석한 결과를 보면, 치료 항생제 처방의 흔한 적응증에는 호흡기 감염(병원획득 폐렴, 지역사회획득 폐렴, 인두염, 세균성 비염 등), 위장관 감염(담도염, 담관염, 감염성 설사), 요로감염(단순 신우신염, 복잡성 신우신염, 방광염) 등이 있다.

그러나 호흡기 감염 치료 항생제 처방 건수의 19%, 위장관 감염 치료 항생제 처방 건수의 14%, 요로 감염 치료 항생제 처

방 건수의 14.5%는 처방이 부적절했다고 평가되는 등 불필요한 약제사용이 적지 않다. 전문가들은 처방불만 줄여서는 내성 문제를 해결할 수 없다고 말한다. 최원석 고려대학교 안산병원 감염내과 교수는 "내성균의 문제는 선택할 수 있는 항생제 종류가 줄어들면서 치료에 한계가 생기는 것"이라면서 "다양한 치료요법을 확보하고, 백신 접종 등을 통해 항생제를 써야 하는 질환의 발병 자체를 줄이는 노력이 필요하다"고 강조했다. 또 "내성균의 전파 경로를 차단하는 것도 필요하다. 내성균의 주요 감염 경로는 접촉이다. 병원체 보유자나 오염된 물품, 환경 표면 등의 접촉을 통해 전파될 수 있기 때문에 감염 관리를 강화해야 한다"고 전했다.

유숙인 쿠키뉴스 기자에 따라 26.5DDD이다. 경제협

우리나라는 다른 국가에 비해 항생제 처방 비율이 높고 남용 문제가 심각하다. 2017년 기준 한국의 외래 항생제량은 의약품 일평균 복용 용량(DDD)에 따라 26.5DDD이다. 경제협

sun92710@kukinews.com

Revising the Uniform Limit Applied to Antimicrobials (antibiotic and synthetic antimicrobials) with No Established Limits

2

Other countries applies “zero tolerance” policy to antimicrobials with no established limits

Other
countries'
practice with
MRLs

EU

Authorized veterinary drugs: Managed with MRLs
Other veterinary drugs: **Zero tolerance** policy

USA

Authorized veterinary drugs: Managed with MRLs
Other veterinary drugs: **Zero tolerance** policy

Japan

Residues with no individual MRLs (or provisional MRLs)
: Managed with uniform MRL (0.01 mg/kg)
→ Except **antimicrobials with no established limits: Zero tolerance** policy

Korea

Antimicrobials with no established limits:
(1) Codex limit; (2) lower limit of the range established for the applicable part of the similar type of livestock; (3) **not more than 0.03 mg/kg**

Revising the Uniform Limit Applied to Antimicrobials (antibiotic and synthetic antimicrobials) with No Established Limits



식품의약품안전처

3 Improving safety control of imported food

▶ Applying the uniform limit (0.03 mg/kg) to antimicrobials, unlike the exporting countries, which apply tougher limits, **creates blind spots in safety control of imported food.**

- * e.g., Antimicrobials that are not authorized for use

- Cannot be used in aquaculture in Korea

- If detected in imported (Canadian) salmon:

In Canada, the food item is unacceptable for use according to “zero tolerance” policy ;

In Korea, it may be cleared the customs if it meets the 0.03 mg/kg criteria.

Revising the Uniform Limit Applied to Antimicrobials (antibiotic and synthetic antimicrobials) with No Established Limits

Revising the uniform limit applied to antimicrobials with no established limits (0.03→**0.01 mg/kg**)

Administrative notice(Dec 2019) → public notice (May 2020) → enforcement (Jan 2022)

Current	Revised (Jan 1, 2022)
<p>8) MRLs for veterinary drugs</p> <p>(1) Limits for veterinary drug residue in food are applied</p> <p>(1) – (4) (skipped)</p> <p>(5) For edible animals, etc. with <u>no MRL specified</u> in the notice, the limit specified in each of the following paragraphs shall be applied successively.</p> <p>(i) CODEX limit</p> <p>(ii) lower limit of the range established for the applicable part of the similar type of livestock</p> <p>(iii) MRLs for antimicrobials are set at 0.03 mg/kg for livestock and fishery products (including milk, eggs, fish oil, and fish roes) and honey (including royal jelly and propolis).</p>	<p>8) MRLs for veterinary drugs in food</p> <p>(1) (same as current)</p> <p>(1) – (4) (same as current)</p> <p>(5) For edible animals, etc. with <u>no MRL specified</u> in the notice, the limit specified in each of the following paragraphs shall be applied successively.</p> <p>(i) CODEX limit</p> <p>(ii) lower limit of the range established for the applicable part of the similar type of livestock</p> <p>(iii) MRLs for antimicrobials are set at 0.01 mg/kg for livestock and fishery products (including milk, eggs, fish oil, and fish roes) and honey (including royal jelly and propolis).</p>

Continuing Risk of Residues in Livestock and Fishery Products



식품의약품안전처



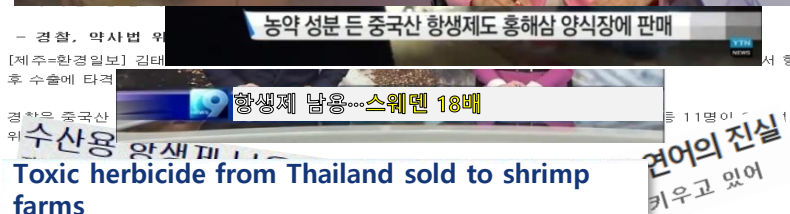
Nitrofuran metabolite detected in US frozen chicken... authority ordered to stop sales and recall

US beef exceeds standards for carcinogenic growth promoters
Ractopamine and vaginal zilpaterol detected... domestic use should be discontinued

Import of frozen salted egg yolk from China stopped due to the detection of banned substances such as “metronidazole” and “ofloxacin” (2019)

Danish chicken imports stopped due to the detection of “nicarbazin” (2019)

Pesticides detected in eggs (2017)



Taiwanese and Thai whiteleg shrimps ordered to be returned/disposed due to “Nitrofuran metabolites” (2020)

- Illegal use of “trifluralin” in shrimp farms (2016)
- Distribution of “livestock antibiotics” to flatfish farms (2015)
- Carcinogenic substances (malachite green) detected in farmed catfish (2014)
- Large amounts of antibiotics and insecticides in Norwegian salmon (2012 & 2015)

Calls for Residue Safety Management for Livestock and Fishery Products



식품의약품안전처

Calls for improved residue safety control system to prevent residues due to misuse/abuse of veterinary drugs and pesticides and stronger safety control of imported livestock and fishery products

President's and Prime Minister's Orders

- To have measures in place to improve food safety control across the government to prevent food safety crisis such as the pesticide-contaminated egg crisis (Aug 2018)
- Joint announcement of "Comprehensive Measures for Food Safety Improvement" by government ministries (Dec 2017)



Introduction of livestock and fishery products PLS

- In the wake of the pesticide-contaminated egg crisis (Aug 14, 2017), negative perception of egg safety increased by 34.1%, and consumption decreased by 46.0%, as of July 30th (Korea Rural Economic Institute)

What is Positive List System (PLS)?

- **A system designed to manage chemical residues using uniform limits (0.01 mg/kg) except for veterinary drugs and pesticides with MRLs established in response to applications for MRL setting for domestic use or imported food**
 - * However, the zero-tolerance policy (quantitation limit of assay) is applied to growth supplements and steroidal anti-inflammatory drugs that may have harmful effects even in trace amounts.

Purpose of implementing PLS (intended effects)

- Improved safety control of veterinary drug residues in domestic livestock and fisher products
 - Preventing misuse/abuse of veterinary drugs (non-compliance with safe usage limits)
- Enhanced safety control of unauthorized residues in imported livestock and fishery products
 - Eliminating the potential sources of chemical residues with no assured safety
 - Preventing authorizing Korean imports and distribution of the livestock and fishery products that are unacceptable in other countries

Supplying Koreans with safe livestock and fishery products

Inter-agency coordination for PLS implementation

- **Inter-agency Residue Safety Control Council (15 meetings between Jan 2018 and Jun 2021)**
 - 9 agencies (the Prime Minister's Office, Ministry of Food and Drug Safety, the Ministry of Agriculture, Food and Rural Affairs, the Ministry of Oceans and Fisheries, the Assessment Service, the Rural Development Administration, the Animal and Plant Quarantine Agency, the National Institute of Fisheries Science, and the National Fishery Products Quality Management Service)
- **Inter-agency working-level meetings (13 meetings between Jan 2018 and Jun 2021)**

Review of the plan for phased introduction of the livestock/fishery products PLS

Starting with the **veterinary drugs PLS** for 5 major livestock products(**cattle, pigs, chickens, milk, and eggs**) and **fish** (**scheduled for 2024**)

Application of Residue Limits According to Veterinary Drugs PLS (Cattle, Pigs, Chickens, Milk, Eggs, and Fish)

Priority introduction of veterinary drugs for livestock products (cattle, pig, chicken, milk, eggs) and fish

Administrative notice (Dec, 2020) → Notification (Jun, 2021) → **Enforcement (Jan, 2024)**

Current	Revision (Jan 1, 2024)
<p>8) MRLs for veterinary drugs</p> <p>(1) Limits for veterinary drug residue in food are applied</p> <p>(1) – (4) [skipped]</p> <p>(5) For edible animals, etc. with <u>no MRL specified</u> in the notice, the limit specified in each of the following paragraphs shall be applied successively.</p> <p>(i) CODEX limit</p> <p>(ii) lower limit of the range established for the applicable part of the similar type of livestock</p> <p>(iii) MRLs for antimicrobials are 0.03 mg/kg (0.01 mg/kg ‘effective on Jun 1, 2022) ‘</p>	<p>8) MRLs for veterinary drugs in food</p> <p>(1) [same as current]</p> <p>(1) – (4) [same as current]</p> <p>⑤ <u>If there is no separate standard for livestock products (cattle, pig, chicken, milk, eggs) and fishery products (fish), less than 0.01 mg/kg is applied.</u></p> <p>However, 'Zero tolerance' applies to growth aids (growth promoting, weight increasing ingredients, etc.) and steroidal anti-inflammatory drugs.</p> <p>⑥ If there is no separate standard for edible animals other than ⑤ above, the standards in each of the following sections are applied sequentially.</p> <p>[same as current]</p>

Application of Residue Limits According to Veterinary Drugs PLS (Cattle, Pigs, Chickens, Milk, Eggs, and Fish)

Current

- ▶ Veterinary drugs with established MRLs
 - Apply the MRLs
- ▶ Veterinary drugs with no established MRLs
 - CODEX limit
 - Lower limit for the similar edible animal
 - Antimicrobial: 0.03 mg/kg
(0.01 mg/kg from Jan 1, 2022)
 - “Zero tolerance” for other veterinary drugs

After Introduction of PLS (2024)

- ▶ Veterinary drugs with established MRLs
 - Apply the MRLs
- ▶ Veterinary drugs with no established MRLs
 - 0.01 mg/kg
 - However, “zero tolerance” is applied to growth supplements and steroidal anti-inflammatory drugs.

- ▶ Other livestock products and animal fishery products except fish: Current limits are applied

2021 Status of Establishment and Revision of MRLs (Veterinary Drugs)

▶ Establishment and revision of MRLs for veterinary drugs

(Administrative notice scheduled)

- * The Maximum residue limits of amprolium in eggs 4.0 mg/kg
- * Expansion of the items subject to the standard application of the four fish types of veterinary drugs for fishery to fish
⇒ [4 types] gentamicin, thiamphenicol, clindamycin, oxolinic acid

Example

Ingredient	MRL (mg/kg)	
	Current	Revision
Gentamicin	Flatfish (0.1) Trout (0.1) Carp (0.1)	Fish (0.1)

2021 Status of Establishment and Revision of MRLs (Veterinary Drugs)



식품의약품안전처

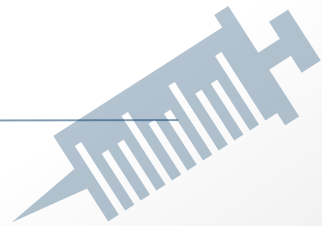
Administrative Notice	Veterinary Drugs	MRL (mg/kg) [Annex5]	
		Current	Revision
Announcement No. 2021-288 (Jun 30, 2021)	Amprolium	-	Eggs (4.0)
	Gentamicin	Bastard halibut (0.1) Cherry almon (0.1) Carp (0.1)	Fishes (0.1)
	Oxolinic acid	Japanese amberjack (0.1) Carp (0.1) Cherry almon (0.1) Salmon (0.1) Ayu sweetfish (0.1) Common eel (0.1)	Fishes (0.1)
	Thiamphenicol	Japanese amberjack (0.05) Bastard halibut (0.05) Cherry almon (0.05) Seabream (0.05) Amur catfish (0.05) Ayu sweetfish (0.05) Tilapia (0.05)	Fishes (0.05)
	Clindamycin	Common eel (0.1) Bastard halibut (0.1)	Fishes (0.1)

2021 Status of Establishment and Revision of MRLs (Residues in livestock products)

Administrative Notice	Pesticides	MRL (mg/kg) [Annex6]	
		Current	Revision
Announcement No. 2021-288 (Jun 30, 2021)	Lufenuron	-	Mammalian : meat(0.1), fat(2.0), by-products(0.15) Poultry : meat(0.02), fat(0.04), by-products(0.02), Milk(0.15), Eggs(0.02)
	Metaflumizone	-	Mammalian : meat(0.02), fat(0.02), by-products(0.02) Milk(0.01)
	Bifenazate	-	Mammalian : meat(0.01), fat(0.05), by-products(0.01) Poultry : meat(0.01), fat(0.01), by-products(0.01), Milk(0.01), Eggs(0.01)
	Cyantraniliprole	-	Mammalian : meat(0.2), fat(0.5), by-products(1.5) Poultry : meat(0.02), fat(0.04), by-products(0.15), Milk(0.6), Eggs(0.2)
	Acetamiprid	-	Mammalian : meat(0.5), fat(0.3), by-products(1.05) Poultry : meat(0.01), fat(0.01), by-products(0.05), Milk(0.2), Eggs(0.01)
	Etofenprox	-	Mammalian : meat(0.05), fat(0.5), by-products(0.05) Milk(0.02)
	Tebufenozide	-	Mammalian : meat(0.01), fat(0.05), by-products(0.02) Poultry : meat(0.02), fat(0.02) Milk(0.01), Eggs(0.02)

Reference

Import Tolerance Application



What is an Import Tolerance?

An MRL established for **veterinary drugs and pesticides** that pose no threats to the human body, based on the safety assessment with **livestock and fishery products** **used according to foreign regulations** despite no established Korean MRLs

Regulatory Bases

- Article 7-3 (Request, etc. for Establishment of Maximum Residue Limits of Pesticides, etc.) of the Food Sanitation Act
- Enforcement Rule of the Food Sanitation Act
 - Article 5-2 (Establishment of Maximum Residue Limits of Pesticides or Veterinary Drugs)
 - Article 5-3 (Change of Maximum Residue Limits, etc.)
- Food Code [Annex7] Guidelines for Setting Maximum Residue Limits for Pesticides and Veterinary Drugs in Food



IT System on Imported Foods

IT is set

- On the pesticides **legally approved** in exporting country
- **At the level** that have **no risk concern** in public health
- By evaluating **scientific evidence (toxicity and residue data)**

IT System is

- Operated under legal evidence(Korea: Food Sanitation Act)
- Procure labor force and budget for annual data evaluation
- Scientific and rational principles (but health safety of the citizens is the priority)

Filing an Import Tolerance Application

식품안전나라 | 공공데이터 | 우리회사 안전관리

(1)  통합민원상담서비스

직원검색 | 기업회원가입 | 개인회원가입 | 로그인



전자민원

종합상담센터

부정불량식품신고

건강기능식품 이상신고

이용안내

민원명을 입력해주세요



(2) 전자 민원 신청

나의 민원
일괄 결제
원재료코드 신청
원재료코드 신청 조회
방문민원 가져오기

방문/화상상담예약

신고센터소개
소비자신고
식품업체이물보고
내부자제보
통신판매 중개업 이물통보

신고센터소개
건강식품안전관리
신고 및 내역확인
신고현황

전자민원
민원신청 매뉴얼
종합상담센터
1399소비자신고
기능개선내역
직원검색

영문증명서신청

수입식품 위생증명서
(중국)신청

수입식품 등
영업등록 신청

수입식품 등
영업자자위승계 신고

음식점 위생등급
지정신청

음식점위생등급
재평가신청

수입식품 잔류허용
기준 설정

위생용품 수입업
영업신고

식품 등 수입신고

주제별 민원

주제별로 민원을 확인하실
수 있습니다.



식품영업 등



수입식품 등



증명서



유전자 변형



시험검사기관
(식품등)



시험검사기관
(축산물)

1. Access the Food Safety Korea website (www.foodsafetykorea.go.kr), and select [Integrated Civil Service Consultation Service] (* Account login required)
2. [e-civil service] > [e-civil service application]

Filing an Import Tolerance Application



식품의약품안전처

주제별 민원

주제별로 민원을 확인하실 수 있습니다.

식품영업 등

수입식품 등

증명서

유전자 변형

시험검사기관 (식품등)

시험검사기관 (축산물)

건강기능식품

위생용품 영업

한시적 기준규격

잔류허용기준

시험검사기관 (위생용품)

시험검사기관 (기타)

품목별 민원

품목별로 민원을 확인하실 수 있습니다.

전체

식품

수입식품

건강기능식품

식품원료·첨가물

축산물

위생용품

Total: 8 Articles

민원

동물용의약품

검색

10개씩

보기

번호	민원사무명	신청구분	유형	신청방법
1	국내식품 중 농약 및 동물용의약품의 잔류허용기준 설정 신청	개인회원	신청	
2	국내식품 중 농약 및 동물용의약품의 잔류허용기준 변경 또는 설정면제 신청	개인회원	신청	
(4)	수입식품 중 농약 및 동물용의약품의 잔류허용기준 설정 요청(독성자료검토)	개인회원	신청	
4	수입식품 중 농약 및 동물용의약품의 잔류허용기준 설정 요청(농약 잔류자료검토, 식품별)	개인회원	신청	
5	수입식품 중 농약 및 동물용의약품의 잔류허용기준 설정 요청(동물용의약품 잔류자료검토, 동물별)	개인회원	신청	
6	수입식품 중 농약 및 동물용의약품의 잔류허용기준 변경 또는 설정면제 요청(독성자료검토)	개인회원	신청	
7	수입식품 중 농약 및 동물용의약품의 잔류허용기준 변경 또는 설정면제 요청(농약 잔류자료검토)	개인회원	신청	
8	수입식품 중 농약 및 동물용의약품의 잔류허용기준 변경 또는 설정면제 요청(동물용의약품 잔류자료검토)	개인회원	신청	

3. Type [pesticide or veterinary drugs] in the civil service search box and click Search.

4. Choose the type of service.

Filing an Import Tolerance Application



식품의약품안전처

Fee by application type

Name of Civil Service			Handlin g Period	Fee
New MRL application	Residue data review	Veterinary drugs (by animal type)	12 months	KRW 10,000,000
		Pesticide (by food item)		KRW 5,000,000
	Toxicity data review			KRW 30,000,000
MRL change/exemption application			7 months	KRW 10,000,000

Q & A



➤ Please write your question " **Chat window** "

☞ We will answer the written questions in order.

➤ You could download the presentation materials from the website of the Ministry of Food and Drug Safety.
(<http://www.mfds.go.kr>)

☞ 식약처 > 법령/자료 > 자료실 > 학술토론회

