

Voluntary Report – Voluntary - Public Distribution

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Report Name: Korea's Plan to Implement a Positive List System for
Veterinary Drugs

Country: Korea - Republic of

Post: Seoul

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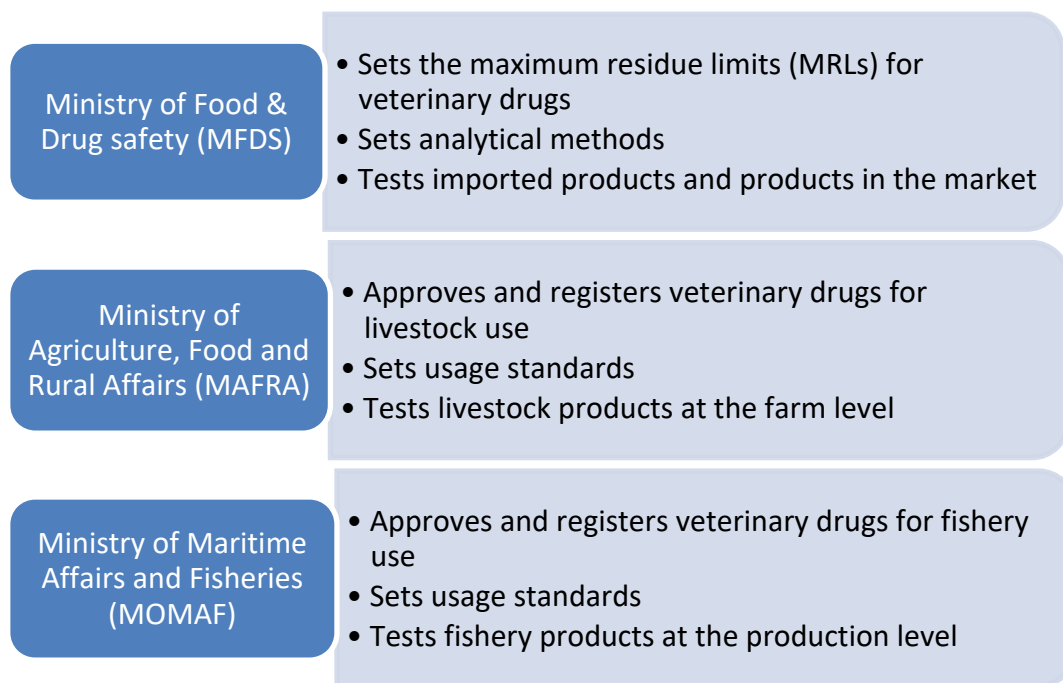
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Report Highlights:

This report is an update on recent efforts by Korea to update their veterinary drug safety management system, which may impact U.S. exports of meat and livestock products to Korea. Part of this update includes a proposed Positive List System (PLS) for vet drugs. This issue will continue to evolve.

In December 2017, Korea announced its latest food safety plan, including the introduction of a positive list system (PLS) for livestock and fishery products. Work towards the vet drug PLS has been ongoing since that time and a draft of the plan was announced on July 21, 2020. The PLS is one part of Korea's vet drug safety management system, which is currently managed by three ministries:



Legal Basis for Veterinary MRLs

- In accordance with Article 10, Paragraph 2 of the Regulation on Handling of Veterinary Drugs, a permit to manufacture or import veterinary drugs will be issued after MRLs are established.
- In accordance with Article 7, Paragraph 3 of the Food Sanitation Act, anyone who seeks to have an MRL established may submit an application to MFDS.
- In accordance with Appendix 7 of the Food Code, MFDS may set MRLs for veterinary drugs that are registered for use in Korea upon request from the Animal and Plant Quarantine Agency (APQA) or the National Institute of Fisheries Science (NIFS). As part of the registration process for new veterinary drugs, APQA or NIFS requests MFDS to set MRLs.
- In accordance with Appendix 7 of the Food Code, MFDS may set import tolerances for veterinary drugs that are not registered for use in Korea but registered and used in foreign countries. In this case, veterinary drug companies should apply for an import tolerance.

Veterinary Drugs or Agricultural Chemicals Currently Listed in the Korean Food Code

1. A list of 25 compounds that shall not be detected in any food products (zero tolerance applies): This is a list of compounds that are not approved for use or import due to safety concerns. The MFDS Minister considers that these compounds may pose a risk to human health. The full list is available from the [Food Code](#). Please see page 59 and 60.
2. A list of current MRLs and import tolerances established for 192 veterinary drugs set in the Food Code: For details on these veterinary drug MRLs, please refer to the following site: [MFDS MRL Site](#)
3. A list of 177 compounds that do not have human health risks or do not leave residues in livestock or fishery products: The full list is provided in Appendix 8 of the Korean Food Code. If you are interested in getting the list, please contact FAS/Seoul at agseoul@fas.usda.gov

Current MRL Default Path

When there is no Korean MRL established for a veterinary drug, the following default paths apply:

1. The CODEX MRL set for a given veterinary drug in the same animal species and in the same animal tissue
2. The lowest MRL set for the same tissue in a similar animal species
3. If #1 and #2 are not applicable, for antimicrobial agents, a 0.03mg/kg default limit applies to livestock & fishery products (including milk and eggs) and honey (including royal jelly and propolis)
4. If #1 through #3 are not applicable, “non-detection” applies

PLS Plans

1. For antimicrobials that do not have Korean MRLs or import tolerances, Korea will apply a 0.01 mg/kg default tolerance starting January 1, 2022. To make this change, MFDS revised its Food Code in May 2020. Starting with 2024, Korea plans to introduce the PLS for five major livestock products and fishery products. The following comparison table shows what changes would be made:

Current	From Jan 1, 2022 to until MFDS implements the PLS	2024 and beyond (date not fixed yet)
1. CODEX 2. Lowest MRL set for same tissue of a similar animal species 3. For antimicrobial, if #1 and #2 are not applicable, 0.03	1. CODEX 2. Lowest MRL set for same tissue of a similar animal species 3. For antimicrobial, if #1 and #2 are not applicable, 0.01	Two step approach: PLS for five livestock products (beef and derivatives, pork and derivatives, poultry and derivatives, milk and eggs) and fishery products will be

mg/kg of the current default limit applies 4. Other than antimicrobial, “non-detection” applies	mg/kg of the new default limit applies 4. Other than antimicrobial, “non-detection” applies	implemented first
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2. The PLS program for veterinary drugs that will be implemented in 2024 or after will be as follows:

- Two-step approach: Five major livestock and fishery products as cited in the table above will be subject to the PLS first.
- For the above listed six product groups, the default to CODEX and the lowest MRL set for a similar species will be deleted.
- Instead, in the absence of Korean MRLs or import tolerances, 0.01mg/kg of the default limit shall apply.
- For species other than six products subject to the PLS, the default to CODEX and the lowest MRL set for a similar species shall apply first. If any of the default paths do not apply, “non-detection” or LOQ shall apply. That is to say, in this case, there is no tolerance and the 0.01mg/kg default tolerance is not applicable.
- For growth supplements and steroid type anti-inflammatory drugs, “non-detection” limit shall apply if there is no established MRL or an import tolerance.

Application for Import Tolerances

For entities seeking to apply for an import tolerance for veterinary drugs in livestock and fishery products, the request is made through the MFDS Public Portal Service. MFDS encourages industry to apply for import tolerances at any time. MFDS charges an application fee of 10 million Korean won (approximately \$8,300 US dollars) per animal species (i.e. no additional charges for multiple MRLs in various tissues of the same animal species). The application review process may take up to 12 months.

PLS for Agricultural Chemical Residues Carried Over from Animal Feeds

MFDS has been considering a PLS for agricultural chemical residues that may have originated from animal feed grains and forages or from the environment. However, MFDS has not determined the timeline for implementation of this PLS. Currently, MFDS has 101 MRLs for agricultural chemical residues in livestock and fishery products. MFDS also applies CODEX MRLs set for a given compound in a given animal tissue in the absence of Korean MRLs. If there is no Korean MRL or CODEX MRL, “non-detection”, i.e., no tolerance shall apply.

MFDS is currently consulting with relevant ministries on how to plan and implement this PLS. To prepare for the PLS:

- MFDS will review 102 compounds that have CODEX MRLs but no corresponding domestic Korean MRLs. They will seek to set appropriate Korean MRLs for these compounds.
- MFDS will review 30 compounds for which Korea has an MRL for agricultural products typically used as feed inputs in the livestock and fisheries industry but that do not have MRLs in the corresponding livestock and fishery products.
- MFDS will also review compounds that may persist in the environment, as such compounds may be unintentionally present in livestock and fishery products.

Post will provide updates when available.

Attachments:

No Attachments.