Provisional Translation

Food Safety Commission of Japan (FSCJ)

Decision of May 18, 2020

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Expert Committee on Veterinary Medicinal Products

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Expert Committee on Feed and Fertilizers

Guidance on Risk Assessments of Veterinary Medicinal Products and Feed Additives for which the Provisional Standards are Established

1. Current status of veterinary medical products and feed additives[1] for which the provisional maximum residue limits (hereinafter referred to as "provisional standards") are established.
   (1) In May 2006, when positive list system for residue for agricultural chemicals, veterinary medical products and feed additives (hereinafter referred to as "agricultural chemicals") in foods was introduced, MHLW established the provisional standards without implementing the risk assessment based on Article 11, item1- (iii) of the Food Safety Basic Act, stating that "(W)here there is no time to conduct an Assessment of the Effect of Food on Health in advance in cases where the measure is urgently necessary to prevent or restrain an adverse effect on human health".
   (2) Since it is stated in Article 11, item 2-(2) of the Food Safety Basic Act, that these so called provisional standards should be subject to risk assessment without delay, MHLW planned to make requests for assessment within 5 years from 2006 ("Introduction of the Positive List System for residue for Agricultural Chemical Residues in Foods", MHLW No. 1128001 dated November 28, 2005). Consequently MHLW has been making requests for assessments based on the Food Safety Basic Act, Article 24, item 2, for these provisional standards for residue of agricultural chemicals including priority assessment substances.
   (3) In order to conduct risk assessment smoothly, the FSCJ has developed[2] "implementation procedure for risk assessment of agricultural chemicals for which the provisional standards are established" (hereinafter referred to as "Implementation Procedure") and has been conducting risk assessments focusing on establishing the ADI.

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[1] Except substances used as agricultural chemicals.

[2] Decision of the FSCJ dated June 29, 2006.

2. Challenges and policy

(1) From the national health protection perspective, risk assessment of the substance for which provisional standards are established, should be implemented promptly based on the latest scientific findings, and the provisional standards should be revised following the results of the assessments. However, for the mentioned substances, data requisite for specifying appropriate ADI are not sufficient enough under the current situation.

(2) On the other hand, for those substances other than priority assessment substances, Article 2-(2)-(ii) of the Implementation Procedure provides that risk assessment should be conducted aiming to establish ADI or using other methods under a certain condition. In addition, as recent data provides a more complete picture of actual amount of exposure to the said substances, experience of risk assessment has been accumulated and a new method for risk assessment has been elaborated, situation relating to risk assessment has changed after introduction of the positive list system.

(3) Under these circumstance, the FSCJ decided to conduct a risk assessment to confirm the validity of the existing risk managements in addition to establishing ADI for the unassessed substances of veterinary medicinal products and feed additives for which provisional standards are established.

(4) Noting that this guidance is elaborated to clarify the specific methods for "other methods" described in the Implementation Procedure for veterinary medicinal products and feed additives, risk assessment of veterinary medicinal products and feed additives other than those fall under the scope of the Implementation Procedure should be conducted based on the "Guideline for the Risk Assessment of Veterinary Medicinal Products" (decision of the FSCJ dated April 10, 2018)" and the "Guideline for the Risk Assessment of Feed Additives"(decision of the FSCJ dated September 25, 2018)," respectively.

3. Guidance on the risk assessment of unassessed substances

The priority assessment substances[3] designated in the Implementation Procedure should be subject to the regular risk assessment based on the Implementation Procedure. With regard to the other substances, assessment should be conducted based on the following categorizations depending on the status of each substance.

(1) Substance for which an ADI is established by an international organization, etc., and the estimated daily intake based on the current risk management does not exceed the said ADI.

Substances that fall under this category are those for which an ADI are established by the international organizations (JECFA, JMPR) and foreign governments, etc. (e.g. the USA, EU, Australia), and as a result of internal discussion, the FSCJ concluded that it is possible to treat the assessment conducted by the said organization, etc. equivalent to those conducted by the FSCJ, and the estimated daily intake does not exceed the said ADI taking into account the risk management measures that have been taken after introduction of positive list system.

Consequently, the risk of the substance of this category to human through foods is considered to be negligible as long as it is appropriately used as a veterinary drug or feed additive following the current risk management measures.

(2) Substance of which its genotoxic carcinogens potential cannot be denied.

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[3] The substances that were designated in "Introduction of the Positive List System for Agricultural Chemical Residues in Foods" (MHLW Notification No. 1128001 dated November 28, 2005 and that shall be given priority to request for risk assessment.

Substances that fall under this category are those do not fall under the category (1), and the potential to be genotoxic carcinogen cannot be denied based on the provided documents, etc.

In case, the said substance has been managed as a substance that should not be detected from foods, risk of this substance to human health through foods can be considered negligible.

(3) Substances of which NOAEL (no-observed-adverse-effect level), etc. can be confirmed from the provided documents, etc.

Substances that fall under this category are those do not fall under the categories (1) and (2), and NOAEL, etc. of said substances can be confirmed from the provided documents, etc.

i Substances with an enough margin between the NOAEL, etc. confirmed from the documents etc. and the estimated dairy intake specified on the basis of current risk management.

Substances that fall under this sub-category are those confirmed to have a sufficient margin between confirmed NOAEL, etc. and the estimated dairy intake after comparing these two points, taking into account the risk management measures that have been taken since implementation of positive list system.

Therefore, the risk of the substance of this category to human through foods is considered to be negligible as long as it is appropriately used as a veterinary drug or feed additive following the current risk management measures.

ii Substances that do not have a sufficient margin between the NOAEL, etc. confirmed from the documents, etc. and the estimated dairy intake specified on the basis of current risk management.

If there is no sufficient margin between NOAEL, etc. and the estimated intake provided based on the existing risk management, conventional risk assessment to specify an ADI should be conducted.

(4) Substances of which the effects on human health cannot be assessed through intake of food.

Substances that fall under this sub-category are those do not fall under the sub-categories (1), (2) and (3). For those substances, the effects on human health cannot be assessed through intake of food since no ADI has been set for the said substances by any international organization, etc., and no documents are available to confirm NOAEL, etc.