This is provisional English translation of an excerpt from the original full report.

Risk Assessment Report

Oral gavage formulation for cattle (Pronamide powder 2% for cattle) containing mosapride citrate as an active substance

(Veterinary Medicinal Product)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

The FSCJ conducted a risk assessment of an oral gavage formulation for cattle (Pronamide powder 2% for cattle) containing mosapride citrate as an active substance, based on the application documents for approval of manufacturing and marketing a veterinary medicinal product.

The main ingredient of this formulation is mosapride citrate hydrate, and the FSCJ specified an acceptable daily intake (ADI) of 0.03mg/kg bw per day for mosapride citrate. As for citrate, the FSCJ determined that to specify an ADI as a veterinary medicinal product or a feed additive would be unnecessary, attributing to its assessment, which clarified no effect on human health through dietary exposure to the residues in food as long as citrate is normally used.

The FSCJ presumed that the additive included in this formulation would have negligible effects on health in the case of consuming this substance, considering its usage, existing toxicity assessments, directions and dosage.

In a residue study conducted by oral gavage administration to cattle with dose schedule of twice per day for 3 days (equivalent to 1mg/kg bw per dose of mosapride citrate), mosapride was detected in the liver and the small intestine and it fell below the limit of quantification 4 days and 3 days respectively after the last administration. For muscle, kidney and fat, it came to be below the limit of quantification 1 day after the last administration. Metabolite M-1 was detected in the liver, kidney and small intestine. In those organs, it decreased below the limit of quantification 2-4 days after the last administration. In muscle and fat, it came to be below the limit of quantification 1 day after the last administration. Mosapride in milk was below the limit of quantification 12 hours after the first administration. Meanwhile, metabolite M-1 was detected 12 hours after the first administration and reached the maximum concentration 6 hours after the last administration. Thereafter, it decreased and fell below the limit of quantification after 36 hours.

As a result of safety and clinical studies, the FSCJ determined that there would be no safety issues for giving a customary dose of this formulation to cattle.

Given the above, the FSCJ speculated that the probability to cause adverse effects on human health through food would be negligible as long as this formulation is appropriately applied.