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

Risk Assessment Report

Econosad, an insecticidal spray for poultry premises, which contains spinosad as an active ingredient

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
February 2015

ABSTRACT

FSCJ conducted a risk assessment of Econosad, an insecticidal spray for poultry premises, which contains spinosad as an active ingredient for marketing approval of new veterinary medicinal products.

Spinosad, the active ingredient of this veterinary medicinal product, is currently used as a pesticide and veterinary medicinal product, and its acceptable daily intake (ADI) has been specified as 0.024 mg/kg bw/day in Japan.

Spinosad residues in poultry tissues were tested after the following applications: direct sprays to chickens, both direct sprays to chickens along with premise sprays, and direct spray to chicken eggs. Spinosad (sum of spinosyn A and spinosyn D) was detected only in the chicken skin at the level of 0.07 μg/g 28 days after the application.

Regarding the additives used in this product, FSCJ concludes that considering the usage, existing toxicity evaluation, dosage and administration, the risk to human health from the intake of these additives as ingredients of this product is negligible.

There were no treatment-related changes caused by administration of this product to chickens in the safety and clinical studies.

Consequently, FSCJ concludes that the risk to human health through consumption of foods is negligible as long as Econosad is appropriately used.

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Risk Assessment Report

Spinosad
(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
February 2015

ABSTRACT

FSCJ conducted a risk assessment of spinosad (CAS No. 168316-95-8[131929-60-7+131929-63-0], a mixture of compounds spinosin A and spinosin D), a macrolide insecticide, produced by the soil actinomycete fungus *Saccaropolyspora spinosa*, based on results from various toxicity studies. For this assessment, data on pharmacokinetics (chickens), residues (chickens), and acute toxicity (rats) were newly submitted from the applicants.

The studies include the fate in animals (rats), fate in plants (paddy rice, cabbages, turnips and apples), residues in crops, pharmokinetics and residues (chickens, goats, sheep and cattle), subacute toxicity (rats, mice and dogs), chronic toxicity (dogs), chronic toxicity and carcinogenicity (rats and mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), and genotoxicity.

Major adverse effects of spinosad was pospholipidosis detected as cytoplasimic vacuolation in tissues and organs. Spinosad did not show any carcinogenicity, teratogenicity and genotoxicity relevant to human health.

The minimum no-observed-adverse-effect level (NOAEL) in the toxicological studies was 2.4 mg/kg bw/day obtained in a two-year chronic/carcinogenicity study in rats. Applying s safety factor of 100 to the NOAEL, FSCJ specified the acceptable daily intake (ADI) of 0.024 mg/kg bw/day.