Appendix V

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS

(at Step 4 of the Elaboration Procedure)

ZILPATEROL HYDROCHLORIDE (β2-adrenoceptor agonist)

Acceptable Daily Intake (ADI): 0-0.04 µg/kg body weight established at the seventy-eighth meeting (WHO TRS No. 988, 2014) and reaffirmed at the eighty-first meeting. (81st JECFA, 2015)

Acute Reference Dose (ARfD): 0.04 µg/kg body weight based on a lowest-observed-adverse-effect level (LOAEL) of 0.76 µg/kg body weight for acute pharmacological effects observed in a single-dose human study, with application of an uncertainty factor of 20, comprising a default uncertainty factor of 10 for human individual variability and an additional uncertainty factor of 2 to account for use of a LOAEL for a slight effect instead of a NOAEL. (81st JECFA, 2015)

Estimated Acute Dietary Exposure (GEADE): 1.9 µg/day for the general population, which represents approximately 80% of the ARfD.
The GEADE is 0.57 µg/day for children, which represents approximately 94% of the ARfD. (81st JECFA, 2015)

Residue Definition: Zilpaterol (free base) in muscle, liver and kidney.

Species	Tissue	MRLs (µg/kg)	Step	JECFA
Cattle	Kidney	3.3	4	81
Cattle	Liver	3.5	4	81
Cattle	Muscle	0.5	4	81