

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Guidance document for WHO monographers and reviewers evaluating veterinary drug residues in food

Geneva



**World Health
Organization**

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List of abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
BMD	benchmark dose
BMDL	lower 95% confidence limit on the benchmark dose
BMDL ₁₀	lower 95% confidence limit on the benchmark dose for a 10% response
BMDS	Benchmark Dose Software (USEPA)
bw	body weight
CAS	Chemical Abstracts Service
CCRVD	Codex Committee on Residues of Veterinary Drugs in Foods
CD-ROM	compact disc read-only memory
DVD	digital video disc
EDI	estimated daily intake
EHC	Environmental Health Criteria
EMA	European Medicine Agency
FAO	Food and Agriculture Organization of the United Nations
GEADE	global estimate of acute dietary exposure
GECDE	global estimate of chronic dietary exposure
GLP	good laboratory practice
INN	International Nonproprietary Name
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC ₅₀	median lethal concentration
LD ₅₀	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOEL	lowest-observed-effect level
MIC	minimum inhibitory concentration
MIC ₅₀	minimum concentration required to inhibit the growth of 50% of organisms
MIC _{calc}	minimum inhibitory concentration derived from the lower 90% confidence limit for the mean MIC ₅₀ of the relevant genera for which the drug is active
MOE	margin of exposure
MRL	maximum residue limit
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
OCR	optical character recognition
OECD	Organisation for Economic Co-operation and Development
PDF	portable document format
POD	point of departure
ppm	parts per million
QA	quality assurance
SI	Le Système international d'unités (International System of Units)
T ₂₅	chronic daily dose that will give 25% of the animals tumours at a specific tissue site, after correction for spontaneous incidence, within the standard lifespan of that species
TMDI	theoretical maximum daily intake
TRS	Technical Report Series
TTC	threshold of toxicological concern
URL	uniform resource locator

USB	universal serial bus
USEPA	United States Environmental Protection Agency
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization

Preface

This guidance document replaces the previous guidance for the hazard evaluation of veterinary drug residues in food by Joint FAO/WHO Expert Committee on Food Additives (JECFA) monographers and reviewers, issued by WHO in 1996. It is intended primarily for WHO Experts (monographers) who prepare monographs for JECFA and for Members (reviewers) who have been assigned to peer review them and propose evaluations. The guidance will also be useful to sponsors who submit dossiers to WHO and other parties interested in understanding the process followed in the evaluation of veterinary drug residues in food by JECFA. Detailed scientific guidance on the interpretation of toxicological and epidemiological data may be found in the monograph Environmental Health Criteria 240 (<http://www.who.int/foodsafety/publications/chemical-food/en/>).

In this guidance document, reference to JECFA is to JECFA (veterinary drug residues), unless otherwise specified.

With the aim of harmonizing the work of JECFA with that of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), this guidance document takes into account the document entitled *Guidance document for WHO monographers and reviewers*, prepared by JMPR in 2015 (http://www.who.int/foodsafety/publications/jmpr_guidance_document_1.pdf?ua=1). The authors of the JMPR guidance document as well as the authors of this guidance document for the evaluation of veterinary drug residues in food are gratefully acknowledged.

It is envisioned that this guidance document will be modified based upon comments received and experience gained in using it. Comments on this guidance document and suggestions for future editions will be gladly accepted by the WHO Joint Secretary, Joint FAO/WHO Expert Committee on Food Additives, World Health Organization, 1211 Geneva 27, Switzerland, at jecfa@who.int.

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