CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Food and Agriculture Organization of the United Nations
World Health Organization

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GLOSSARY OF TERMS AND DEFINITIONS

(Residues of veterinary drugs in foods)

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FOREWORD

The glossary of terms and definitions has been elaborated by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) with a view to providing information and guidance to the Committee and is intended for internal Codex use only.

The glossary is intended to be an open list that is subject to review by the CCRVDF in order to update, modify or add to the list of terms. Relevant terms elaborated by other Codex Committees are included. Attention is drawn to the notes following the terms.

Acceptable daily intake (ADI): An estimate by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of the amount of a veterinary drug, expressed in a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (standard man = 60 kg) (See Note 3).

Bioavailable residues: Those residues that can be shown by means of an appropriate method (e.g. Gallo-Torres method) to be absorbed into systemic circulation when fed to laboratory animals (See Note 3).

Bound residue: Residues derived from the covalent binding of the parent drug or a metabolite of the drug, and a cellular biological soluble or insoluble macromolecule. These residues are not extractable from the macromolecule by exhaustive extraction, denaturation or solubilization techniques. They do not result from the incorporation of metabolized, radiolabelled fragments of the drug into endogenous compounds or the same macromolecule by normal biosynthetic pathways. Information concerning the calculation of bound residues may be found in Annex 3 of the 34th Report of JECFA (pages 58–61, WHO TRS 788).

Egg: The fresh edible portion of the spheroid body produced by female birds, especially domestic fowl.

Portion of the commodity to which the MRL applies: The edible portion of the egg, including the yolk and egg white after removal of the shell.

Extractable residue: Those residues extracted from tissues or biological fluids by means of aqueous acidic or basic media, organic solvents and/or hydrolysis with enzymes (e.g. sulfatase or glucuronidase) to hydrolyse conjugates. The extraction conditions must be such that the compounds of interest are not destroyed (See Note 2).

Fat: The lipid-based tissue that is trimmable from an animal carcass or cuts from an animal carcass. It may include subcutaneous, omental, or perirenal fat. It does not include interstitial or intramuscular carcass fat or milk fat.

Portion of the commodity to which the MRL applies: The whole commodity. For fat-soluble compounds, the fat is analysed, and the maximum residue limits (MRLs) apply to the fat. For those compounds where the trimmable fat is insufficient to provide a suitable test sample, the whole commodity (muscle and fat but without bone) is analysed, and the MRL applies to the whole commodity (e.g. rabbit meat).

Fish: Means any of the cold-blooded aquatic vertebrate animals commonly known as such. This includes Pisces, Elasmobranchs, and Cyclostomes. Aquatic mammals, invertebrate animals, and amphibians are not included. It should be noted, however, that this term may also apply to certain invertebrates, particularly Cephalopods.

Good practice in the use of veterinary drugs (GPVD): Is the official recommended or authorized usage, including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions (See Note 1).

Marker residue: A residue whose concentration decreases in a known relationship to the level of total residues in tissues, eggs, milk, or other animal tissues. A specific quantitative analytical method for measuring the concentration of the residue with the required sensitivity must be available (See Note 3).

Maximum residue limit for veterinary drugs (MRLVD): Is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or μg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food (See Note 1).

It is based on the type and amount of residue considered to be without any toxicological hazard for human health, as expressed by the acceptable daily intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects.

When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available.

Meat: The edible part of any mammal.

Milk: Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.

Portion of the commodity to which the MRL applies: Codex MRLs for fat-soluble compounds in milk are expressed on a whole commodity basis.

Muscle: Muscle is the skeletal tissue of an animal carcass or cuts of these tissues from an animal carcass that contains interstitial and intramuscular fat. The muscular tissue may also include bone, connective tissue, tendons as well as nerves and lymph nodes in natural portions. It does not include edible offal or trimmable fat.

Portion of the commodity to which the MRL applies: The whole commodity without bones.

Non-extractable residues (See Note 2): These residues are obtained by subtracting the extractable residues from the total residues and comprise:

(i) Residues of the drug incorporated through normal metabolic pathways into endogenous compounds (e.g. amino acids, proteins, nucleic acid). These residues are of no toxicological concern.

(ii) Chemically-bound residues derived by the interaction of residues of parent drug or its metabolites with macromolecules. These residues may be of toxicological concern.

Edible offal: Those parts of an animal, apart from the skeletal muscle, fat, and attached skin, that are considered fit for human consumption.

Poultry: Means any domesticated bird, including chickens, turkeys, ducks, geese, guinea-fowls, or pigeons.

Regulatory method of analysis: A method that has been legally enacted and/or validated in a multi-laboratory study and can be applied by trained analysts using commercial laboratory equipment and instrumentation to detect and determine the concentration of a residue of a veterinary drug in edible animal products for the purpose of determining compliance with the MRL.

Residues of veterinary drugs: Include the parent compounds and/or their metabolites in any edible portion of the animal product and include residues of associated impurities of the veterinary drug concerned (See Note 1).

Screening method: A rapid, relatively inexpensive, and rugged field method used for testing for a specific substance or closely related group of substances which are sufficiently selective and sensitive to allow at least semi-quantitative detection of residues in contents in accordance with the established maximum limit.

Temporary acceptable daily intake (TADI): Used by JECFA when data are sufficient to conclude that the use of the substance is safe over the relatively short period of time required to generate and evaluate further safety data but are insufficient to conclude that the use of the substance is safe over a lifetime. A higher-than-normal safety factor is used when establishing a temporary ADI and an expiration date is established by which time appropriate data to resolve the safety issue should be submitted to JECFA (See Note 2).

Tissue: All edible animal tissue, including muscle and by-products (See Note 2).

Tissue, control: Tissue from animals not treated with veterinary drugs of the same species, sex, age, and physiological status as the target species.

Tissue, dosed: Tissue from animals of the test species that have been treated with the drug according to its intended use.

Tissue, spiked, or fortified: Tissue containing known concentrations of the analyte added to the sample of control tissue.

Total residue: The total residue of a drug in animal-derived food consists of the parent drug together with all the metabolites and drug-based products that remain in the food after administration of the drug to food-producing animals. The amount of total residues is generally determined by means of a study using the radiolabelled drug and is expressed as the parent drug equivalent in mg/kg of the food (See Note 2).

Validated method: An analytical method that has been subjected to a multi-laboratory study for accuracy, precision, reproducibility performance, and ruggedness. Concise written procedures for sample selection, preparation, and quantitative analysis are provided for inter-laboratory quality assurance and consistency of results, on which an appropriate regulatory method of analysis can be established.

Veterinarian client–patient relationship: The relationship is recognized when the livestock enterprise, premises, and husbandry practices are known to the veterinarian as a result of a recent professional visit to the site; the veterinarian is available for emergency on-site consultation and is responsible for preventive medicine programmes.

Veterinary drug: Any substance applied or administered to any food-producing animal, such as meat or milk-producing animals, poultry, fish, or bees, whether used for therapeutic, prophylactic, or diagnostic purposes or modification of physiological functions or behaviour (See Note 1).

Withdrawal time and withholding time: This is the period of time between the last administration of a drug and the collection of edible tissue or products from a treated animal that ensures the contents of residues in food comply with the maximum residue limit for this veterinary drug (MRLVD).

Notes:

1. Definitions for the purposes of the Codex Alimentarius see *Codex Alimentarius Procedural Manual*.

2. Definitions established and adopted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

3. Definitions previously established and adopted by the JECFA, which have been modified by the Codex Committee on Residues of Veterinary Drugs in Foods