

highest authorized use, applied in a manner that leaves a residue, which is the smallest amount practicable.

Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations.

Actual conditions include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed.

8. *Codex Maximum Limit for Pesticide Residues (MRLP)* is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLPs are based on their toxicological effects and on GAP data and foods derived from commodities that comply with the respective MRLPs are intended to be toxicologically acceptable.

Codex MRLPs, which are primarily intended to apply in international trade, are derived from reviews conducted by the JMPR following:

(a) toxicological assessment of the pesticide and its residue, and  
(b) review of residue data from supervised trials and supervised uses including those reflecting national good agricultural practices. Data from supervised trials conducted at the highest nationally recommended, authorized, or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLPs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices.

Consideration of the various dietary residue intake estimates and determinations both at the national and international level in comparison with the ADI, should indicate that foods complying with Codex MRLPs are safe for human consumption.

9. *Veterinary Drug* means 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 for modification of physiological functions or behavior.

10. *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.

11. *Codex Maximum Limit for Residues of 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 food.

An MRLVD 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. An MRLVD also takes into account other relevant public health risks as well as food technological aspects.

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

12. *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 practicable conditions.

13. *Processing Aid* means any substance or material, not including apparatus or utensils, not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

#### Definitions of Risk Analysis Terms Related to Food Safety

*Hazard*: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

*Risk*: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

*Risk analysis*: A process consisting of three components: risk assessment, risk management and risk communication.

*Risk assessment*: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

*Hazard identification*: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be

present in a particular food or group of foods.

*Hazard characterization*: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents that may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

*Dose-response assessment*: The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

*Exposure assessment*: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

*Risk characterization*: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

*Risk management*: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

*Risk communication*: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, related risk factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

#### Attachment 5

##### Part 1

##### *Uniform Procedure for the Elaboration of Codex Standards and Related Texts*

##### Steps 1, 2 and 3

(1) The Commission decides, taking into account the "Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies," to elaborate a Worldwide Codex Standard and also decides which