

## CHLORTETRACYCLINE, OXYTETRACYCLINE AND TETRACYCLINE

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At its 12<sup>th</sup>, 36<sup>th</sup> (Oxytetracycline only), 45<sup>th</sup> and 47<sup>th</sup> meetings of the Committee evaluated chlortetracycline, oxytetracycline and tetracycline and recommended at its 47<sup>th</sup> meeting the following Maximum Residue Limits (MRLs), expressed as parent drug, singly or in combination: 100 µg/kg in muscle; 300 µg/kg in liver; 600 µg/kg in kidney of cattle, pigs, sheep and poultry, and 100 µg/L in cattle and sheep milk, and 200 µg/kg in egg (poultry). An MRL of 100 µg/kg for oxytetracycline in muscle of giant prawn was also recommended. The Committee evaluated the analytical methods for measuring residues at these MRLs.

At previous Committee meetings the limiting factor in setting of the MRLs was the low value of the ADI, 0-3 µg/kg of body weight. As a result some of the MRL values were close to the limit of quantification (LOQ) of the methods available. However, this practical approach based on the limitations of the analytical methods resulted in theoretical maximum daily intake values 30% higher than the ADI.

With the new assignment of an ADI of 0-30 µg/kg of body weight, ten-fold higher than the previous ADI, the Committee recognised that the constraints placed on the recommended MRL assignments no longer exist. In particular, the LOQ of the currently available methods for tissues that have been performance tested would permit a satisfactory control of residues at twice the value of the previously established MRL. The analytical methods for monitoring tetracyclines in milk have LOQ values (15 µg/L) considerably lower than the present MRL set for milk. The Committee, therefore, considered rising the MRLs in tissues and milk.

The Committee recommended doubling the MRL values in edible tissues. The resulting MRLs are consistent with available methods and with good practice in the use of veterinary drugs. The Committee did not have information on the concentration of tetracyclines in milk that would interfere with the production of milk products such as yoghurt. The Committee, therefore, recommended no change in the MRL for milk.

The Committee recommended MRLs for chlortetracycline, oxytetracycline and tetracycline, expressed as parent drug, alone or in combination, as follows:

Muscle	200 µg/kg	for cattle, pigs, sheep and poultry
Liver	600 µg/kg	for cattle, pigs, sheep and poultry
Kidney	1200 µg/kg	for cattle, pigs, sheep and poultry
Eggs	400 µg/kg	for poultry
Milk	100 µg/L	for cattle and sheep

At its 36<sup>th</sup> meeting the Committee recommended for oxytetracycline an MRL of 100 µg/kg in muscle for all species. Fish was one of the species for which residue depletion data had been provided. At the present meeting the Committee recommended extrapolating this MRL in fish to 200 µg/kg. It further recommended that this MRL should remain temporary until data on the use patterns of oxytetracycline in aquaculture can be evaluated.

At its 47<sup>th</sup> meeting the Committee recommended an MRL of 100 µg/kg for oxytetracycline in muscle of giant prawn (*Penaeus monodon*). In view of available residue depletion data and the substantial increase in the ADI, the Committee recommended a full MRL of 200 µg/kg for oxytetracycline in muscle of giant prawn, expressed as parent drug.

The MRLs recommended above will result in a theoretical maximum daily intake of 370 µg of residues.