

European Union reply to CL 2012/23-RVDF

Part A: The draft MRLs for monepantel at step 6

The EU notes that 20th CCRVDF requested JECFA to evaluate the safety of a set of higher MRLs¹ than originally recommended by JECFA. The EU suggests keeping the draft MRLs at step 7 and considering their advancement after receiving JECFA's response.

Part B: The proposed draft risk management recommendations for chloramphenicol and malachite green

For both substances the JECFA conclusions are very clear:

- For chloramphenicol, JECFA considered the substance to be a health related hazard because of (a) carcinogenicity with the evidence of a genotoxic mechanism and (b) epidemiological studies in humans showed that it is not possible to establish any dose-relationship or threshold dose for the induction of a potentially fatal aplastic anemia. JECFA concluded that a concentration of chloramphenicol in food could not be established below which an exposure may be expected to be deemed safe.
- For malachite green, JECFA did not support the use of this substance for food-producing animals due to genotoxic and carcinogenic properties of its main metabolite leucomalachite green.

In the light of JECFA conclusions, it is clear that these substances should not enter the food chain. The EU would therefore prefer a strong language for risk management recommendations clearly stating that these substances should not be used in food producing animals.

However, the EU appreciates the efforts made at the 20th CCRVDF to find compromise language and can therefore agree with the risk management recommendations agreed at the 20th CCRVDF. The EU therefore supports the recommended risk management measures for chloramphenicol and malachite green as proposed in Appendices I and II of CL 2012/23-RVDF.

As a further comment, the EU suggests aligning the language of the recommended risk management measure for malachite green with that of chloramphenicol. So the recommended risk management measure for malachite green would read:

"In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of malachite green or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of malachite green in food. This can be accomplished by not using malachite green in food producing animals."

¹ Muscle 700 µg/kg, liver 5000 µg/kg, kidney 2000 µg/kg, fat 7000 µg/kg