Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 (Text with EEA relevance)

ANNEX I

Methodological principles for the scientific risk assessment referred to in Article 6 of Regulation (EC) No 470/2009

II.6.4.2.4. Although OECD Test Guideline 424 does not specifically address effects...
II.6.4.2.5. If a substance has been shown to cause neuropathology or...
II.6.4.2.6. Organophosphates shall be tested for delayed neurotoxicity in a hen...
II.6.4.2.7. The neurotoxicity studies shall allow the establishment of NO(A)ELs or...
II.6.4.3. Microbiological properties of residues
II.6.4.3. Potential effects on the human gut flora
II.6.4.3.1. For substances with antimicrobial activity, antimicrobial effects on the human...
II.6.4.3.2. The data shall be used to derive a microbiological ADI....
II.6.4.3.3. The risks that result from residues shall be clearly distinguished...
II.6.4.3.4. As described in the VICH GL36, the following two endpoints...
II.6.4.3.5. Any departures from the established guidance shall be justified and...
II.6.4.3.6. If no testing for effects on the human intestinal flora...
II.6.4.4. Observations in humans
II.6.4.4.1. Any available data on health effects seen in humans following...
II.6.4.4.2. The data related to exposure of humans may provide valuable...
II.6.5. Findings of other EU or international scientific bodies
II.6.5.1. If relevant safety evaluations of the substance have been undertaken...
II.6.6. Determination of an ADI or alternative limit
II.6.6.1. Determination of an ADI
II.6.6.1. Derivation of the toxicological ADI
II.6.6.1.1. The toxicological ADI shall be derived by dividing the selected...
II.6.6.1.2. The formula used to determine the toxicological ADI shall be...
II.6.6.1.3. The choice of the NO(A)EL or BMDL and the uncertainty...
II.6.6.1.4. Unless otherwise justified, the toxicological ADI shall be derived from...
II.6.6.1.5. If using the benchmark dose (‘BMD’) approach, the BMDL shall...
II.6.6.1.6. In selecting the default values for the magnitude of the...
II.6.6.1.7. In relation to uncertainty factors, the default assumption is that...
II.6.6.1.8. Where the results of animal studies indicate teratogenic effects at...
II.6.6.1.9. It may occur that the most sensitive endpoint is observed...
II.6.6.1.10. The choice of uncertainty factors for use in deriving the...

ANNEX II

Methodological principles for the risk management recommendations referred to in Article 7 of Regulation (EC) No 470/2009

(**1**) OJ L 152, 16.6.2009, p. 11.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2018/782.