Commission Regulation (EU) 2017/880 of 23 May 2017 laying down rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for other species, in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (Text with EEA relevance)

Article 7

Extrapolation across food commodities

When considering the extrapolation across food commodities, the **[**[F1]appropriate authority**]** shall apply the following criteria:

(a) for extrapolation across food commodities, the lowest established MRL in the species shall be selected as the point of departure for derivation of the MRL in the concerned food commodity;

(b) use of the remaining portion of the ADI as the point of departure and direct calculation of the MRL may also be possible;

(c) in addition, for the estimation of exposure, a conservative estimate of the ratio of marker to total residues to calculate the TMDI shall be used;

(d) extrapolation between commodities may require adjustment of the MRL values to account for differences in consumption figures;

(e) when extrapolating MRL from other tissues to milk within the same species, consideration shall be given to the physicochemical characteristics of the active substance and how these characteristics may influence accumulation in milk. Use of the lowest ratio of marker to total residues in tissues may be an acceptable point of departure from which to determine the ratio to use for milk;

(f) extrapolation of MRLs from poultry tissues to poultry eggs shall not be carried out;

(g) in the case of extrapolation of MRLs to honey the following points shall be considered:

  (i) physico-chemical and biological data on the stability of the marker residue and likely (major) degradation products and their possible formation may be required from the applicant;

  (ii) taking into account that ‘zero days’ withdrawal period is desired for honey, residue data shall be needed to demonstrate that the intended use of the substance in bees leads to safe residue levels in honey, without applying a withdrawal period. Such data may also be used for deriving the MRL;

  (iii) MRLs may only be extrapolated to honey when information is available to confirm the toxicological relevance of the major residues (including degradation products) in honey and when it is clear that honey from treated bees contains residues below the MRL even without application of a withdrawal period.

Textual Amendments

F1 Words in Arts. 4-7 substituted (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **9(4)**; 2020 c. 1, **Sch. 5 para. 1(1)**