23.11.2022

Interpretation of CIR (EU) 2021/808 requirements

Classification of A and B substances (according to CDR (EU) 1644/2022)

- If a substance is listed in table 1 of CR (EU) 37/2010 it counts as a "B-substance" - but there may be very few exceptions for individual substances (e.g. medroxyprogesterone, clenbuterol, isoxsuprine...).

- Listing of substances in table 1 of CR (EU) 37/2010 means that there was an individual evaluation of the substance with regard to potential health risks to consumers. Hence, it is appropriate to make the classification primarily independent of specific restrictions given in table 1. This means that **not** the combination of a substance with a species/matrix is relevant for the classification, but **only the listing of the substance itself**. In conclusion: if there are restrictions as "not for use in aquaculture" or "only for poultry", or .... this does not change the classification as B-substance.

Conclusions for Validation requirements

- the alpha-error is 5 % for all B-substances

- B-substances are validated usually down to 0.1* x the MRL (or the 0.1* X cascade MRL for "off-label" use)

- "A-substances" are validated as low as possible (but CCα for confirmation and CCβ for screening should be < MMPR)

**) as target value if reasonable feasible*