Conversion of specifications developed under "old procedure" and review of specifications developed under new procedure

Conversion of specifications developed under FAO "old procedure"

Note: this subsection is a temporary one and shall be removed, when all FAO specifications developed and published under old procedure are either converted into new procedure ones or withdrawn.

Specifications developed under the FAO "old procedure" (cf. Section "Background to FAO and WHO specifications for pesticides", pp. XI onward) are reviewed at intervals based on suitable criteria like whether the compounds are still in use.

The information as outlined in Section 3.1 will apply for conversion of old procedure specifications into new ones. However, some particular aspects different than for the proposal of reference specifications for technical and formulated pesticides are considered by JMPS.

For the conversion process, the manufacturer providing the most complete hazard data package (see Section 3.1 A 9) supporting a recent purity and impurity profile of the technical material produced will be considered by JMPS as main data proposer and the specifications developed will be considered as reference specifications. In cases where such a firm link between a full hazard data and the purity and impurity profile of a technical material cannot be established by a manufacturer, JMPS will consider a proposal from a manufacturer submitting a data package similar as for an equivalence case (see Section 3.2, Minimum data requirements for extension of an existing specification to an additional manufacturer or a new manufacturing route, point E 1 for Tier-1). The Meeting will, in addition to the data submitted, consider the published subchronic, chronic, mutagenicity, neurotoxicity and reproduction toxicity studies on the active ingredient and their results that have been reviewed and evaluated by JMPR. A proposal for a TC or TK is deemed acceptable by JMPS provided that

i) the technical material under evaluation does not produce a response in the *in-vitro* mutagenicity test worse than that for the material whose hazard profile has been evaluated by JMPR

i) no qualitatively new adverse effect is observed in the repeated dose studies (28 or 90 days repeated dose studies in rodents) and

ii) The “no observed adverse effect level” (NOAEL) or bench-mark dose for any toxicity end point is not more than a factor of $10^{-0.5}$ lower than that evaluated for the technical material evaluated and published by JMPR