S40-4 The ecological effect of the pharmaceuticals

◯Norihisa TATARAZAKO[1]

[1]National Institute for Environmental Studies

In 2006, European Medicine Agency (EMEA) has established the guideline about the environmental risk (ER) evaluation of pharmaceuticals. Assuming that the basic ideas for the ER evaluation for existing chemicals can be also applied to pharmaceuticals, EMEA recommends the following tests as test of the ecotoxicity for pharmaceuticals; TG201(Algae), TG202, TG211 (Crustacea), TG203, TG210 (Fish), TG207 (worm), TG216 (microbiota), TG218, TG219 (chironomid), TG232 (collembolan) in the OECD test guidelines. A hazard ratio (HQ = PEC/PNEC) is calculated from the hazardous property of chemicals (PNEC) which are derived from the biological test mentioned above and the predictive concentration of discharged chemicals in the environment (PEC). And it is generally considered that there is an environment risk where HQ is larger than 1. Some points as described below should be reconsidered. (1) The mode of action for the wildlife is not clear. What is appropriate as an endpoint? (2) Normally the pharmaceuticals are discharged to environment though a sewage treatment plant. How do you define the "field" to evaluate an ER? (3) How should we use ecotoxicity data prepared independently for each chemical? (4) When an ER and benefit to humans are compared, benefit is superior obviously. How should we face an ER?