

Annex A - Discussion paper on novel formulations of supplement compounds designed to increase oral bioavailability

# Case studies of supplement formulations with increased bioavailability

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77. The following paragraphs outline three case studies of supplement compounds prepared as novel formulations. The case studies are intended to provide empirical pharmacokinetic outcomes of the mechanisms and

physiological parameters discussed above and, specifically, to assess how novel formulations of supplement compounds may significantly affect plasma levels of active compounds. Some of these examples, therefore, may have toxicological implications.

78. The case studies are focused on controlled human trials in which novel and standard formulations are compared, rather than on *in vivo* and/or *in vitro* data. These studies are not exhaustive and attempt to provide an overview of realistic scenarios of how novel formulations of supplements may impact their bioavailability.