Executive Summary

In this guide

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Over the past couple of decades there has been an increasing trend within the supplement industry toward the formulation and marketing of bioactive agents (such as vitamins, minerals, and plant metabolites) in novel ways that are designed to increase oral bioavailability. Amongst these formulations are lipid-based preparations such as liposomal, micellar, and emulsions, as well as non-lipid-based preparations including micronisation and co-formulation with polysaccharides. Although these preparations are often marketed as having improved absorption relative to more traditional formulations, there is a lack of evidence and a large degree of uncertainty as to these effects. This is complicated by the heterogeneity of novel formulation types and the lack of data characterising their physical-chemical properties. The effects of supplement formulation on toxicological effects are similarly uncertain and of potential concern, particularly with respect to under-characterised active agents and/or vulnerable populations. Given this situation, the Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment (COT) have discussed the possible toxicological risks associated with the consumption of supplement compounds formulated in novel ways and the possible increase oral bioavailability of these. The Discussion Paper sets out the physical-chemical characterisation of several lipid-based and non-lipid-based formulations designed to increase oral bioavailability, the possible physiological mechanisms through which they act, and several case studies reviewing their effects drawn from the

literature (curcuminoids, vitamin C, and CBD). The uncertainties surrounding novel bioavailable formulations are also discussed. The Discussion Paper can be found in Annex A and this Special Topics Report provides an overview of the paper's contents and the COT's discussions thereon.