Research projects with foodstuffs and dietary supplements

Which ordinance is applicable to studies done with foodstuffs and/or dietary supplements? Should the foodstuffs and dietary supplements be made according to the requirements set in GMP or to the requirements set in the Foodstuffs Act (Federal Act on Foodstuffs and Utility Articles, FSA)?

- A clinical trial (open or blinded), in which a foodstuff or dietary supplement is being tested on its own or compared to a foodstuff or dietary supplement, is a clinical trial as per ClinO, Chapter 4, Other Clinical Trials, Art. 60-61. The foodstuff or dietary supplement must be made in compliance with the requirements set in the Foodstuffs Act (FSA).
- If a foodstuff or dietary supplement is tested as a pharmaceutical product (i.e. having a medicinal effect) it is considered a clinical trial of a medicinal product as per ClinO, Chapter 2. The foodstuff or dietary supplement must be made in compliance with the GMP requirements.
- If a research project evaluates a food stuff that is not assigned as part of the project, the project is not considered interventional according to ClinO and thus classified as per HRO, Chapter 2. The Ethics Committee will define the risk category as per HRO, article 7.

The categorization of research projects is done by the Ethics Committees. If you are unsure about the categorization, please submit a “clarification of responsibility” through the BASEC submission portal.

Important Note: The procedure applies only to foodstuffs and dietary supplements that can be placed on the market [“authorized foodstuffs/dietary supplements”]. It does not apply to foodstuffs/ dietary supplements that do not fulfill the requirements set in the Foodstuffs Act (Federal Act on Foodstuffs and Utility Articles, FSA) or that are considered medicinal products as per the Federal Act on Medicinal Products and Medical Devices Art. 4 Abs 1 Ziff a (Therapeutic Products Act, TPA)