

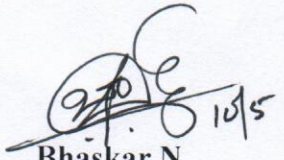
10<sup>th</sup> May, 2022

**Order**

**Subject: Direction under section 16(5) of the Food Safety and Standards Act, 2006 regarding operationalization of FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Probiotic and Probiotic Food) Regulations, 2022. [FSS (Nutra) Regulations, 2022]**

This is in continuation to direction issued dated 29<sup>th</sup> March 2022 on the subject cited above.

2. In this regard, it is to mention that during examination of recently operationalized regulations following were observed:
  - i. As per provision 5(4)(a) of Nutra regulations 2022, a cross reference to the GMP table (Appendix 'A') of the FSS (FPS&FA) Regulations, 2011 has been given for the list of food additives to be used at GMP levels. However, some of the additives namely- *Ammonium acetate, Ammonium lactate, Choline salt and esters, Cross carmellose sodium, Potassium hydrogen malate, Sodium starch glycolate and Sucrose oligoesters-Type I and II* which were present in the Schedule VE of the previous FSS (Nutraceutical) Regulations, 2016 are not present in the GMP table (Appendix 'A') of the FSS (FPS&FA) Regulations, 2011.
  - ii. Further, as per provision 6(1)(b) of the FSS (Nutra) Regulations, 2022, the proteins and enzymes specified under Schedule III have been inadvertently excluded for use in Health supplement.
3. In view of the above, the following has been decided:
  - i. FBOs may use additives as mentioned in para 2(i) above at GMP level, in addition to additives listed under GMP table (Appendix 'A') of the FSS (FPS&FA) Regulations, 2011.
  - ii. Enzymes and proteins listed under Schedule III of the FSS (Nutra) Regulations, 2022 are allowed in the manufacture of Health supplement.
4. This issues with the approval of the Competent Authority.

  
Bhaskar N

**Advisor (Science and Standards)**

**To**

1. ED(CS) with a request to communicate to Food Safety Commissioners of all States/UTs
2. Advisor (QA)
3. Head (RCD)/Head (Regulations)/ Head (Legal)
4. Director (TICD)-with a request to communicate to all Authorized Officers
5. All Regional Directors, FSSAI
6. CITO, FSSAI-with a request to upload this on FSSAI website

**Copy to:**

1. PPS to Chairperson, FSSAI,
2. PS to CEO, FSSAI,