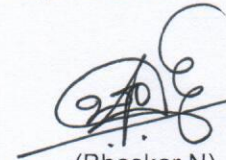


F. No. Std/SP-17/A-1.21
Food Safety and Standards Authority of India
(A Statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)
(Science & Standards Division)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 11th January, 2022

Subject: Direction under Section 16 (5) of Food Safety and Standards Act, 2006 regarding use of *Paullinia cupana* (Guarana) as a source of caffeine.

- FSSAI vide its order dated 31st December 2018 [F.No. Stds/Nutra(DCGI)/FSSAI-2017 (Pt 1)], directed FBOs to discontinue use of *Paullinia Cupana* (Guarana) in the products covered under Nutraceutical Regulations with immediate effect due to lack of adequate data such as history of safe usage in India for 15 years and also the specific advantage of these plants over already listed Indian plants/ botanicals.
2. Further, FSSAI vide its order dated 10th May, 2019 [F.No. Stds/Nutra(DCGI)/FSSAI-2017 (Pt 1)] issued the directions that an ingredient which is not allowed for inclusion under Nutraceutical regulations vide directions dated 29.12.2017, 29.06.2018, 24.08.2018 & 31.12.2018, is not allowed to be used in any food product, except if the use of this ingredient is specifically permitted by other regulations under Food Safety and Standards Regulations.
 3. In partial modification of the direction of even number dated 10th May, 2019 [F.No. Stds/Nutra(DCGI)/FSSAI-2017 (Pt 1)] the following decisions are further conveyed for information and necessary action:
 - a) *Paullinia cupana* (Guarana) as a source of caffeine is allowed as long as the caffeine isolated and purified has the same structure and properties as pure caffeine. Such caffeine sourced from Guarana and the level of such caffeine should comply with FSSR.
 - b) In case Guarana extract with standardized content of caffeine along with other active components are to be used either as a supplement or as nutraceutical ingredient, such ingredient shall need prior approval under NSF&FI regulations.
 4. This direction will supersede the earlier direction of even number dated 10th May, 2019 [F.No. Stds/Nutra(DCGI)/FSSAI-2017 (Pt 1)] with respect to use of *Paullinia cupana* (Guarana) as a source of caffeine.
 5. This issues with the approval of the Competent Authority, in exercise of the powers vested under Section 16 (5) of Food Safety and Standards Act, 2006.


(Bhaskar N)

Advisor (Science & Standards)

To

1. All Food Safety Commissioners
2. All Authorized Officers, FSSAI
3. All Designated Officers, FSSAI

Copy to

1. PPS to Chairperson, FSSAI, New Delhi.
2. Sr. PS to CEO, FSSAI, New Delhi.
3. ED (CS)
4. Head (RCD)/ Head (Regulations)
5. CITO, FSSAI for necessary action and uploading on FSSAI website.