



Upcoming Changes in India Standards – Extraction Solvents and Processing Aids: Implications for the Nutraceuticals Industry

April 12, 2021

PLEASE NOTE THAT THE INFORMATION CONTAINED IN THIS DECK IS CURRENT AS OF APRIL 12, 2021: THE CONTENT WILL CONTINUE TO BE REVISED AS WE OBTAIN MORE INFORMATION FROM FSSAI AND OUR TRADE ASSOCIATION PARTNERS IN INDIA

Background:

- **Food Safety and Standards Authority (FSSA), 2006:** governs the regulatory standards of all food products, beverages and nutraceuticals (botanicals)
- **Section 22, FSSA, 2006:** included language around the use of solvents
 - *“a Food Business Operator may use water, ethyl alcohol or hydro alcoholic process for obtaining plant or botanical extracts used in the products covered under these regulations.”*
 - any new extraction method requires prior approval from the Authority
- **In 2016,** India introduced a draft regulation specific to nutraceuticals and foods for special diets and medical purposes.
 - defined these categories based on ingredients, labelling, additives, contaminants, and health and nutritional claims
 - determined the criteria for the manufacturing and sale of these categories of foods and recommended doses or consumption levels
- **Despite the evolution of these regulations, since 2006, the extraction solvent clause has never been translated in the regulations and has not been enforced in the Indian market**

Recent Developments in Nutraceutical Regulations under the FSSA since July 2020

- July 2020: FSSAI is intending to implement the extraction solvent clause mentioned in Section 22 of the FSS Act
- July 2020: As part of our advocacy efforts, OAHT provided comments to FSSAI (through trade associations in India), to include the following language in the regulation:
 - *“Food Business Operator may use water, ethyl or hydro alcoholic or any other solvents, which are safe and internationally recognized, for obtaining plants or botanicals extracts used in the products covered under the regulations.”*
 - our proposal was based on the solvent guidelines from US, Canada and Australia
 - neither we nor our industry partners have since received any response from FSSAI on this proposal
- March 23, 2021: FSSAI met internally to discuss and clarify their position on the residual solvents' permissibility in Nutraceutical products
- March 29, 2021: FSSAI announced that the extraction solvent clause will be incorporated into the draft Nutraceutical regulation document issued by FSSAI in November 2020 – furthermore, the clause is intended to implemented on January 1, 2022

Issues and Impact Associated with Implementation of the Extraction Solvent Clause from Section 22, FSS Act 2006

*The FBO **may** use **water, ethyl alcohol or hydro alcoholic** process of extraction for obtaining plants or botanicals extract used in the products covered under these regulations.*

❑ Issues:

- This was not part of the original **Draft Regulation (Nov 2020)** and has been included **without public consultation**
- There is **ambiguity in terms of how the language is drafted** - it does not use the words **must** or **only** and leaves it open to interpretation
- **Misalignment with FSS (FPS & FA) Third Amendment Regulations, 2020** that allows **13 solvents** in “**Spice Oleoresins**” (constituents of spices & herbs) that are the raw materials for many Schedule IV and VI ingredients
- Currently most of the schedule IV and schedule VI botanicals and ingredients are extracted using different solvents which are recognized safe and hence allowed by various global food regulatory authorities, like, **US FDA, Australia TGA, Health Canada, Japan MHLW, Korea MFDS**
- Implementation date of **January 1, 2022** is aggressive and can interrupt business continuity

❑ Impact:

- **Compromise health and wellness** of the Indian population who rely on nutraceuticals to support overall wellbeing
- Significant **economic impact** on the current Nutraceutical industry and **compromises continuity of business operations**
- It will **slow down the speed of innovation** in this area of science in India

Implementation of the Extraction Solvent Clause from Section 22, FSS Act 2006: Next steps from the industry

☐ Recommendations:

- Modify the language of the clause: ***"The FBO may use water, ethyl or hydro alcoholic or any other solvents, which are safe and internationally recognized, for obtaining plants or botanicals extracts used in the products covered under the regulations."***
- This should be presented as a **draft regulation for public consultation with a new extended timeline**
- There should be a process for approval of solvents excluded from the Act and that are currently safely being used in commercial products

☐ How will this help?

- Bring clarity and eliminate any ambiguity with the currently proposed clause, especially with the use of words "may use"
- Be consistent with global regulations
- Necessary to support business continuity and allow access to innovative products developed with advanced scientific processes

Recent Developments Regulations Related to Processing Aids

- For decades, the Conventional Food, Beverage and the Nutraceutical Industry in India has been using several types of processing aids, as permitted by different global authorities
- **October 2020:** for the first time, FSSAI drafted a list of **Permitted Processing Aids** for foods and beverages **(but it is not clear if this would be applicable to nutraceuticals)** with an enforcement date of **July 1, 2021**
- Although there have been **no announcements and guidance from the authorities if Nutraceuticals will be impacted**, FSSAI has indicated that this is a dynamic list and will be creating a new list of processing aids in the next couple of months, and the enforcement date is **likely to be extended till Jan 1, 2022**
- OAHT continues to closely monitor these developments and work with its industry trade association partners