



Nutraceutical Regulations in India – What's NEXT

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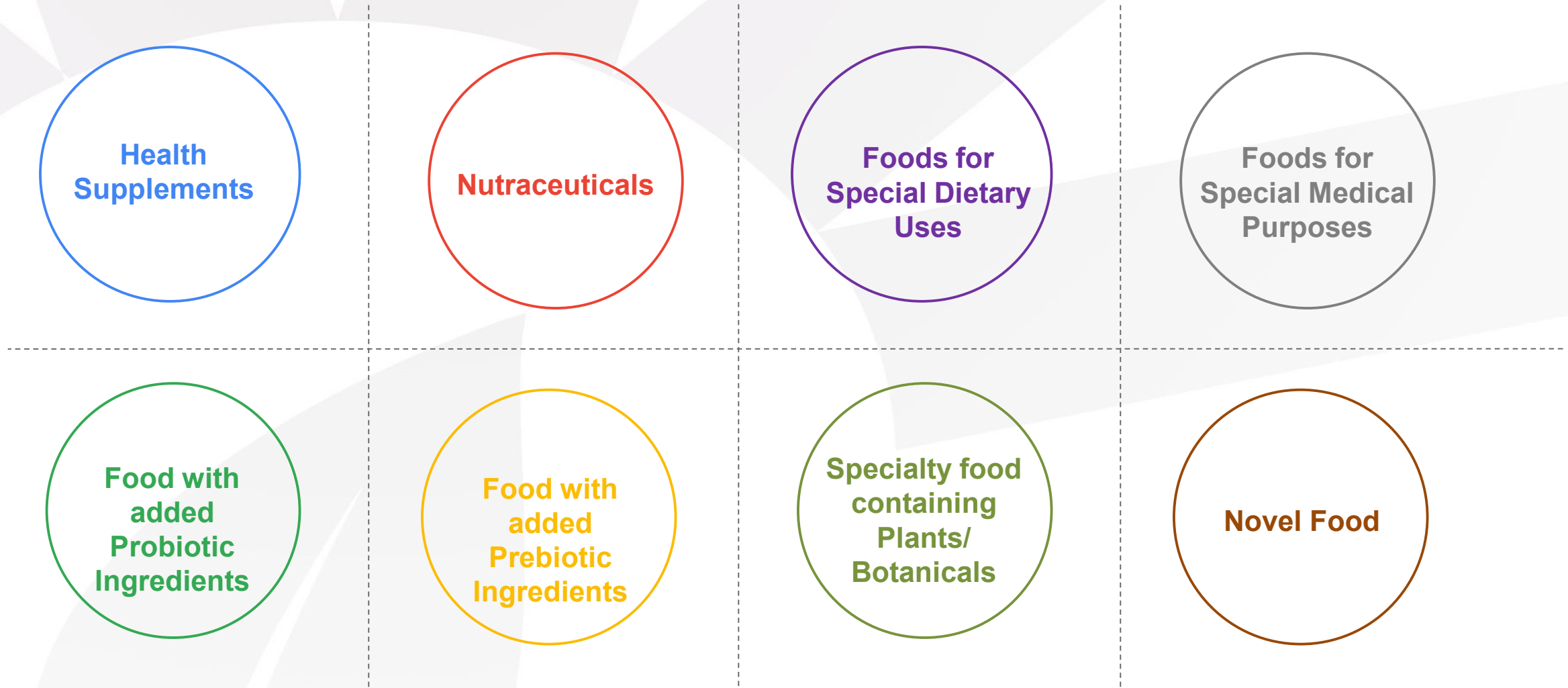
Global Scientific & Regulatory Affairs
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**PLEASE NOTE THAT THE INFORMATION CONTAINED IN THIS DECK IS CURRENT AS OF JULY 22, 2021:
THE CONTENT IS SUBJECT TO CHANGE BASED ON ANY CHANGE IN UPCOMING NOTIFICATION OF FSSAI'S NUTRACEUTICAL REGULATION**

Agenda

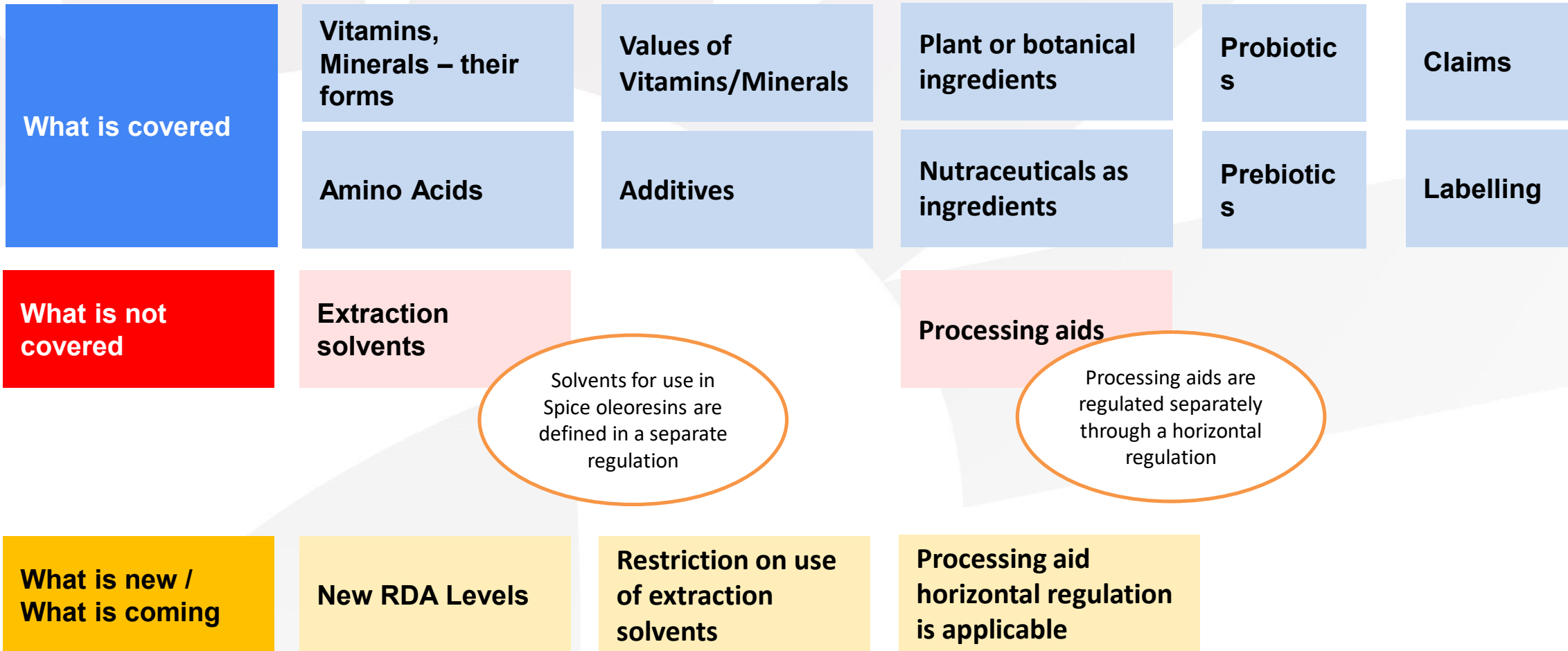
1. FSSAI Regulation on Nutraceutical and Allied Products
2. Snapshot of the Nutraceutical Regulation
3. What is coming next – Extraction solvents
4. What is missing – Processing aids

FSSAI's Nutraceutical Regulation- Product categories covered



Ref: Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food & Novel Food) Regulations, 2016

FSSAI's Nutraceutical Regulation- What is covered



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FSSAI's Nutraceutical Regulation- What is coming next

Issue

The following clause is proposed for inclusion to Nutraceutical Regulation in line with FSS Act, 2006

*The FBO may use **water, ethyl alcohol or hydro alcoholic** process of extraction for obtaining plants or botanicals extracts*

Challenges

This would pose significant challenges for sale of nutraceutical products in Indian market

- **Advancements in extraction technologies post 2006 are not considered**
- **Industry uses different solvents allowed by various global food regulatory authorities**
- **FSSAI allows 13 solvent for use in SPICE OLEORESINS**

Impact

- Will be detrimental to ease of doing business for overseas and Indian companies
- Will slow down the speed of innovation in this area of science in India

Recommendation

- **13 solvents** currently allowed in Oleoresins should also be allowed for extraction/processing of Plants & Botanicals
- Additional solvents which are **safe and/or internationally recognized** should also be permitted

Justification

- **Spice oleoresins are used as raw materials** for many Nutraceutical products
- Ease of doing business due to **alignment with global regulations** on solvents
- **Business continuity**

FSSAI's Nutraceutical Regulation- What is missing

Issue

Positive list of **Processing Aids is not included** unlike the positive lists of Botanicals, Ingredients, Vitamins, Minerals etc.
Horizontal Regulation of Processing Aids (applicable across regular F&Bs) would apply

Challenges

- Specific Processing Aids required in specialized manufacturing processes of Nutraceuticals are not considered in Processing Aids' Horizontal standard

Impact

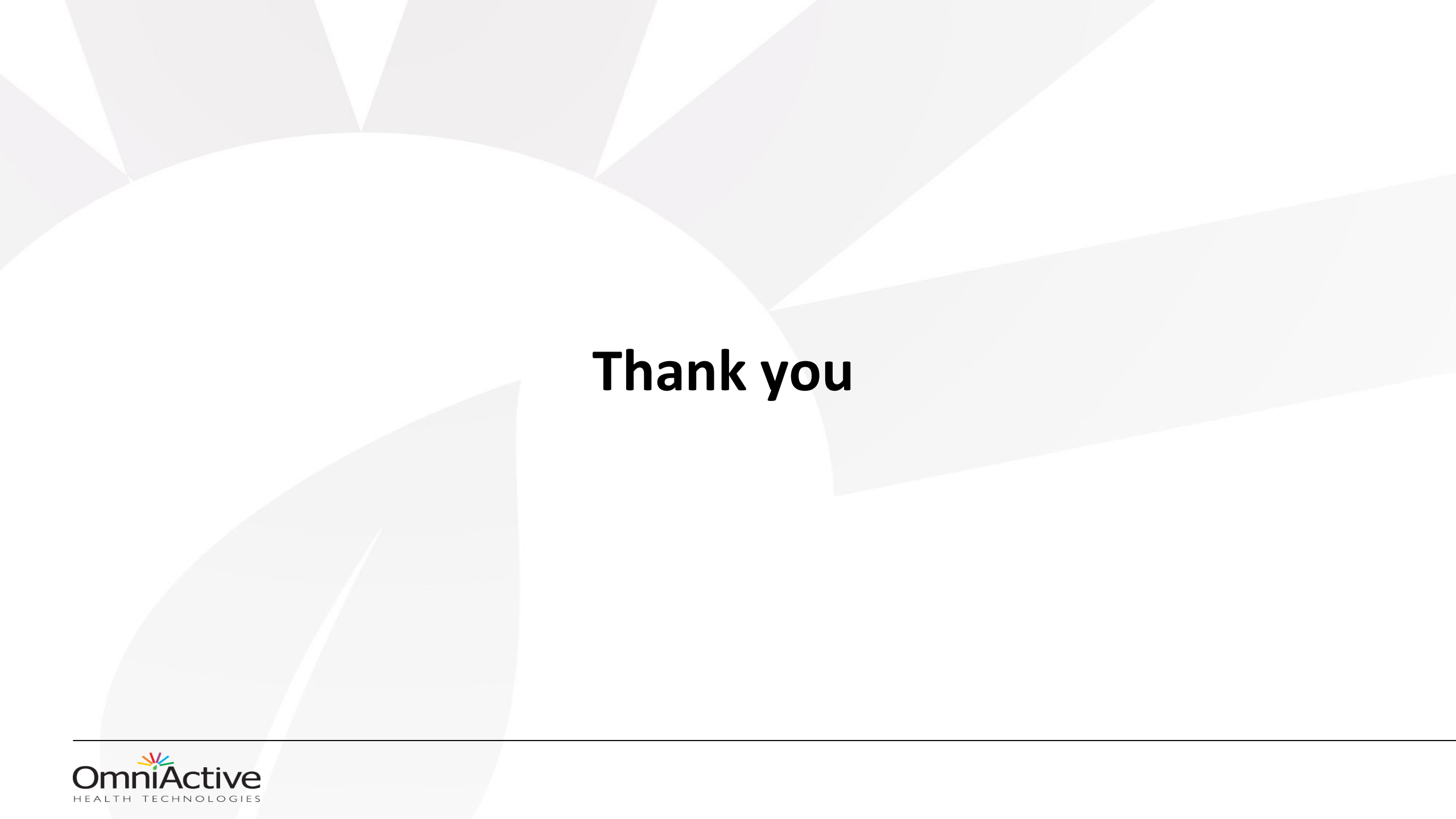
- Will be detrimental to ease of doing business for overseas and Indian companies
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Recommendation

- **Inclusion of positive list of Processing** Aids in Nutraceutical regulation

Justification

- Nutra regulation has its own positive lists for additives, in spite of the Horizontal standards on Additives

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Thank you