

WEBINAR ON RETROSPECTION ON THE NUTRA REGULATION: FREQUENT CHANGES & STRESS OF COPING WITH COMPLIANCE

AUTHOR

Dr Shashank Bhalkar,

Asst Director,
PFNDIA



Dr. Shashank Bhalkar,
Regulatory coordinator to give
a brief introduction to the
Webinar.

Dr. Bhalkar in his presentation
described how the Nutra
regulations brought in clarity
to FBOs for this important
category of products also
authorities to regulate such
products. He further explained
how a small change in
Regulation is challenging as it
would trigger a series of
multifunctional activities to
comply with the change for
the FBOs.

Dr. B. Sesikeran, Chairman
Scientific Advisory Committee

PFNDIA was not
able to be present
for the event. He
however shared
his thoughts via
video recording.
In his message he
mentioned how
this 2016
Regulation is
changing and said
this change should
be accepted for

this constantly changing
dynamic segment of
Nutraceuticals. He further
stressed that the new
regulation should be better
than earlier one. Addition of
new substances and botanical
should have proven health
benefits. He
wished success
to the Webinar.

Dr. J. S. Pai,
Executive
Director
PFNDIA
welcomed all
in the
beginning and
requested



Dr Jagadish
Pai



Dr Shashank
Bhalkar

Frequent changes in
regulations are
always challenging
for industry. Because
at times there is
difficulty in
maintaining
availability of
existing leading
brands in
marketplace while
meeting the timelines
set by Regulators. Nutra
regulations which came into
existence in 2016 have
undergone so many changes
over the period.
ProteinFoods and Nutrition
Development Association of
India (PFNDIA) organized a
Regulatory Webinar on
"Retrospection on the Nutra
Regulation Frequent
Changes & Stress of Coping
with Compliance" on 18th
November 2022. The
sponsors of the Webinar
were Herbalife Nutrition,
Abbott Healthcare & Amway
India.



Ms Rini Sanyal,
Director, Global
Regulatory Affairs &
Product Compliance,
Herbalife Nutrition
spoke on "Health
Supplements and
Nutraceutical:
Deviations from Nutra
2016 and global
practice". In her
informative
presentation
she explained
the journey
of this
Regulation of
2016 which
started with
progressive
thought
process,
underwent so
many small
and big



Ms Rini Sanyal

global practice, he
briefed on the
Evolution of Nutra
Regulation where he
mentioned about
the new
introduction in FSDU
i.e., 1. A special
category of food for
Sports person,
2. In March 2022
FSSAI published FSS
(Nutra) Regulation
which was

operationalized with
immediate effect.

He further mentioned on the
Changes introduced in
Operationalized FSS (Nutra)
Regulation 2022 which are
until now not mentioned in
original or the amended
regulation. He explained in
detail on the Codex General
Standards for Labelling Claims
& Claims for Pre-packaged
food for special Dietary uses
(FSDU). He ended his talk by
explaining the Global Food
Regulation
Framework.

Ms Dolly Soni,
Manager Marketing
and Projects
PFNDAI introduced
all the speakers.



Ms Dolly Soni

Dr Shatadru Sengupta, Vice
President - Legal,
Hardcastle
Restaurants Pvt
Ltd; Chairman,
PFNDAI gave a talk
on, "Regulation-making
procedures under the FSS Act,
2006". In his excellent
presentation explained so
many things about the act
which we ought to know. That
includes basic things like
differentiation between Act,
Rules, and
regulations. Sec 92 of act
gives power
to authority
to make the
regulation
which are to
be placed
before
parliament as
per Sec 93.
While making
standards the
authority must consider local
agricultural as well logistics
conditions and also
international standards and
practices. The standards
should be risk based and made
by a transparent process.

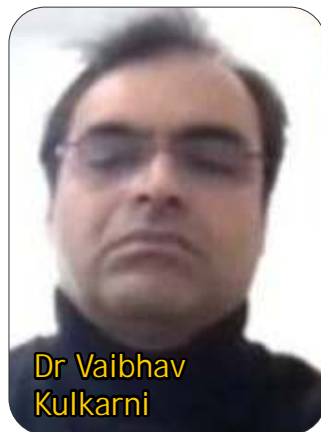


Dr Shatadru Sengupta

changes and now the latest
overhaul draft in 2022 issued
for stakeholder consultation.

She also explained
Administrative and Technical
GAPS identified and addressed
during this evolution. The
impact of frequent changes
on overall business was
discussed as every change
involves cost, time at times
losing consumer confidence
because of no product in
market.

Dr Vaibhav Kulkarni,
Director &
Senior
Leadership Team
Member Abbott
Nutrition
Regulatory Affairs,
Abbott Nutrition
gave a talk on FSDU
and FSMP:
Deviations from
Nutra 2016 and



Dr Vaibhav Kulkarni





Dr Adip Roy, Associate Vice President - Regulatory Affairs, Amway India Enterprises Pvt. Ltd presented on "Nutraaceutical Regulation: Innovation Challenges."

He opened his talk by stressing importance of Regulatory compliance which helps smooth, fair operations within the market, finally boosting economy. While describing the evolution of Nutra regulations, he said the original regulations opened eight categories giving new opportunities for differentiated offerings to the consumers.



Dr Adip Roy

However, 2022 amendments redefined these products into five categories. Also because of additives, format restrictions and complexity of schedules have

become more challenging for innovations. Innovations always propel demand for supplements.

For example, tablets capsules are convenient to carry formats and can deliver higher level of micronutrients.

Additive should have been allowed across the categories based on toxicological risk assessment.

Similarly, there is challenge for Vitamins Minerals which to be added with prior approval in FSDU and FSMP. The regulations if mapped to international guidelines would have helped to develop products of global parity.



Dr Joseph Lewis

The last session of panel discussion was moderated by **Dr Joseph Lewis**, Chairman-Regulatory Affairs Committee, PFND AI.



Sponsored by



Amway



Protein Foods & Nutrition Development
Association of India

Organized a Regulatory Webinar on

Retrospection on the Nutra Regulation Frequent Changes & Stress of Coping with Compliance

Held on 18th November 2022



Dr Shatadru Sengupta



Ms Rini Sanyal



Dr Vaibhav Kulkarni



Dr Adip Roy



Dr Joseph Lewis



Dr Vijendra Prakash



**Ms Kumud Ashish
Singh**



Ms Veena Sharma



Dr Shashank Bhalkar



Dr Jagadish Pai



**Ms Dolly Soni
(Webinar Convenor)**