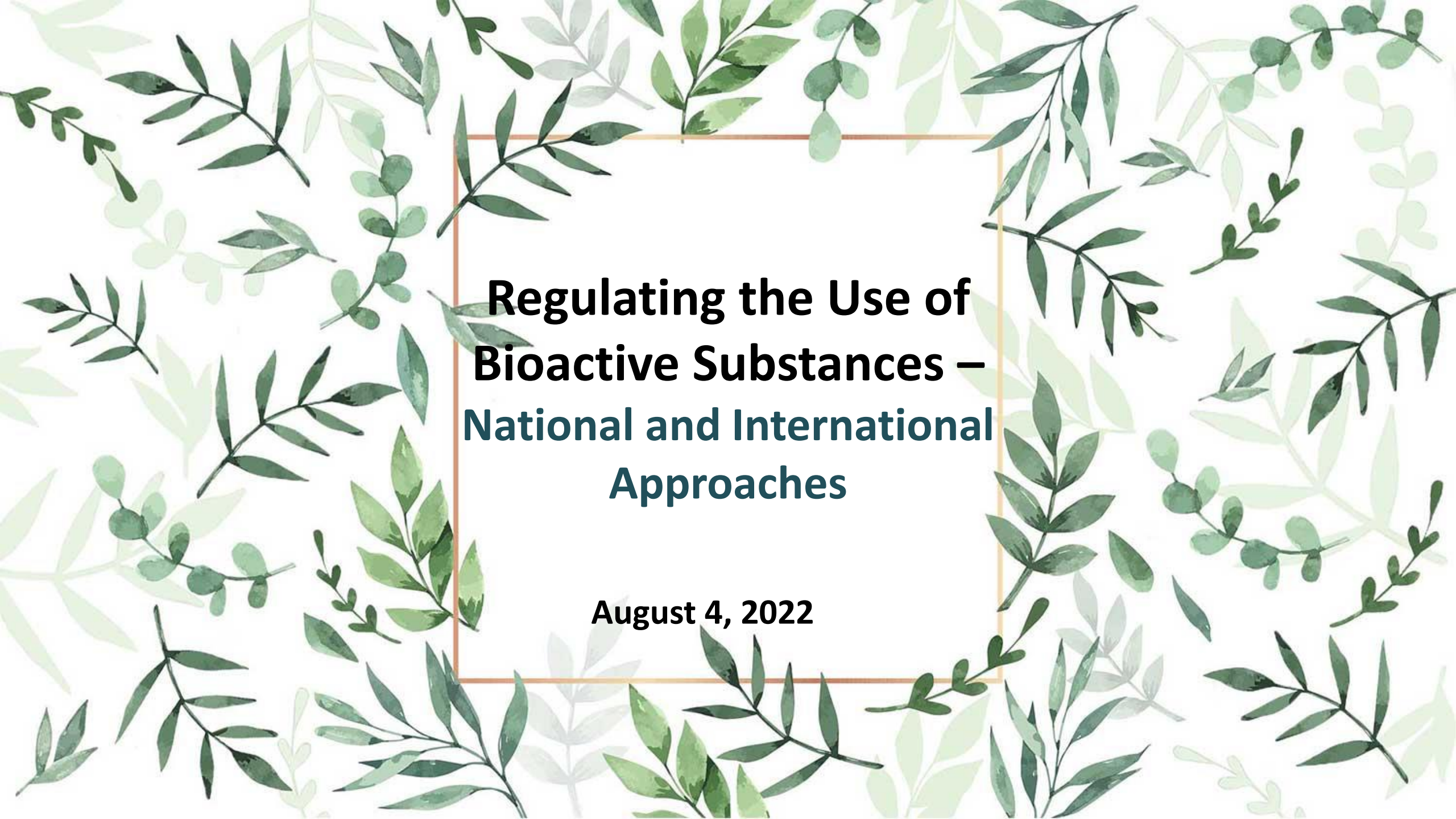


DISCLAIMER

The opinions expressed in this presentation and on the following slides are solely those of the presenter based on food regulations and not necessarily those of Herbalife Nutrition.



**Regulating the Use of
Bioactive Substances –
National and International
Approaches**

August 4, 2022



TOPICS

01

The definitional aspect and status

02

Application of evolving science for use in Foods

03

Regulatory developments / approaches

04

Future Trend

05

Takeaways

DEFINITION

Basic definition of a bioactive compound found in many language dictionaries is “**having or producing an effect on a living organism**”.

However, available broad definition is not very specific enough for the current regulatory framework as it does not specify:


- If the effect is beneficial
- If beneficial, if the type of effect is pharmacological or nutritional



Bioactive compounds are defined as components of food that have an impact on **physiological or cellular activities** in the humans or animals that consume such compounds.

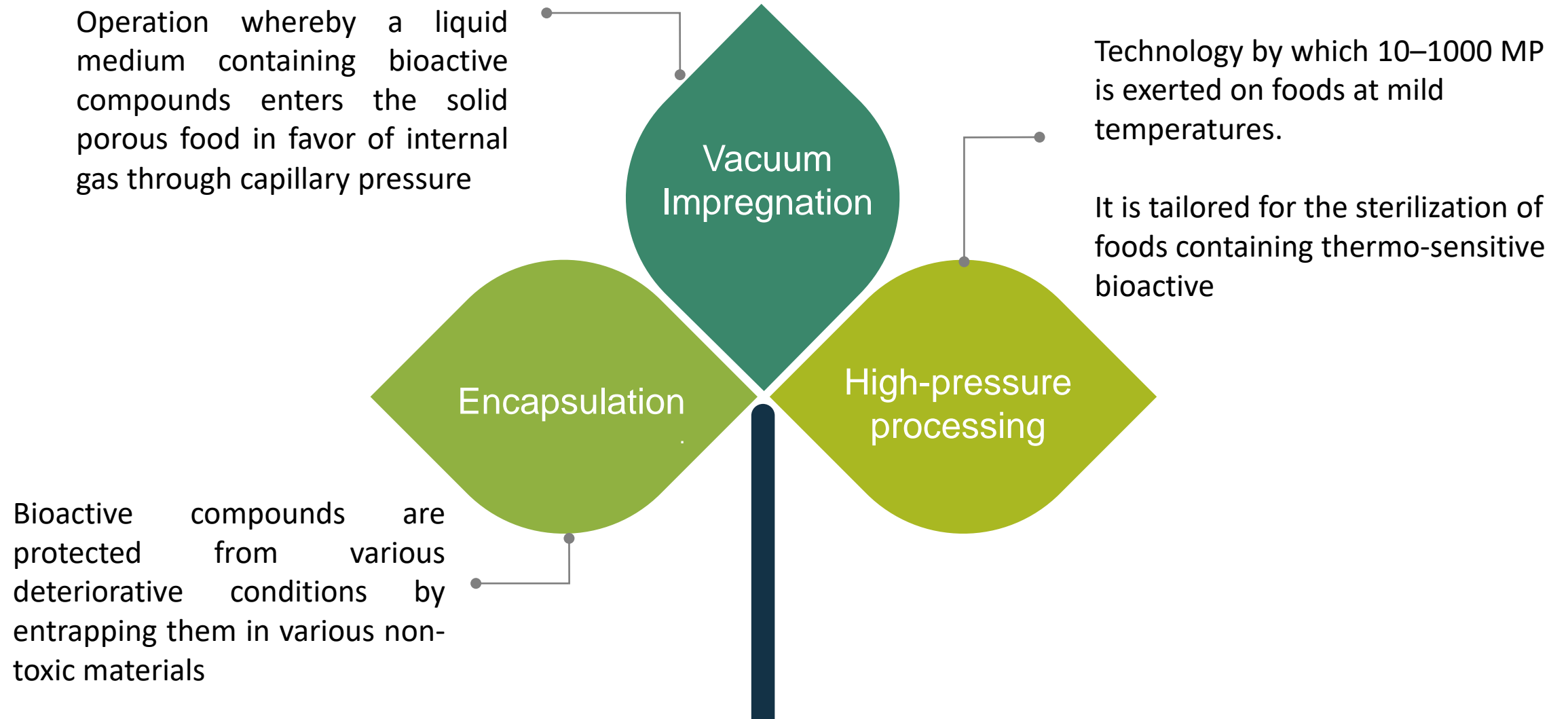
Bioactive compounds, such as **plant secondary metabolites, probiotics, bioactive peptide, and minerals**, which can be incorporated into foodstuffs to improve their nutritional values and can be **protective against various diseases and metabolic disorders**



The background of the slide is a repeating pattern of watercolor-style green leaves and branches. The leaves are in various shades of green, from light to dark, and are scattered across the white background. The branches are thin and dark green. In the center of the slide, there is a light green rectangular box with a thin orange border. Inside this box, the text "Application of evolving science for use in Foods" is written in a bold, black, sans-serif font.

**Application of evolving
science for use in Foods**

Food technology and its impact on functional food development



Recent advances in production of Bioactive compounds

Fermentation by probiotic bacteria is an approach used to the preservation of food for a long time.



Ultrasound-assisted extraction is a non-thermal and green technology that works based upon mechanical waves with frequencies of higher than 20 kHz, which traverses through a medium

The background of the slide is a repeating pattern of watercolor-style green leaves and branches. The leaves are in various shades of green, from light to dark, and are scattered across the white background. A central light green rectangular box with a thin orange border contains the text.

Regulatory Developments / Approaches

REGULATORY SCENARIO

“Bioactive compounds”, “nutraceuticals”, and “functional foods” are some of the terms widely used in the food context, however, the margins between them all are not clear and are very often used interchangeably.

There are various available definitions of “bioactive” found in the several literature.

Though all these terms are widely & commonly used worldwide, However, there is no globally agreed upon definition and there is no consensus on their meaning.



Indian Regulatory Framework



The term 'bioactive compound' is not defined in the Indian regulations, however, since they can be part of nutraceuticals food, they are included within the regulatory requirements as “**Molecules/isolates/extracts**”

“NUTRACEUTICAL IS A CATEGORY OF FOODS WHICH CONSISTS OF EXTRACTS, ISOLATES AND PURIFIED CHEMICAL COMPOUNDS HAVING A PHYSIOLOGICAL BENEFIT AND HELP TO MAINTAIN HEALTH”

Indian Regulatory Framework

Schedule II (Plant or botanicals)

Schedule III (Molecules/isolates/extracts other than Schedule II)- Specific for Nutraceuticals only like Lycopene , Lutein etc

Limits as specified in with standardisation to marker compounds specified and at daily usage levels specified therein

Adopt the usage level based on relevant scientific data, if not provided

If standardisation of the marker compound not specified shall comply with manufacturer specifications or quality requirements and purity criteria as specified in regulation

CLAIMS



Structure, function or general well-being of the body allowed by the Food Authority if the statement is supported by the generally accepted scientific data.

Nutritional or health claims or reduction of disease risk claims (DRR) that are listed under FSS (Claims and Advertisements) Regulations, 2018.

For making any other claims, prior approval of the Food Authority need be obtained.



INGREDIENTS

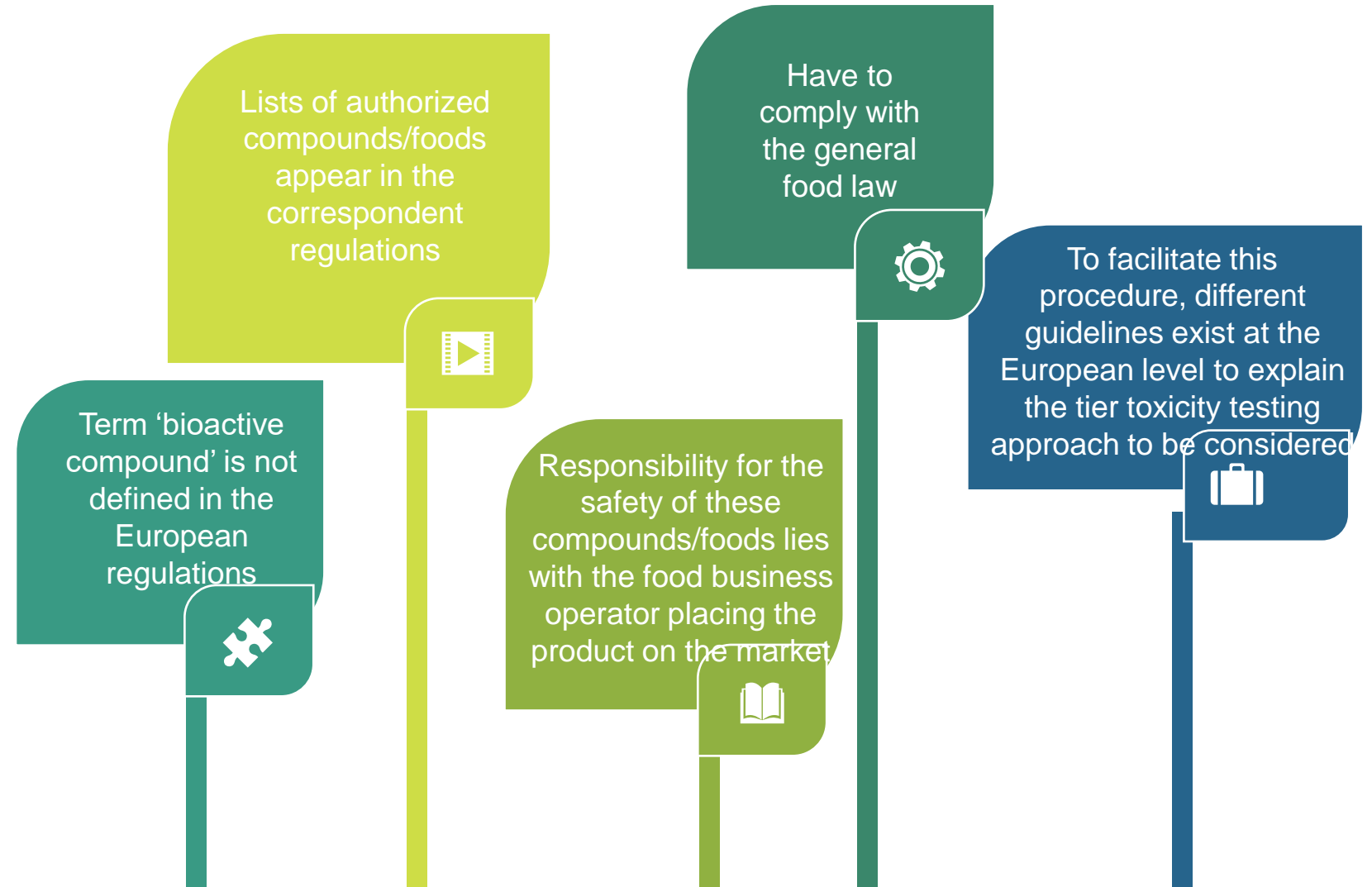
EUROPEAN REGULATORY FRAMEWORK

Bioactive compounds aimed to be used in food could fall under one (or several) of the regulations affecting:

- (i) food supplements,
- (ii) substance for the fortification of food,
- (iii) food for specific groups, and
- (iv) novel foods.

On the other hand, depending on the type of bioactive compound, they can be classified as

- (i) vitamins and minerals,
- (ii) other substances, or
- (iii) botanicals



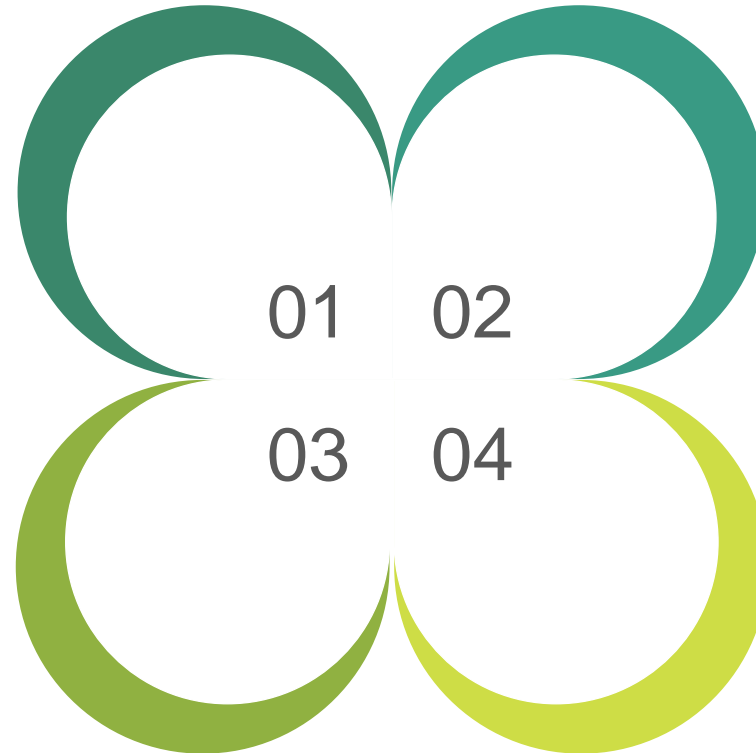
U.S.A REGULATORY FRAMEWORK



As per UFDA regulations, most nutraceuticals could be categorized as “dietary supplements”. As these are extracts, concentrates or combinations of vitamins, minerals, botanicals, herbs, or dietary substances “for use by man to supplement the diet by increasing the total dietary intake.”



Manufacturers have to make sure that the information on the product label is truthful and not misleading



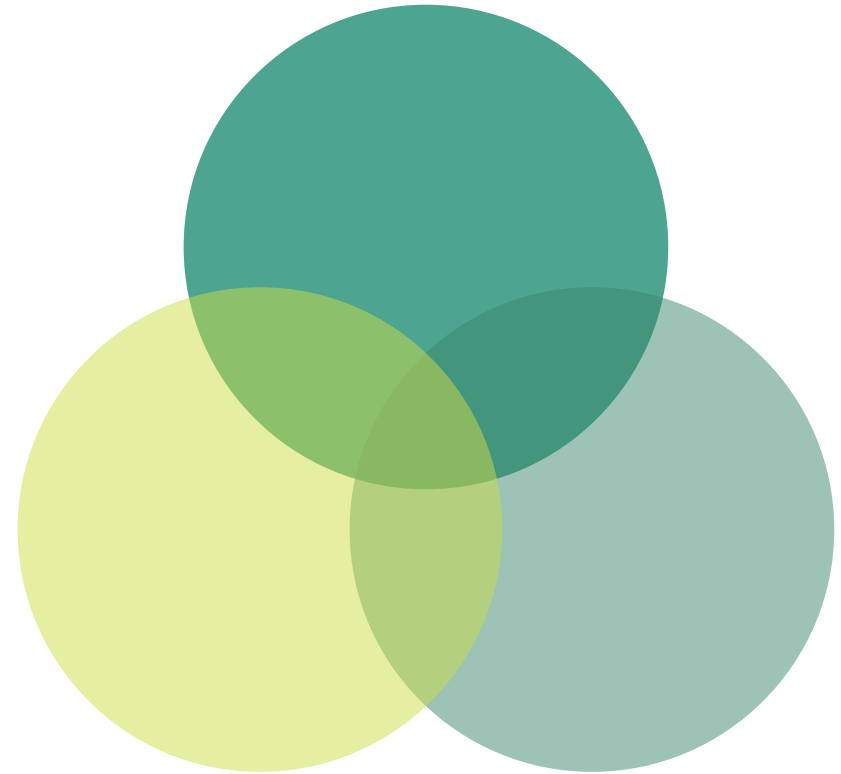
Producers of nutraceuticals classified as dietary supplements are required to register their facility with the FDA.



Labeling standards for dietary supplements are lumped together with those for foods.

Asia Pacific regions or in Association of Southeast Asian Nations (ASEAN) Countries

- 1.** Till now there is no uniform regulatory requirements in different regions for Nutraceuticals
- 2.** ASEAN Consultative Committee for Standards and Quality Traditional Medicines and Health Supplements Product Working Group (ACCSQ TMHS PWG) has been working on the harmonization of Health Supplement standards and requirement.
- 3.** The development of the harmonized technical standards and requirements has been completed and the ASEAN Senior Economic Official Meeting (SEOM) has given approval for the signing of the ASEAN Health Supplement Agreement by 3rd Quarter of 2022



IADSA- The Risk Assessment and Safety of Bioactive Substances in Food Supplements

Members of the IADSA scientific group with the guidance of experts in the bioactive substances covered.

01



02

Intended to complement IADSA's earlier publication on the safety of vitamins and minerals and

03

First in a series of risk assessments that it is hoped will provide important guidance to governments and scientific bodies worldwide .

04

Safety methodology for non-essential nutrients (bioactive components)

05


Describes the method used in detail and sets out the results of its application to a selection of bioactive ingredients

06

Details risk assessments performed on a selection of bioactive substances in food.

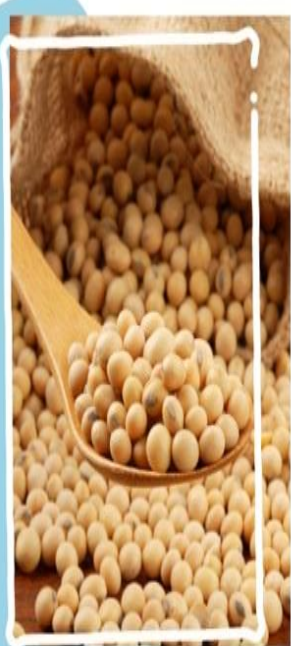
- ❖ Glucosamine
- ❖ Chondroitin
- ❖ Coenzyme Q10 (Ubiquinone)
- ❖ Lutein

- ❖ Lycopene
- ❖ Omega-3
- ❖ Creatine
- ❖ Carnitine

The background is a repeating pattern of watercolor-style green leaves and branches in various shades of green, from light to dark. A thin, light brown rectangular border is centered on the page, enclosing a light green rectangular box. Inside this box, the text "Future Trend" is written in a bold, black, sans-serif font.

Future Trend

BIO PEPTIDES



Short sequences of amino acids, which in most cases are composed of 2–20 hydrophobic amino acids in the peptide chain



Utilized in foodstuffs to produce functional foods due to the numerous health-promoting outcomes, such as imparting antihypertension, antithrombotic, anti-cancer, antimicrobial, antioxidant, and immunomodulatory to the human body.



Several natural sources of bioactive peptides are exploitable, including soybean, cereals germ, potato, nuts, dairy products, egg, and meat proteins. Moreover, marine microorganisms, for instance, microalgae, recently captivated increasing attention as a source of bioactive peptides.



Take Aways

Bioactive compounds have emerged as key food components related to **healthy status** and disease prevention.

These compounds are regarded as an interesting alternative for disease prevention and treatment, in various cases.

Enhanced by the increased need for natural products with sustainable solutions for improvement of quality of life focused on personalized nutrition.

Knowledge of chemistry of natural products together with their mechanistic approach is key elements for the development of new solutions for this sector.

References:

1. Hosseini et al. Bioactive Ingredients in Functional Foods: Current Status and Future Trends DOI: <http://dx.doi.org/10.5772/intechopen.104416>
2. Sharma et al. Journal of Pharmacognosy and Phytochemistry 2019; 8(5): 385-395
3. Walia et al. *Acta Scientific Medical Sciences* 3.9 (2019): 25-33.
4. [European Regulatory Framework and Safety Assessment of Food-Related Bioactive Compounds - PMC \(nih.gov\)](#)
5. Yasmeen R., Fukagawa N.K., Wang T.T. Establishing health benefits of bioactive food components: A basic research scientist's perspective. *Curr. Opin. Biotechnol.* 2017;44:109–114. doi: 10.1016/j.copbio.2016.11.016.
6. National Cancer Institute. [(accessed on 8 November 2019)]; Available online: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/bioactive-compound>
7. The European Food Information Council (EUFIC) [(accessed on 8 November 2019)]; Available online: <https://www.eufic.org/en/whats-in-food/category/bioactives>
8. <https://www.vitafoodsinsights.com/regulation/asean-harmonised-standards-and-requirements-health-supplements>
9. <https://food.chemlinked.com/new-webinar/update-on-asean-harmonization-of-health-supplements-requirements-impact-tips>
10. IADSA- The Risk Assessment and Safety of Bioactive Substances in Food Supplements



Rini Sanyal

Director, Global Regulatory
Affairs & Product
Compliance – India
Herbalife Nutrition

Mobile +91 9971746668
rinis@herbalife.com

**THANK
YOU**