Association of Veterinary Consultants

Neuroactive Compounds in Functional Foods: Cognitive Promise or Emerging Risk?

33rd EFSA StaDG-ER meeting – 4-5 June 2025, Parma

Dr Mirka Piskorikova, AVC Junior Vice President

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- www.avc-eu.de

AVC Intro & Engagement

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AVC is a voice of the community of independent veterinary consultants & SME involved in regulatory and scientific advisory activities related with Animal & Human Health, Animal Nutrition, Public Health and Food Safety.

AVC is an eligible stakeholder of the EFSA, EMA and the European Commission and listed on the EU Transparency Register.

AVC represents Practitioners category in the EFSA Stakeholder Bureau

60 members

21 countries

AVC Membership 2025

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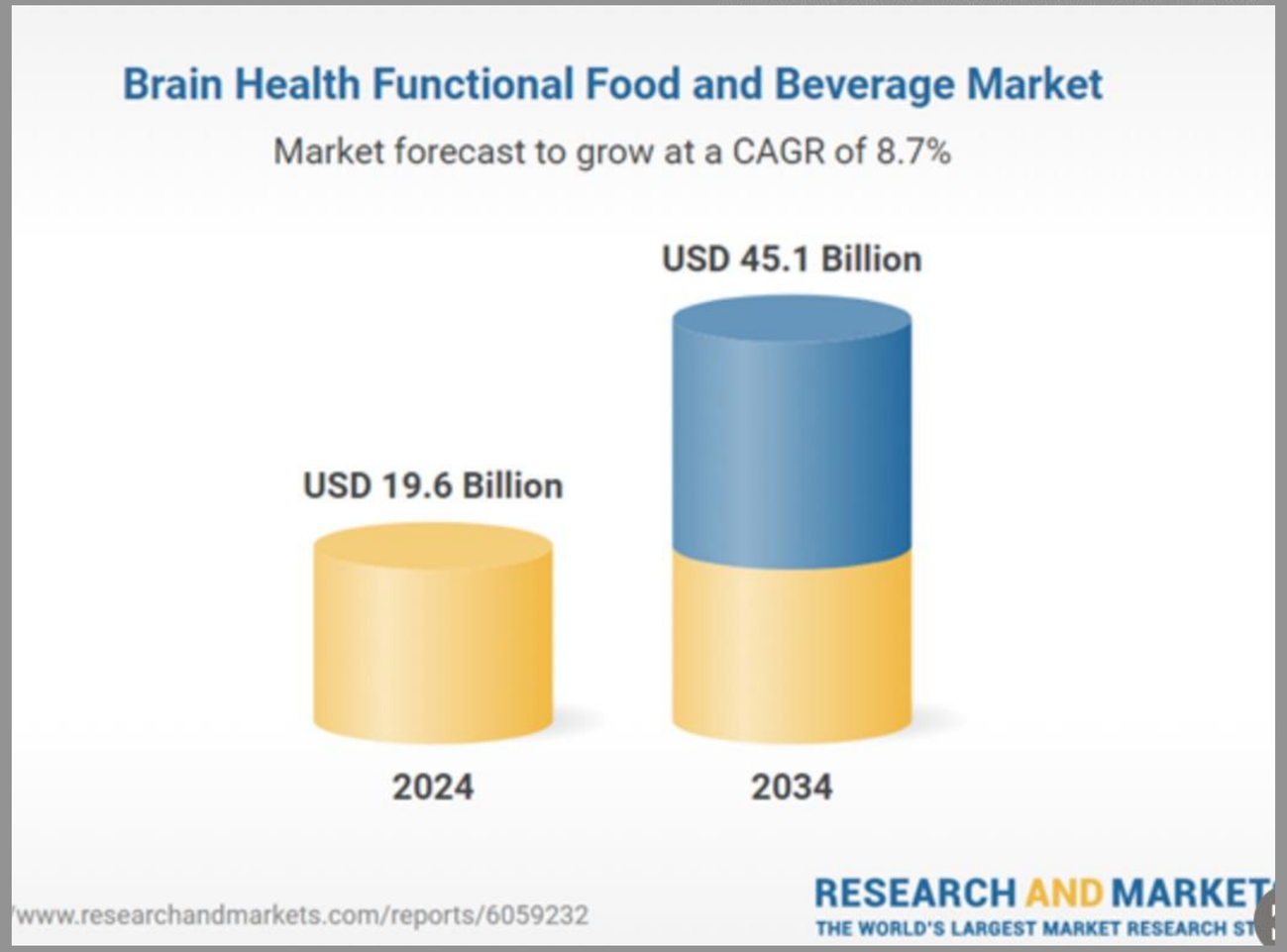
INTRODUCTION TO FUNCTIONAL NEUROFOODS

- Foods and drinks with ingredients supporting cognition or mood
- Examples: L-theanine drinks, GABA gummies, adaptogen teas
- Market driven by mental wellness trends



SCOPE OF RISK ASSESSMENT

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- No legal ‘functional food’ category
- Regs: EC 1924/2006 (Health Claims), EU 2015/2283 (Novel Foods)
- Covers safety, efficacy, exposure, interactions
- Vulnerable groups: children, elderly, mental health patients
- EFSA Ref: EFSA Journal 2011;9(4):2076

$45+ Bn Brain Health Functional Food and Beverage Market Opportunities and Strategies to 2034, Fueled by Aging Populations and Rising Neurological Disorder Prevalence,

HAZARD INDENTIFICATION AND CHARACTERISATION

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Hazard identification

- Compound types: amino acids, adaptogens, nootropics, polyphenols
- Mechanisms: GABA, serotonin, HPA axis
- EFSA Botanicals Compendium (2009)
- Risk: variability, off-target effects
- Kennedy, 2016 (highlights variability and lack of standardisation, calls for long-term efficacy studies and safety data)
- Regulators should be aware of the diversity and pharmacological activity of these compounds. The lack of standard profiles increases risk.

Hazard characterisation

- Lack of NOAELs, long-term data, pediatric studies
- Hormesis: low dose benefit, high dose risk
- EFSA Ref: EFSA Journal 2012;10(7):2769
- Pelkonen et al. 2014, (addresses transition of herbal products to mainstream food use, emphasizes contamination, adulteration, interaction risks and advocates for thorough toxicological assessments)
- Pallas et al. 2020 (explores neuroprotection via dietary polyphenols, notes preclinical promise but lack of human trials and calls for research in elderly and vulnerable populations)
- Challenge in determining safe intake levels. Most compounds lack toxicological benchmarks, especially for chronic use.

SAFETY & ETHICAL CONCERNS

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Exposure

- Consider multi-product use, self-stacking, accidental exposure
- EFSA Exposure Guidance (2021)
- Real-life models needed for risk estimates

Risk characterisation

- Risk = hazard + exposure
- Vulnerable groups at higher risk
- EFSA Ref: EFSA Journal 2018;16(1):5123

Uncertainities & data gaps

- No biomarkers, little post-market surveillance
- Proprietary blends obscure safety
- Propose EFSA nutrivigilance system

REGULATIONS FOR FOOD & ACADEMIC REFERENCES

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- **General Food Law (Regulation (EC) No 178/2002)**: Ensures the safety and traceability of food across the EU, applicable to all stages of production.
- **Novel Foods Regulation (Regulation (EU) 2015/2283)**: Governs new and innovative food products, requiring safety assessments before market entry.
- **Health Claims Regulation (EC 1924/2006)**: Governs nutritional and health claims made on foods.
- **Kennedy, D.O. (2016).** Nutrition Reviews, 74(6): 385–399
- **Pallàs, M., et al. (2020)**. Nutrients, 12(6), 1802
- **Pelkonen, O., et al. (2014)**. Toxicology Letters, 230(2): 82–94

SAFETY & ETHICAL CONCERNS RELATED TO MENTAL HEALTH

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🌍 Global Mental Health Overview

- **Prevalence:** As of 2024, approximately 970 million people worldwide live with a mental disorder, equating to 1 in 8 individuals. Huntington Psychological Services
- **Common Disorders:** Depression and anxiety are the most prevalent, affecting 5% and 4% of the global adult population, respectively. Huntington Psychological Services
- **Youth Impact:** About 15% of adolescents aged 10 to 19 have a mental health condition. Project HOPE
- **Economic Burden:** Mental health conditions result in significant economic costs, with depression and anxiety leading to 12 billion lost working days annually, costing the global economy $1 trillion each year Financial Times
- **Ethical Concerns:** Significant increase of social media influencers & podcasts promoting neuroactive food supplements/foods via affiliate marketing schemes, Amazon without no health specialist inputs. Previously raised by AVC and EFSA KNOW (link).

REGULATORY GAP FOR NEUROACTIVE FOODS

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- **EU regulations:** Cover Novel Food and Nutritional Health Claims, if food do not fall under any of these categories proper risk assessment is not made. Considering the low regulatory success of health claims and significant investment in data generation companies choose to make inderict claims via certified health specialist.
- **Functional food definition:** Curent regulations don’t define this category. However, it is significantly used by food industry and lead to misleading of consumers.
- **Social Media Advertising:** Promotion of food supplements via affiliate marketing, influencers and podcasts. Advertising directly to consumers without any health specialist consultation and scientific evidence, making unverified claims.
- **Long-Term Efficacy and Safety**: Lack of data for multi-product use, self-stacking, accidental exposure, no biomarkers use in existing data.

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SUMMARY

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- Neuroactive functional foods are rising in popularity for mood, cognition, and stress.
- Regulatory frameworks exist (EC 1924/2006, EU 2015/2283), but lack neuro-specific guidance for ingredients that do not fall under these regulations.
- Safety gaps: long-term effects, interactions, and impact on vulnerable groups.
- Literature supports need for tiered toxicology, harmonized labeling, and surveillance.
- Collaboration between EFSA, EC, and stakeholders is key to address emerging risks.

CONCLUSION

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- Urgent need to identify risks posed by neuroactive food ingredients early in the innovation cycle.
- Key concerns include unknown pharmacological activity, cumulative exposure, and vulnerable groups.
- EFSA and stakeholders should prioritise detection of subclinical neurotoxicity and behavioural endpoints.
- Encourage data collection on real-world use patterns, including stacking and multi-product exposure.
- A shared scientific approach to risk identification is critical to inform future regulatory frameworks.

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THANK YOU

DR MIRKA PISKORIKOVA

AVC Junior Vice President

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