IADSA NEWSFLASH

APRIL 2018

IADSA: 20 years young

Looking back to 1998

In early 1998, IADSA was formed in London. This was the first time that associations from across the globe had come together to share information and knowledge in a structured way. And at that time, the world was starting to heat up on regulation in the supplement field. Some of headlines from the first Newsflash from that time:

-FAO/WHO Experts to revised vitamin and mineral requirements
-New Japanese regulation on herbal products announced
-Draft Italian law on herbal products under development
-Canadian government Advisory Panel calls for less restrictive rules for natural health products
-Draft French law on food supplements under discussion
-Revised Dutch guidelines on claims published.
-St Johns Wort classified as a medicine in the UK
-US FDA warning on Chinese supplement 'sleeping buddha'.

ßMany of the above proposals or discussions on regulation were 'finalised', some, such as the Italian botanical law many years later. But we also know from experience that regulation is never resolved. A case is just closed for a certain amount of time before it is reopened, sometimes for the better sometimes not. The world's regulatory environment is constantly changing and we must continually work to be better prepared and better coordinated to engage and shape that.

At the time, the opportunity of regulatory change brought about by the development of Codex Guidelines on Vitamin and Mineral Supplements was the key stimulus that brought IADSA together. While those hugely important Guidelines were adopted in 2005, Codex remains a key part of our programme today.

2018 and beyond

The IADSA Alliance has of course also evolved. Our network has expanded significantly. There are also vastly more associations in action every day across the world than the small group of 21 associations who met to create the Alliance in 1998. Tens of thousands of IADSA scientific, technical and policy publications have been circulated and used by governments and the sector in all corners of the world. And, very importantly, we have also gained recognition across government and industry for our experience and insights into how to interpret and engage with regulatory change and how to analyse and manage regulatory and policy risk.

The Annual Meeting in June will provide a unique opportunity to analyse the changes over the past 20 years and forward to the opportunities ahead. We look forward to seeing many of you in London.

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IADSA
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Regulatory news

ASEAN

Blocking footnote on “non-violation complaint” to be withdrawn

A barrier to the adoption of the Health Supplement Agreement arose last year with the proposal of Indonesia to integrate a new footnote regarding the dispute settlement mechanism. Indonesia has recently agreed in Siem Reap Cambodia to remove the inclusion of the footnote on “non-violation complaints” in the ASEAN agreement on Traditional Medicines and Health Supplements, following a decision of the ASEAN Taskforce on Enhanced Dispute Settlement Mechanism (EDSM) meeting in March 2018.

Thailand to opt out of GMP and stability study requirements

A new issue has been identified by Thailand that will push back adoption of the Agreement. Thailand has carried out an internal survey of their industry and discovered that a majority of their industry cannot comply with the GMP and stability study requirements. This has resulted in a long discussion with the initial conclusion that opt out clauses in the ASEAN GMP & Stability guidelines will need to be considered. The projected signing date by the Member States of the ASEAN agreements is now scheduled for October 2019.

Indonesia

BPOM to develop claims guidelines for supplements

BPOM, the, Indonesian National Agency of Drug and Food Control, is developing draft guidelines for claims made on health supplements. The guidelines foresee the setting of principles for claims substantiation, types of evidence required, provisions on language and wording used.

Taiwan

Taiwan FDA set rules for (6S)-5 - Methyltetrahydrofolate Glucosamine Salt

Taiwan FDA has announced new rules related to the use of (6S)-5-methyltetrahydrofolic acid, glucosamine salt (a folate) as a food ingredient. These include chemical and physical requirements. Maximum levels should not exceed the limits set by the Ministry of Health and Welfare for folic acid, namely 225 µg/day.

South Korea

Korea reviews its functional ingredients

The Korean authorities have announced the revision of the Health Functional Foods Act and will re-evaluate 16 functional ingredients in health food including xylitol, glucosamine and vitamin D. Conclusions of this re-evaluation should be expected in December.

New Korean Regulation for food and supplements

The regulations on the labelling and advertising of the foods undertaken by the "Food Sanitation Act", the "Health Functional Food Act", and the "Livestock Sanitation Management Act" have been integrated into a single regulation under the name of "Act on the Labelling of food advertising".

India

FSSAI Issues Draft Notification on Advertisements and Claims Regulation

Through a notification uploaded on 23 March 2018, the FSSAI has notified the draft regulations pertaining to claims and advertisements. These regulations are aimed at establishing fairness in claims and advertisements of food products and make food businesses accountable for such claims/ advertisements so as to protect consumer interests.

FSSAI consults on the revision of the composition of health supplements and nutraceuticals

Under the proposed amendments to the newly implemented regulations, FSSAI is suggesting to make mandatory the presence of vitamins/ minerals and/or amino acids /nucleotides in health supplements. For nutraceuticals, it is proposed to make obligatory the inclusion of ‘nutraceutical ingredients’ listed in Schedule VI. This amendment regrettably does not address the issue of having similar compositions marketed under different product categories.

European Union

European Commission to clarify limits for sweeteners and colours in supplements requiring dilution

The European Commission and Member States are discussing the reorganisation of the food additives categories for supplements. This discussion emerged from interpretation issues that had arisen around additive limits in supplement forms requiring dilution before being consumed (e.g. effervescent forms). The new proposal aims to re-align the provisions for in particular sweeteners and colours with the old Directives for food additives in which the limits were referring to the food supplements ready for consumption and not as sold.

EFSA unable to assess the safety of silver hydrosol

The European Food Safety Authority has concluded that data are insufficient to characterise the silver hydrosol regarding its nano specific properties and to assess either its bioavailability or its safety as a source of silver added for nutritional purposes to food supplements.

The re-examination of the safety of the nano-material was reopened in 2016 after EFSA concluded in 2008 their inability to provide a safety evaluation of the substance.

Silver hydrosol is an aqueous colloidal suspension of particles of silver that is proposed to be added for nutritional purposes to food supplements. Silver hydrosol is currently not authorised under the EU Food Supplement Directive.

EU sets limits for 3-MCPD in vegetable oils

The European Commission has recently set a maximum level of 1000 µg/kg glycidyl fatty acid esters expressed as glycidol in vegetable oils and fats for use as an ingredient in food including supplements.

While the consumption levels of 3-MCPD in food are considered safe for most consumers, there is a potential health concern among high consumers in younger age groups said EFSA.

3-monochloropropane diol (3-MCPD) and 3-MCPD esters are food processing contaminants found in some processed foods and vegetable oils, mainly palm oil. 3-MCPD and its esters are formed unintentionally in particular during oil refining processes.

Limits for 3-MCPD and its esters for fish oil supplements are also under consideration.

EFSA proposes safety catechin levels for green tea

EFSA has assessed the safety of green tea catechins from dietary sources, following concerns regarding their possible harmful effects on the liver, raised by Denmark, Norway and Sweden.

EFSA concluded that catechins from green tea infusions and similar drinks are generally safe. When taken as food supplements, however, catechin doses at or above 800 mg/day may pose health concerns.

EFSA is recommending that further studies on the effects of green tea catechins be carried out and clearer labelling of green tea products (in particular food supplements) regarding catechin content and their possible health risks.

Decisions regarding conditions of use and labelling provisions will need to be addressed by the European Commission and Member States.

EFSA supports continued use of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) as food additives

EFSA has concluded that there is no need for a numerical ADI and that the food additives sodium, potassium, calcium and magnesium salts of fatty acids (E 470a and E 470b) are of no safety concern at the reported uses and use levels.

The safety assessment of the additives was part of the EFSA re-evaluation programme which aims to review by 2020 all food additives authorised for use in the EU prior to 20 January 2009.

Sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) are authorised in the EU with a maximum level at *Quantum Satis* levels.

Seaweed products to be monitored for heavy metals and iodine

The European Commission is recommending to monitor for a period of three years limits of arsenic, cadmium, iodine, lead and mercury. The recommendation will cover seaweed supplements.

Data gathered will be provided on regular basis to EFSA in a format they will define.

Green light for a novel herbal preparation

An extract of three novel herbal roots (*Cynanchum wilfordii Hemsley, Phlomis umbrosa Turcz.* and *Angelica gigas Nakai)* has been authorised for use in food supplements for adult populations at a maximum level of 175 mg/day, lower than the level of 514 mg proposed by the applicant.

A labelling statement will be required to alert people known to be allergic to celery. *Angelica gigas Nakai* and Celery both belonging to the same botanical family (i.e. Apiaceae).

Marine polyphenols authorised as novel food

The European Regulation authorising *Ecklonia cava* phlorotannins as novel food has been published in the Official Journal. The ingredient is authorised to be marketed as food supplement at a maximum daily intake of 360 mg for adults, 230 mg for adolescents above 14 y.o. and 163 mg for adolescents from 12 to 14 years of age.

As reported by the applicant, the novel ingredient is an alcohol extract of *Ecklonia cava*, which is an edible marine brown alga species with a long tradition of food use in a number of Asian countries.

Given its high iodine content, the novel food is required to be appropriately labelled to warn consumers not to use it together with other supplements containing iodine.

High levels of illegal internet supplements flagged

On the request of the European Commission, Member States have monitored websites which offer food supplements with misleading statements including food supplements with information that attributes to them the property of preventing, treating or curing bone and joint diseases.

Nearly all Member States, namely 25 plus Switzerland and Norway, participated in this control plan. The authorities checked nearly 1100 websites and found 428 offers of unauthorised novel foods and 351 food supplements with medicinal claims which add to 779 offers for sale of products which were non-compliant with EU legislation.

The control authorities focussed their controls mainly on their nationally located traders (482 offers) but also found offers in their respective official language(s) from traders located in other EU Member States (142 offers) or third countries (110 offers), in particular US and China.

The European Commission has concluded that the high percentage of non-compliant offers is a clear sign that the eCommerce control today needs to be strengthened. The launch of a second and more ambitious coordinated control plan on eCommerce control is under consideration.

Norway

Some of the suggested maximum limits for molybdenum in food supplements may lead to molybdenum intakes above the tolerable upper intake level says VKM

The Norwegian Scientific Committee for Food and Environment (VKM) has evaluated intake of molybdenum, tolerable upper intake levels and consequences of establishing maximum limits for molybdenum in food supplements at 100, 250, 500 or 1000 µg per day.

According to the scenario, only the highest suggested maximum limit of 1000 µg molybdenum from food supplements will lead to exceeding the UL for adults.

VKM concluded they could support the tolerable upper intake level suggested by the EU's Scientific Committee on Food (predecessor of EFSA) in 2000 of 600 µg/day.

Maximum limits for chromium in food supplements below the tolerable daily intake at 300 µg/kg body weight per day

The Norwegian Scientific Committee for Food and Environment (VKM) has evaluated the intake of chromium, and the tolerable upper intake levels and consequences of establishing maximum limits for chromium in food supplements at 50, 125, 200 or 300 µg per day.

No tolerable upper intake level has been established for chromium. The EFSA CONTAM Panel has, however, suggested a tolerable daily intake of chromium at 300 µg/kg body weight per day.

In all age groups except for the youngest children, VKM reported that the chromium intakes will be ten times lower than this tolerable daily intake, even with the highest suggested maximum limit for chromium in food supplements.

VKM assesses suggested maximum limits for vitamin K in food supplements

In adults and adolescents 15-17 years old, maximum limits of 100, 200, 300, 600 and 800 µg/day are below Guidance Level for upper intake level according to the Norwegian Scientific Committee for Food and Environment.

In 2003, the UK Expert Group on Vitamins and Minerals (EVM) proposed a guidance level (GL) for safe upper intake of supplemental phylloquinone of 1 mg/day in adults.

This GL was later supported by a double-blind randomised study cited in the Nordic Nutrition Recommendations in 2012.

Safety concerns raised for manganese supplements

Doses at 1, 5 or 10 mg manganese in food supplements may increase risk for irreversible neurotoxic adverse effects. This is the conclusion from the Norwegian Scientific Committee on Food and Environment (VKM) in an assessment of dietary intake of manganese in relation to tolerable upper intake level.

VKM has evaluated doses at 1, 5 and 10 mg manganese per day. The previous maximum limit for manganese in food supplements was 5 mg.

Norwegian authorities have not suggested any recommendations for intake of manganese. In 2013, the European Food Safety Authority (EFSA) suggested 3 mg/day to represent an adequate intake (AI) of manganese.

France

Titanium Dioxide in the hot seat

An amendment to a French law in the agricultural sector and food sector is targeting titanium dioxide.

Backing the 2017 study by INRA (French Institute of Agricultural Research) which found that nanoparticles of titanium dioxide could cause precancerous lesions in the colon, members of the National Assembly's Committee on Sustainable Development adopted an amendment that would lead to the suspension on the French market of any food product containing titanium dioxide as a food additive from 1 June 2018. Titanium dioxide is widely used in supplements.

To enter into force, the amendment should however go first to the Committee of Economic Affairs before being put on the table the national parliament for a vote at end of May.

From a regional perspective, the European Commission and other Member States have agreed that no urgent measure would be required at this moment and has decided to await the EFSA opinion on the four new studies submitted by France.

France recommends that certain populations avoid the consumption of food supplements containing melatonin

Under the national nutrivigilance scheme, reports of adverse effects likely to be associated with the consumption of food supplements containing melatonin have been brought to the attention of the French Agency for Food, Environmental and Occupational Health & Safety.

The Agency highlights the existence of populations and situations at risk, for which the consumption of melatonin in the form of a food supplement should be avoided or medical advice should be sought. This mainly concerns pregnant and breastfeeding women, children and adolescents, people suffering from inflammatory or autoimmune diseases, people with epilepsy, asthma, or suffering from mood, behaviour or personality disorders, and anyone being treated with medication. People carrying out any activity requiring sustained vigilance where drowsiness could pose a safety problem should also avoid its consumption.

In France, melatonin is used in food supplements (at daily level below 2 mg) and in medicinal products.

Spain

Spain sets new rules for food supplements on 'other substances'

New provisions for supplements have been set for 'other substances' that may be used in food supplements. This includes fatty acids, amino acids and other nitrogen compounds, dipeptides and peptides, coenzymes, flavonoids, carotenoids, nucleotides, polysaccharides and oligosaccharides and other substances.

Ingredients used in products previously falling in the scope of the PARNUTS dietetic foods EU legislation (repealed in July 2016) have also been inserted in the positive list: wheat germ, pollen, royal jelly, beer yeast, soya lecithin and propolis (with no maximum level). The draft provisions have been under discussion since 2011.

Bolivia

Risk classification for registration

The sanitary authority in charge of controlling and evaluating foodstuffs, including food supplements, has issued Resolution N° 015-2018 which establishes the risk classification for food products for registration purposes. This is based on low, medium or high risk depending on both the safety profile and perishability of the product. Food supplements are classified as risk B (ie medium level).

Although this classification has been made for registration purposes, it does not at this point differentiate the requirements between the three categories (A, B, C). This classification will be used to establish the fee for

the authorisation of manufacturing plants and warehouses (in the case of imported products).

Free Sales Certificate Procedures

Resolution N° 020-2018 has been issued to establish the procedures to request a free sales certificate locally. The regulation applies to all foodstuffs and includes food supplements locally manufactured. The process can be carried out online and will take up to two days.

Costa Rica

Recognition of imported food supplement registration / notification proposed

The Ministry of Health has opened for public consultation a proposal to recognize the sanitary registry/notification of imported food supplements coming from countries with a similar or more restrictive regulation than the one in Costa Rica. The Ministry of Health aims to first evaluate countries on a case-by-case basis for then start drafting a formal list of countries. This process aims to accelerate the market access of imported products. The final date for providing comments is 26 May 2018.

Ecuador

The re-classification of medicines to supplements is underway

In relation to the new regulation for food supplements approved in Ecuador in 2017, the National Agency of Regulation, Control and Sanitary Surveillance (ARCSA) has approved the Resolution ARCSA-002-2018-JCGO which provides guidelines for the re-classification of food supplements registered as medicines.

The authorities have been given three months to carry out the technical and documentary review of all the medicines which could potentially be reclassified as food supplements. A list of the eligible products will be released on ARCSA's web-site. Once published, product holders will have 180 days to formally notify their products as food supplements. The Resolution foresees a transition period of 1 year for products already on the market.

Mexico

Regulation for food additives is again updated

The sanitary authorities from the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) has updated the regulation for food additives, which impacts all food categories, including food supplements. New specifications have been introduced for steviol glycosides, cassia gum, tocopherols and flavourings. In relation to steviol glycosides, it is now permitted to use rebaudioside M isolated from enzymatically-treated stevia Rebaudiana bertoni with Pichia pastoris or Escherichia Coli, and rebaudioside DM obtained from Saccharomyces cerevisiae. Cassia gum is now authorized for use in food supplements. 21 new natural flavourings and 4 nature-identical substances are now authorized for use in supplements. The following forms of tocopherols are now permitted as antioxidants in those food supplements containing oil of marine origin: d-alpha-tocopherol concentrate (INS 307 a); mix of tocopherols containing: d-alpha, d-beta-, d-gamma-, d-delta-tocopherols (INS 307 b); and dl-alpha-tocopherol (307 c).

United Sates

FDA takes action against highly concentrated caffeine products

The Food and Drug Administration has announced the release of a guidance for industry on "Highly Concentrated Caffeine in Dietary Supplements."

FDA has indicated that it considers some dietary supplements that consist of only or primarily pure or highly concentrated caffeine to be adulterated.

This guidance is designed to help Food Business Operators to determine whether their products are or would be adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and to help them understand how to reduce the likelihood that their products will be considered adulterated.

Belarus

Functional food claims will need to be backed by scientific evidence

The 28 February 2018 session of the interdepartmental coordination council on nutrition under Belarus's National Academy of Science, which involved representatives of medical research organisations reporting to the Health Ministry, discussed the scientific substantiation of claims associated with functional foods. The council recommended making it mandatory for such claims to be backed with scientific evidence, particularly as applied to foods containing functional ingredients which were not previously used in Belarus. The council recommended the Scientific-Practical Centre for Foodstuffs and the Scientific-Practical Centre for Hygiene to launch the development of associated regulatory documents.

The council also stressed the importance of state registration for food additives, flavouring agents, plant extracts used as flavouring agents and raw material components, probiotic microorganisms, starter cultures and materials, technological processing aids including enzyme preparations, nanomaterials, foods manufactured with the use of nanotechnologies, and individual types of functional foods.

New ingredients will only be allowed to be used following tests to assess their toxicity, metabolic properties, long-term effects on the next two to three generations, clinical trials and subsequent monitoring of such ingredients in circulation. Work is still to be carried out to develop labelling requirements for food additives, flavouring agents and technological processing aids, including enzyme preparations manufactured with the use of GMO.

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FAO/WHO Guidelines for the Evaluation of Probiotics in Food, 2003

Its origin

The FAO/WHO work originated from a request made by the Argentinian Government to solve an international trade litigation on a powdered milk containing lactic acid bacteria defined as “probiotics”

Terms of Reference of the Expert Consultation

1. Examine scientific information in relation to the dietary impact of the introduction of live lactic acid bacteria in milk for human consumption;
2. Evaluate the properties, benefits, safety, and nutritional features, as well as the potential adverse effects of powder milk with added live lactic acid bacteria on the basis of available scientific data, taking into consideration the work done by national authorities, FAO, WHO, other international organizations and other relevant international bodies;
3. Review the scientific basis for the health claims and legislative/regulatory needs;
4. Discuss existing strategies for the safety and nutritional assessment of this type of probiotic, taking into account the ever increasing public concerns and experiences accumulated in food safety evaluation;
5. Make recommendations on further research needs, priorities for the evaluation of safety, and nutritional aspects of probiotics as well as regulatory actions if required.

01

1 to 4 October, 2001, Cordoba, Argentina: 11 experts from 10 countries participated in a joint FAO/WHO Expert Consultation on Health and Nutritional Properties of Powder Milk with Live Lactic Acid Bacteria. The 10 countries: Chile, New Zealand, Sweden, Italy, Argentina, Finland, France, Ireland, Canada, USA.

Outcome -2001 meeting included

Agreement that probiotic microorganisms must be able to confer defined health benefits on the host in the product vehicle that will be made available to humans.

Agreement that there is evidence that specific strains of probiotics are safe for human use and able to confer some health benefits on the host, but such benefits cannot be extrapolated to other strains without experimentation.

02/03

WHO Report 2002 Introduction

[The Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food….recognized that there is a need for guidelines to set out a systematic approach for the evaluation of probiotics in food leading to the substantiation of health claims}. The Working Group was requested by FAO/WHO to generate guidelines and recommend criteria and methodology for the evaluation of probiotics, and to identify and define what data need to be available to accurately substantiate health claims.

03

The probiotic results and recommendations of the Consultation and the Guidelines for the Evaluation of Probiotics in Foods have been presented to two Codex Committees CCFL and CCNFSDU. It was explained that the Guidelines were a possible model for scientific criteria for the evaluation of health claims, as part of the science-based risk assessment process and not a management recommendation. It was pointed out that they needed to consider these recommendations in detail at the national level and that it was too early to recommend their use in the framework of the criteria for the scientific basis of health claims to be developed.

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FAO/WHO Guidelines for the Evaluation of Probiotics in Food, 2003

History of the definition

1907 The original observation of the positive role played by some selected bacteria is attributed to Eli Metchnikoff (1907), the Russian born Nobel Prize winner working at the Pasteur Institute at the beginning of the last century, who suggested that *"The dependence of microbes on the food makes it possible to adopt measures to modify the flora in our bodies and to replace the harmful microbes by useful microbes"*

At this time Henry Tissier, a French paediatrician, observed that children with diarrhea had in their stools a low number of bacteria characterized by a peculiar, Yshaped morphology. These *"bifid"* bacteria were, on the contrary, abundant in healthy children (Tissier, 1906).

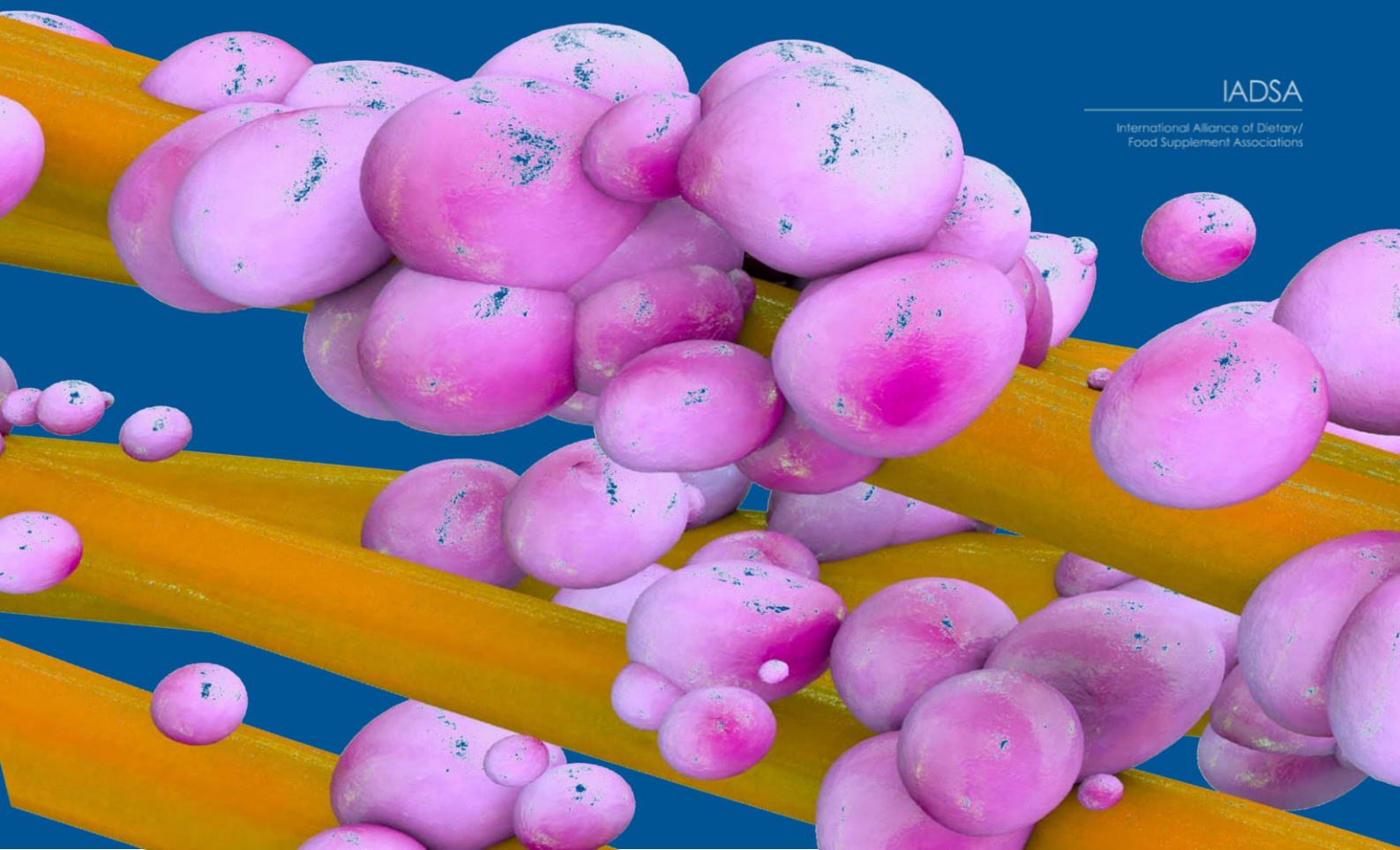
1965 The works of Metchnikoff and Tissier were the first to make scientific suggestions concerning the probiotic use of bacteria, even if the word *"probiotic"* was not coined until 1960, to name *substances produced by microorganisms which promoted the growth of other microorganisms* (Lilly and Stillwell, 1965).

1989 Fuller refocused the definition on bacteria and used this term to mean *"a live microbial feed supplement which beneficially affects the host animal by improving its intestinal balance."* The definition was intended to be used for animal feeding.

1992 The use of specifically selected and characterised beneficial bacteria in humans was referred to in the Havenaar et al's definition: *"a viable mono or mixed culture of bacteria which, when applied to animal or man, beneficially affects the host by improving the properties of the indigenous flora."*

1998 The term was further refined by Guarner and Schaafsma (1998) and endorsed by Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria: *"live microorganisms which, when consumed in adequate amounts, confer a health effect on the host."*

Source: Probiotics in food Health and nutritional properties and guidelines for evaluation:FAO Food and Nutrition paper 85
FAO/WHO Guidelines on Probiotics 10 Years Later Lorenzo Morelli, PhD and Lucio Capurso, MD



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FAO/WHO Guidelines for the Evaluation of Probiotics in Food, 2003

Requirements in short

Definition: Live microorganisms which when administered in adequate amounts confer a health benefit on the host.

Characterisation: Molecular techniques to identify the microorganism at the species and strain level are listed as mandatory,and compilation in an International Culture Collection is strongly recommended.

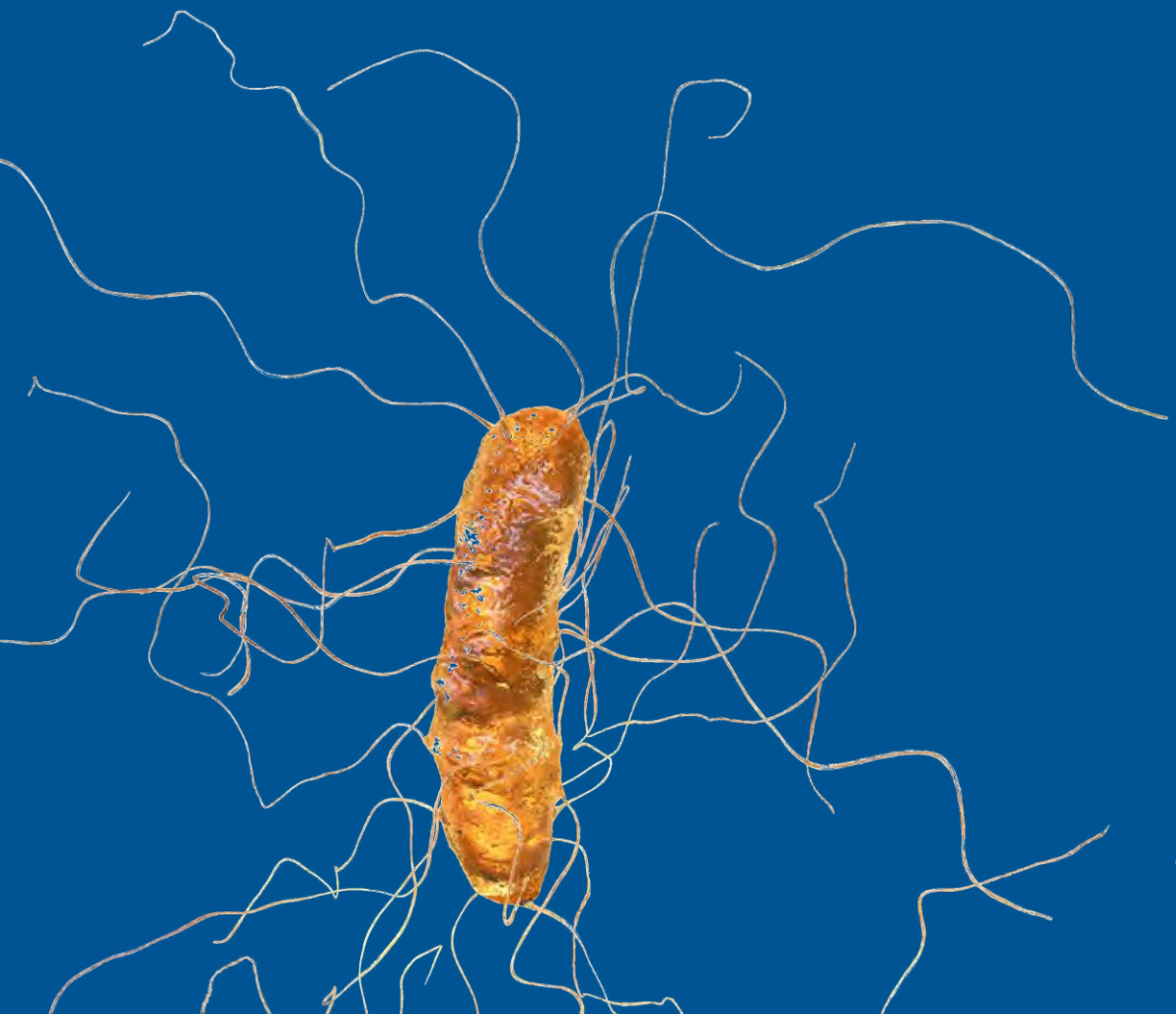
Safety: It should be granted at the species level. Antibiotic resistance profile is to be assessed at the strain level.

Beneficial effect: The Guidelines recommended that specific health claims be allowed where sufficient scientific evidence is available preferably supported by an independent third-party review by scientific experts.

Before in vivo trials are undertaken, proper in vitro studies should establish the potential health benefits of probiotics For in vivo testing, preferably a minimum of two randomized double-blind placebo-controlled human trials should be undertaken to establish the efficacy of the probiotic product. Consideration should be given to clinically relevant outcomes in the population being studied.

Good manufacturing practices (GMP): GMP must be applied with quality assurance and shelf-life conditions.

Labelling: The following information to be described on the label is recommended: Genus, species, strain designation minimum/ dosage/ proper storage conditions/ suggested serving size must that deliver the effective dose of probiotics related to the health claim /health claim(s) / corporate contact details for consumer information.



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