# IADSA CONNECT

#04 June 2019

# Japan's evolving health claims legislation

SEEDS OF OPPORTUNITY: BOTANICALS TAKE CENTRE STAGE AS FDA LAUNCHES NEW SAFETY INITIATIVE

TURKEY'S YOUTHFUL POPULATION POINTS TO A BRIGHT FUTURE

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IADSA
International Alliance of Dietary/
Food Supplement Associations

# #04

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Simon Pettman,
Executive Director, IADSA

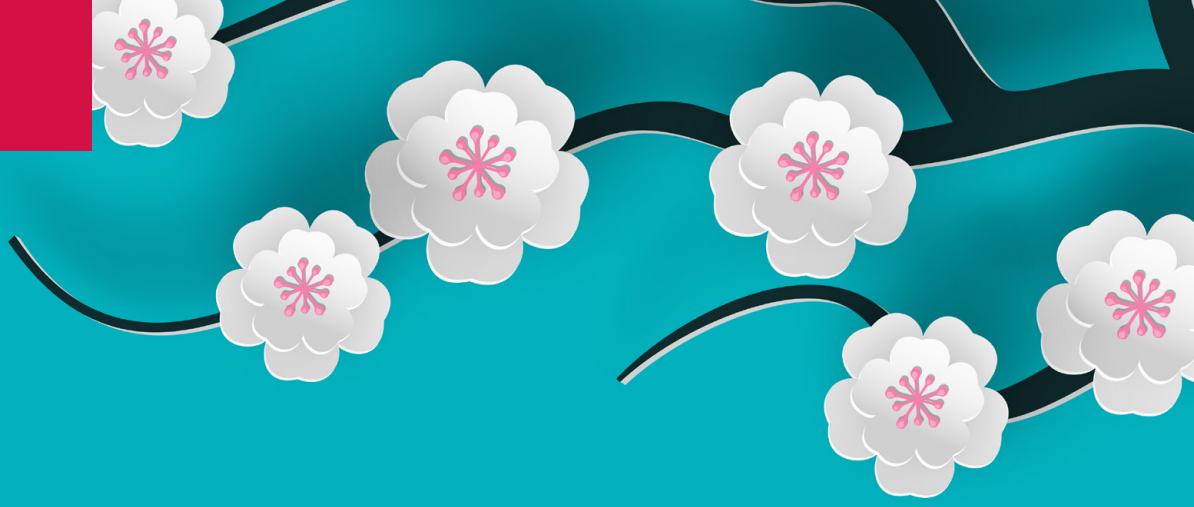
# WELCOME TO IADSA CONNECT

Dear Members

The IADSA Annual Week in Sydney was an excellent way for many of our members to meet, discuss, learn and develop plans for the future. However, not everyone could get to Sydney. We therefore hope that this issue of Connect will be at least a partial alternative.

Simon Pettman
Executive Director

JAPAN



# OLDER AND WISER: 'SUPER-AGEING' JAPAN LEADS THE WORLD IN LONGEVITY AS HEALTH CLAIMS LEGISLATION EVOLVES

The General Incorporated Association of International Foods and Nutrition (AIFN) and the Japanese Institute for Health Food Standards (JIHFS) are two of IADSA's three Japanese member associations. IADSA Connect met with Shinji Wakisaka (CEO of AIFN) and Hideko Ikeda (Chair of JIHFS) in Sydney to look at how Japanese regulation and the market are evolving.

Japan holds its senior citizens in high regard. Every year, in September, there is a 'Respect for the Aged' national public holiday to celebrate their contribution to Japanese life. Average life expectancy in Japan is higher than anywhere else in the world[1] and 27% of its 127 million citizens are aged 65 or over.[2] "We are not an ageing society," says Hideko Ikeda, Chair of JIHFS. "We are a super-ageing society."

However, there's a price to pay for this global leadership in longevity. In 2018, Japan spent $378 billion on healthcare and is keen to find ways to bring this figure down.[3] "Worried," is how Shinji Wakisaka, CEO of AIFN, describes the Japanese government's feelings about this state of affairs.

All three of IADSA's Japanese member associations are committed to working with policymakers in Japan to improve the regulatory environment for dietary supplements and make it easier for companies – especially small and medium sized businesses – to innovate. They believe this will encourage more widespread consumption of supplements and that, in turn, represents one way in which healthcare costs could be reduced.

The regulatory landscape has evolved gradually in Japan and there are signs that, slowly, the environment for supplement companies is developing in the right direction. But it has been a long journey and, as Ms. Ikeda notes, the government's attitude towards supplements has not always been as positive as it is now.

In 1991, the regulation for Foods for Specified Health Uses (FOSHU) was introduced, permitting the use of pre-approved function claims and reduction of disease risk claims for calcium and folic acid. But the bar to approval was set at an off-putting height, with extensive, lengthy and expensive human clinical trials required to substantiate efficacy and safety. Ms. Ikeda says that only 1,068 products have been approved in 28 years of FOSHU, and just 350 of these are currently on the market.

A decade later and the year 2001 saw the implementation of the regulation for Foods with Nutrient Function Claims (FNFC), allowing companies to make nutrient function claims without the need for pre-approval.

However, its scope is limited to just 20 nutrients – 13 vitamins, six minerals and n-3 fatty acids – and only 26 claims can be made, which are fixed in stone and must be used verbatim. The advent of FNFC offered a degree of progress but, with such limited coverage, it has failed to provide truly meaningful opportunities for dietary supplement companies to innovate.

Fourteen years on, in 2015, the Japanese government implemented the regulation for Foods with Function Claims (FFC). It was a major step forward, enabling companies to submit a notification of any functional claim it wished to use supported by existing scientific evidence. In the four years since it was implemented, says Ms. Ikeda, 1,850 products carrying health claims have been approved – hundreds more than have been accepted in nearly three decades under FOSHU. Furthermore, while there are only nine categories of health claims in FOSHU, under FFC there is a much wider range, providing a far less restrictive field in which companies can operate.

The greater liberty granted to nutrition businesses by FFC has not, thus far, provided a boost to supplement sales and they remain flat. But Ms. Ikeda is confident that, in time, the regulation will start to feed into market growth, as its benefits are felt by companies who find they have more freedom to innovate.

In the meantime, IADSA's Japanese members believe there is more work to be done. In particular, as Mr. Wakisaka explains, they would like to see dietary supplements given their own classification in law. This would, it is believed, increase overall product quality, efficacy and safety and – in turn – levels of consumer trust. As it stands, regulations in Japan treat supplements the same as any other product carrying a health claim, whether that product is a pack of sausages, a chocolate bar, or a bag of fresh fruit.

In recent years, says Ms. Ikeda, the Japanese government has come to realize that supplements are an established feature of Japanese lifestyles. She explains that the Prime Minister, Shinzo Abe, recognizes their economic value and that he was instrumental in the creation of FFC in 2015. Despite the lack of market growth, supplement sales are still twice those of OTC medicines in Japan. This has motivated policymakers to pay more attention to a sector that is of great importance to millions of Japanese consumers – including the 34 million who are aged over 65. When it comes to supplements, the signs are that Japan is growing wiser, as well as older.

In such a context, our sector will have a key role to play in improving the lives of our region's citizens.


Hideko Ikeda, Chair, JIHFS

JIHFS was founded in 2005 and started GMP certification for food/dietary supplement manufacturing sites. The standard was made by reference to the Japanese drug GMP and US FDA cGMP draft. JIHFS has today 4 certification programmes for finished products and raw materials whether they are produced in Japan or overseas.


Shinji Wakisaka, CEO, AIFN

AIFN focusses on the development of the dietary/ food supplements market in Japan making consumer satisfaction and reassurance of safety a primary concern. The association is a part of JAOHFA (Japan Alliance of Health Food Associations) and cooperates with other Japanese groups representing the sector in the country.

1. www.who.int/en/news-room/detail/19-05-2016-life-expectancy-increased-by-5-years-since-2000-but-health-inequalities-persist
2. www8.cao.go.jp/kourei/english/annualreport/2016/pdf/c1-1.pdf
3. www.mhlw.go.jp/english/database/db-hss/dl/digest2016.pdf

Ric Hobby,
Chairman Emeritus, IADSA

# DIPLOMACY STANDS FIRM AGAINST THE POPULIST WAVE

Protectionist policies threaten the principles of free trade that lie at the heart of globalisation. Ric Hobby, Chairman Emeritus, explains why IADSA's diplomatic approach is still the most effective way to make sure the supplement sector's voice is heard above the populist rhetoric.

Once a seemingly unstoppable force, globalisation is under threat. Populism and protectionism are encroaching on free trade, while the imposition of tariffs (or the threat of imposition) has become the political weapon of choice for some in positions of authority. What does this mean for the food supplement sector?

"It's a major challenge," says Ric Hobby, IADSA's Chairman Emeritus, an advisory position held by the immediate predecessor to the currently serving Chair. "Populism runs counter to our belief in building trust around the world and enhancing economies through free trade. It means that, in addition to advising members and regulators on scientific and technical issues, conversations about cross-border trade and tariffs are becoming more frequent. This takes IADSA into a new area."

Ric was a leading figure in the creation of IADSA 21 years ago, at a time when there was no international, unified voice for the dietary supplements sector. Codex Alimentarius was drawing up the world's first global standards for supplements and it was recognised that the industry needed to be represented globally in this process. More than two decades on, Codex remains a vital part of IADSA's work, but its scope has widened to include a greater range of scientific and technical issues – as well as the impact of the changing economic and political landscape.

IADSA's success over the years can be attributed to the way in which it has developed meaningful relationships with regulators that are based on mutual trust. "IADSA will never tell a national government what to do, but we will provide advice on best practice," says Ric.

For this reason, many national and regional governments consider IADSA to be a reliable source of information.

But is this thoughtful approach still relevant in an era when it feels like whoever shouts loudest is most likely to be listened to? "There are trade associations around the world, including in our own sector, who see themselves as activists," says Ric. "They adopt a strategy of agitating against what they perceive as unjust regulation, or unjust proposals for regulation, and will try to bully a government into submission. That's a long, long way from IADSA's approach. We know from experience, and from more than 20 years of success, that winning and maintaining the trust of policymakers and regulators is by far the most effective way to make sure your voice is heard."

Elsewhere, another emerging challenge is the risk that advances in technology could exert a disproportionate influence over regulation. Ric cites contaminants as an example. "It's possible today to detect contaminants at a minute level – the equivalent of picking up one or two grains of sand on a beach where there are trillions," he explains. "As a result, some regulators are asking the question: If we can detect something in a product, no matter how low the level, should we ban it from sale to consumers? It is, therefore, a priority for IADSA to promote best practice and the importance of making assessments on the basis of safety and not simply on the principle of detection."

So much for the challenges; what of the opportunities? There are many, says, Ric – thanks largely to the failure of every government in the world to meet targets on healthy lifestyles voted through at a World Health Organization (WHO) assembly in 2005. "In most parts of the world, people are getting plenty of food, but not enough good nutrition," he says. "This has led to a rampant rise in obesity levels and all of the non-communicable diseases associated with that. We live in an age where medical science has developed to such an extent that we should really be living much more healthy lives, but that's not the case. We're actually living less healthy lives today than in the past. It provides an enormous opportunity for the supplement sector to support policymakers in their efforts to address this imbalance."

Imposing tariffs on the cross-border trade of supplements could make it harder – or at least more expensive – for people to lead healthier lives. If so, this would be out of step with policymakers' efforts to encourage healthier living, making it even more unlikely that countries could meet those WHO targets agreed 14 years ago. The temptation might be to howl with frustration and attack those responsible for the slow collapse of globalisation. But it isn't one IADSA will give into. "We know that diplomacy is the path that works best," says Ric, "so that's the path we will continue to follow."

Michael McGuffin,
President, AHPA

# SEEDS OF OPPORTUNITY: BOTANICALS TAKE CENTRE STAGE AS FDA LAUNCHES NEW SAFETY INITIATIVE

Founded in 1982, the American Herbal Products Association (AHPA) is the national trade association of the herbal products industry. AHPA is comprised of more than 350 member companies, consisting primarily of domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products as foods, dietary supplements, cosmetics, and non-prescription drugs, and also including companies that provide expert services to the herbal trade.

The American Herbal Products Association is an IADSA member organisation representing suppliers of botanical ingredients and supplements across the USA. Its President, Michael McGuffin, spoke to Connect about FDA's new Botanical Safety Consortium.

Earlier this year the US Food & Drug Administration (FDA) announced the creation of the Botanical Safety Consortium. It was described as "a public-private partnership that will gather leading scientific minds from industry, academia and government to promote scientific advances in evaluating the safety of botanical ingredients and mixtures in dietary supplements." [1]

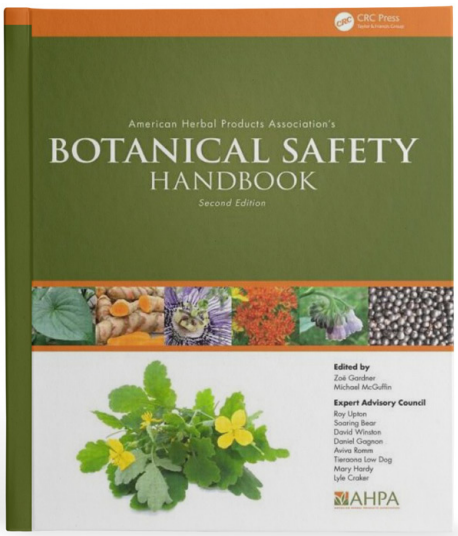
It is a potentially significant development that could mark a shift in how some in the US view botanicals, which has not always been in the most positive light. "Regulators perceive them as highly complex," says Michael McGuffin, President of the American Herbal Products Association (AHPA). "They don't look at them as plants that we've been consuming orally for centuries and generations."

The reason for this, he believes, is a lack of understanding. "It's a challenge across the regulatory world, that people with a focus on chemistry and toxicology have a tendency to be mystified by the complex organism that a plant is. One person at FDA recently told me: 'Vitamins and minerals are so simple; when we get to botanicals, they're complicated'."

On the whole, the regulatory environment for botanicals in the US is relatively benign. The Dietary Supplement Health & Education Act of 1994 (DSHEA) gives companies the freedom to market almost any botanical ingredient besides tobacco. Following their removal from the market by the authorities on safety grounds, ephedra and plants containing pyrrolizidine alkaloids or aristolochic acid are also banned. In addition, companies are permitted to make structure/function claims for botanical ingredients, such as 'promotes healthy digestion'.

In large part, this can be attributed to efforts by the industry to build trust in botanicals among regulators and scientists. In 1997, AHPA published the Botanical Safety Handbook, a reference guide that collates summary statements on the safety of about 600 botanicals, based on contemporary research.[2] A revised edition was published in 2013, and the text is reviewed and updated periodically by a panel of herbalists, medical doctors and toxicologists.

Nevertheless, there remains concern that a degree of mistrust of botanicals among some stakeholders is preventing them from reaching their potential. In particular, where there is strong evidence supporting certain health benefits, botanicals companies want to be able to present this to consumers, but the current regulatory situation does not allow them to do so.




Will the new Botanical Safety Consortium help bring about a change in approach in this respect? It is far too early to say, but AHPA is pleased by FDA's decision to set it up. "I think it's positive," says Michael. "It does not appear to be an effort by the regulators to prove us wrong. It appears to be an effort to engage in a process that can draw more certain conclusions than regulators, in particular, have believed are credible to-date." Safety, he adds, is a shared value. "It's what the regulators want, it's what the industry wants and it's what consumers expect. And we owe it to consumers to fulfil that expectation."

A reassuring aspect of the Consortium, in which AHPA will participate, is that there appears to be no desire to tear up existing information about the traditional use of botanicals and start over. Michael says: "They're not going to say, 'We don't know anything about chamomile, so we'll go and find out if it's safe.' They're going to assume that there's some knowledge already. They'll recompile this and evaluate it through a body of experts."

Botanicals have been used safely all over the world for hundreds, even thousands of years, not only in India, China and across Asia, but in Europe and the Americas, too. Their popularity among consumers persists to this day and shows no sign of waning. Regulators, perhaps, have been somewhat slow to recognise this. FDA's latest move indicates they are catching up at last.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

1. www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary
2. www.ahpa.org/Resources/BotanicalSafetyHandbook.aspx

# TURKEY'S YOUTHFUL POPULATION POINTS TO A BRIGHT FUTURE

Food Supplement and Nutrition Association (GTBD) brings together leading companies to promote the category and its reputation and work with the authorities to resolve sectoral challenges. Since GTBD was established, it has been informing the public about nutrition, health and food supplementation through web site, social media and other digital platforms, conferences and the GTBD Food and Nutrition Magazine.

Samet Serttaş is Chairman of Turkish association GTBD, a member of IADSA since 2016. Here, he describes the development of Turkey's food supplement sector over the past 10 years.

Turkey has the youngest population in Europe and one of the best educated, too. As a result, it is culturally modern and has enthusiastically embraced the potential of digital technology. For food supplement companies doing business in Turkey, this represents a golden opportunity. It is a chance to get in at the ground-level and build a long-term relationship with a youthful consumer demographic – one that could endure for decades to come.

But while the Turkish supplement sector is standing at the threshold of an exciting future, much of this potential remains unrealized. Research commissioned by GTBD found that only 13% of Turkish consumers buy supplements. To tap into this opportunity, GTBD has harnessed both traditional and social media channels to communicate positive stories about supplements. In doing so, it has helped to reverse the negativity that once surrounded Turkey's supplement sector.

At the beginning of this decade, there was little or no regulation of Turkey's supplement sector. Rogue traders – mostly operating online – took advantage to sell all manner of adulterated products that they labelled as supplements. Many contained pharmaceutical actives, such as the sexual performance enhancer sildenafil (better known as Viagra), while others were made with banned substances like the weight loss aid sibutramine.

In the case of the latter, there was a spate of fatalities reported that were associated with taking sibutramine purchased on the Internet. In response, in 2013, the Turkish government sprang into action, drawing up a new regulation to put a stop to the free-for-all by insisting that only supplements officially approved as safe could be sold in Turkey. It was decided that responsibility for regulating the supplement market should be given to Turkey's Ministry of Agriculture. It was a move that paid off, and there are now more than 5,000 approved supplement products on sale in Turkey.

The next stage of reform is now underway. In December 2018, the Turkish Parliament voted to move responsibility for regulating health claims for supplements to the Ministry of Health, with responsibility for imports, safety and labelling of products staying with the Ministry of Agriculture. GTBD is currently awaiting new proposals for assessing health claims from the Ministry of Health, which it hopes to see before August. There is optimism that a positive way forward will be found. Constructive dialogue is ongoing with the Turkish government, which values the collaborative approach taken by GTBD with the support of IADSA.

Samet Serttaş, Chairman, GTBD

Positive engagement is at the heart of GTBD's approach, whether that is with regulators, the media or directly with consumers. It publishes its own magazine and has produced several animated videos explaining the benefits of supplementation. It posts regularly on social media and organises an annual conference on food and nutrition for a range of key stakeholders and influencers, including academics, bloggers, journalists and government officials. About 250 delegates attend every year.

The outlook for the Turkish supplement sector is promising. In addition to the exciting prospects offered by its young population, a helping hand has also come from the retail pharmacy sector. A recent government ruling cut the price of medicines by around 60%, reducing pharmacists' profits. Many have now started to concentrate on selling food supplements in an attempt to rebuild their revenue streams. This is an important development because GTBD's research found that pharmacists, besides doctors, are the main source of advice about supplements for those consumers who use them.

Turkey is a country that embraces the spirit of innovation across all business areas and there are few more innovative industries than the food supplement sector. Against this positive backdrop, GTBD will continue to cultivate a strong relationship with regulators and, with IADSA's support, help guide them as they develop a new regulatory framework for the next decade. In the meantime, through its various activities and programmes, GTBD will continue to spread positive news about supplements to consumers in Turkey, especially those young people who are the country's future.

GTBD
Gıda Takviyesi ve Beslenme Derneği

Gridiron Building
One Pancras Square
London, N1C 4AG
United Kingdom

iadsa.org

IADSA

International Alliance of Dietary/
Food Supplement Associations