

# IADSA CONNECT

**#06** MARCH 2020

## Positive list of supplement ingredients in Thailand

HEALTH SUPPLEMENTS:  
SMALL MEASURED STEPS  
CAN GET YOU THERE

UK EU EXIT: WHAT NOW?

# #06

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Simon Pettman,  
Executive Director, IADSA

# WELCOME TO IADSA CONNECT

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Dear Members

Welcome to the latest issue of Connect.

With so many travel restrictions in place across the world at present, we hope that this edition will allow you an alternative way to gain insights from four countries engaged in significant regulatory change.

Simon Pettman  
Executive Director

# HIGH HOPES: MEXICAN SUPPLEMENT SECTOR AWAITS OUTCOME OF CRUCIAL VOTE

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Mexico's Senate will soon vote on the biggest change to the country's food supplement regulations for more than 20 years. For the full story, IADSA Connect spoke with ANAISA, the Mexican supplement sector organisation.

For the past decade, Mexico's food supplement sector has been operating under some of the tightest marketing regulations in the world. Manufacturers are, in effect, prohibited from making any health, nutrition or functional claims for their products. They are restricted instead to making simple statements about the amount of a nutrient their supplement will contribute to the diet.

For La Asociación Nacional de la Industria de Suplementos Alimenticios (ANAISA), Mexico's health supplement sector association, trying to work with the government to have a world class regulation has been its top priority since it was formed by six like-minded companies in 2011. Now with 17 members, it stands on the brink of achieving its chief aim. At the end of May this year, Mexican legislators are expected to agree changes that will permit the marketing of supplements using functional nutrition statements drawn from a pre-determined list of approved structure-function claims of nutrients.

Juan Pablo Fueyo is Vice President of the Board at ANAISA and has worked within the organisation since its inception. He says he has “high hopes” that the new claims regime will get the green light from the Mexican national Senate – heralding the start of a new and brighter era for Mexico’s supplements industry.

Life wasn’t always so challenging. Mexico’s current national food supplement regulation was enacted in 1997. For several years afterwards, the law worked just fine. But as time went on, the Ministry of Health became concerned that some supplements were being marketed with outlandish health claims, including promises to cure serious diseases such as cancer. In 2010, regulators launched a crackdown on the whole industry. As a result, even reputable supplement companies found themselves severely limited in terms of what they could say when marketing their products.

Until this point, Mexico didn’t even have a dedicated food supplement sector association. But, faced with such a strict new regime, a group of leading companies banded together to establish ANAISA. The aim was to act as the face of Mexico’s reputable supplements industry and to win the trust of the country’s regulators. Perhaps surprisingly, given their somewhat hostile outlook, Fueyo says government officials immediately welcomed the formation of ANAISA and now recognises it as the official voice of Mexico’s supplement sector. “Over the years we’ve built a very good relationship,” he says. “They were happy to work with us on the forthcoming changes.”

Despite the difficulties of the past ten years, Mexico’s supplement sector has continued to flourish. The market grew in value by 17% between 2012 and 2017, and from 2018 to 2022 it is expected to expand by a further 12%. It is a strong performance, and impressive since Mexico’s overall economy is not in the best shape, having shrunk by 0.1% in 2019.

Fueyo says the market is doing well mainly for two reasons. Firstly, a growing number of Mexican consumers are interested in enhancing their nutrition and wellbeing, and they see supplements as one way to achieve this. Secondly, the direct selling market is strong in Mexico, thanks to the easy opportunity it offers people to set up their own business and increase their income.



In tandem with its regulatory-focused work, ANAISA has focused resources on promoting the industry more widely. General Manager Coral Moctezuma, who joined the organisation in 2017, has overseen a successful social media operation, delivering regular, positive messages about the safety of supplements to large numbers of followers on Facebook and Twitter.

It has also invested resources in engaging with the nutritionist community, exchanging information to understand better the role of supplements and highlight that products marketed by ANAISA members can be trusted. “We’re helping people to learn how to tell the difference between those products that are reputable and those which are not,” says Moctezuma.

Meanwhile, all eyes will be on Mexico City at the end of May, when it is hoped the Senate will approve the biggest changes to Mexico’s food supplement regulations for a generation. Given the hard work and patience of ANAISA over the past ten years or so, it will be a success that is richly deserved.





Pichit Pongsukvechkul,  
President, HFSA

## POSITIVE LIST OF SUPPLEMENT INGREDIENTS AND ASEAN DOMINATE THE AGENDA IN THAILAND

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Thailand's Health Food & Supplements Association (HFSA) is working closely with government officials to implement new regulatory reforms. Pichit Pongsukvechkul, HFSA President, provided IADSA Connect with an update.

Thailand is one of south east Asia's largest markets for health supplements and it is a key member of the Association of Southeast Asian Nations (ASEAN). Thai regulators have historically taken a relatively hard-line approach to the control of supplements, requiring businesses in the sector to negotiate complex, time consuming and often expensive rules before obtaining approval to launch a new product.

Against this backdrop, nearly 25 years ago, the Health Food & Supplements Association (HFSA) was established to represent the industry's interests and work with the Thai government to optimise the regulatory environment.

Today, HFSA has 22 member companies and is itself a member of both IADSA and the regional association, the ASEAN Alliance of Health Supplement Associations (AAHSA).

ASEAN is central to HFSA's work. The trading bloc is edging towards harmonisation of the supplements market between member countries, with most experts expecting it to be finalised later this year. This process has proved to be a catalyst for the Thai government to explore changes to how supplements are regulated within its own borders, with HFSA providing valuable advice and support along the way.



Chief among the steps being taken is the creation of a positive list for herbal ingredients used in supplements. Pichit Pongsukvechkul, HFSA President, is optimistic that this positive list – which will include herbal ingredients the authorities consider to be low risk – will dramatically cut the time it takes to gain approval to launch a new product from around six months now to as little as a single day. Time to market will therefore be reduced, as will registration costs, which is particularly good news for Thailand’s many small and medium sized businesses.

Pichit expects an initial list of 100 ingredients to be published as early as the first quarter of 2020, marking a significant step towards reducing red tape. He says he has noticed a change in attitude among Thai regulators, with officials now more open than in the past to finding ways to enable responsible supplement businesses to prosper. HFSA meets regularly with Thailand’s Food & Drug Administration to discuss the government reforms and has been pleased by the agency’s sympathetic approach.

This is illustrated by the Thai government’s efforts to gain an exemption from ASEAN GMP rules for smaller supplement companies. It argues that, for most of them, compliance will be too difficult and that the more achievable Codex General Principles of Food Hygiene are more appropriate. Despite pushback among some ASEAN member states, a compromise has now been reached that should allow

Thailand to defer implementing ASEAN GMP for small businesses for at least five years, at which point the exemption will be reviewed.

HFSA has a busy agenda in the coming months. ASEAN harmonisation looms large, and there is still much to be done to ensure the new positive list continues to be extended beyond the initial 100 ingredients. There are also important discussions taking place around health claims and the use of additives in supplements. In the case of the latter, HFSA would like to see approval granted for its members to formulate with additives that are already considered safe for inclusion in pharmaceuticals.

Significant changes are coming for Thailand’s supplement sector – domestically, regionally and globally. Encouragingly, many of these look set to be positive for Thai businesses, illustrating how – just as the country prepares to enter a new era following ASEAN harmonisation – HFSA’s constructive approach to working with regulators is paying off.

## EU EXIT: WHAT NOW?

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The Council for Responsible Nutrition or CRN UK is a trade association representing the food supplement industry in the UK. CRN UK is leading the industry in the focus and quality of its technical and scientific work.

On 23 June 2016, almost 52% of the UK's electorate who turned out to vote indicated that they wanted the United Kingdom (UK) to leave the European Union (EU). This date was followed by more than three years of uncertainty and three potential departure dates in 2019 before the UK finally left the EU on 31st January 2020. The UK's departure from the EU (known as 'Brexit') ended their relationship of just over 47 years, and has prompted the question: "What now?"

During the past 3½ years, the Council for Responsible Nutrition UK (CRN UK) has been working alongside others in the UK food sector to highlight to the UK government the critical importance of the food sector to the UK's future. The food sector Roundtable on EU Exit, which was attended by representatives from industry and the UK Government, provided the ideal opportunity for open discussion on different Brexit issues impacting the UK food sector, and it became noticeable over the years how much the government agencies came to rely on the insight and information they could obtain from the Roundtable group.



The Roundtable was particularly crucial during the periods when the UK was facing a “no deal” departure from the EU. Issues raised during this time for the supplements sector included concerns with ID Health marks on fish oil supplements; the resource and financial implications of multiple label changes for supplements; the need for EU approval of UK facilities producing products of animal origin; issues surrounding imports and exports of supplements, especially those containing products of animal origin (e.g. fish oil, whey powders, collagen etc.); and many other topics. The Roundtable-led website [Brexitfoodhub.co.uk](http://Brexitfoodhub.co.uk) was created to help food businesses navigate their way through the many hundreds of government information bulletins that were published at the time. It was a rocky, stressful and incredibly busy period of time!

Now the UK has left the EU and has become a “third country”. However, as the departure ended up being via a Withdrawal Agreement, the UK is currently in an eleven-month transition period, which ends on 31st December 2020. During this time, it is theoretically ‘business as usual’. However, in reality, much has changed. The UK is no longer on EU Commission working groups, so has no voice in discussions. The UK no longer has a vote on legislation – but still has to implement any legislation that is published up until the end of this year. Businesses still face uncertainty, this time over what type of trade deal will be agreed with the EU, and how will trade deals with other ‘third countries’ impact discussions with the EU? To increase the uncertainty, UK food industry is now facing a government who has no understanding of the sector’s importance to trade and the UK’s future.

Adding to the complications, the UK is not an entire country in itself; it is actually made up of four nations: England, Wales, Scotland and Northern Ireland. Now that the UK is not part of the EU, there is the potential for legislative divergence not just with our EU mainland neighbours, but also within the four nations themselves! The possibility for this is being restricted by the creation of ‘Common Frameworks’ covering nutrition, food and feed safety, and labelling, which require cooperation and agreement between the four nations. However, there is still an opening for domestic divergence in the UK as the years move on.

The EU Exit Roundtable has now become the Roundtable on the Future UK-EU Relationship and continues its strong engagement with the UK government. Challenging, scary, exciting... however it is viewed, we have an interesting time ahead of us!



Parminder Kaur, Chair of CRN UK



# HEALTH SUPPLEMENTS: SMALL MEASURED STEPS CAN GET YOU THERE

Establishing credentials in a sector popularly discerned more by form - tablets capsules and pills – than its role of supplementing the diet, takes time. The task is to get stakeholders to understand this; small measured steps is perhaps the way to go. Domestically produced and imported supplements had been marketed for thirty years and more without clear regulatory domains set. Until then products were wandering between being a ‘proprietary food’ (foods not standardized under the erstwhile Prevention of Food Adulteration Act, 1954) and a drug. While the Food Safety and Standards Act 2006 succeeded in settling the domain it had yet not dealt with standards for health supplements in the period 2006-2016. Another step?

The Food Safety and Standards (Health Supplements, Nutraceuticals, Foods for special dietary uses, Foods for special medical purposes, functional foods, novel foods) Regulation 2016 is the specific regulation governing composition, labelling and claims for health supplements (and nutraceutical). The descriptions of health supplements are closely similar to terms used elsewhere such as food or dietary supplements. An additional term ‘nutraceutical’ is used along with health supplements; both are categorized under 13.6 and the difference lies in their compositional make-up. Labels are required to declare whether the product is a health supplement or nutraceutical. Nutraceutical products have a wider choice of permitted ingredients drawn from Schedule IV: plants and botanicals, and Schedule VI: nutraceutical ingredients; health supplements cannot draw on ingredients from Schedule VI except for enzymes.

Since the emergence of the regulation, CEO, FSSAI, Shri Pawan Kumar Agarwal tactically ‘nudging in’ compliance before enforcement measures kicked in was a refreshing change for easing business anxieties. He wanted India’s first time regulated food supplement sector to benefit from global practices and encouraged collaborations with national and international organizations. Facilitating the partnership between IADSA and the Confederation of Indian Industries (CII) a Resource Centre for Health Supplements and Nutraceuticals ([www.rechan.in](http://www.rechan.in)) was set up to provide credible science based information. The collaborative effort with the Authority is by far the most significant step for ReCHaN when one views the food control landscape. While the Central government makes the law, the prodigious task of implementing it consistently across the country lies with 37 States/Union Territories FDA’s covering over a billion consumers. Further with the licensing or registering of food businesses (small to large multinationals) likely to cover an estimated 6 million from the current 3.2 million is a humongous task.



Dr. Joe Lewis, Advisor to IADSA and ReCHaN in India

The sector being new needs to develop the ecosystem from basics; several guidance documents on compliance, good manufacturing practices and training programs up to the point of sale are being conducted under the ReCHaN banner.

The Scientific Panel on functional foods, nutraceuticals, dietetic products and other similar products, regularly receives applications and approves their use by expanding the positive lists. Vitamins and minerals are currently restricted to levels not exceeding the recommended dietary allowance (RDA). With the publication of the tolerable upper levels by the Indian Council of Medical Research maximum levels (beyond RDA) are required to be set in accordance with risk management principles provided under the Act.

Several regulatory domains exist and another emerging for ayurvedic ingredients. The Ministry of AYUSH in collaboration with FSSAI is expected to bring in within the food supplement framework a new entity named Ayurveda Aahar to promote the goodness of Ayurveda foods. Where an already ephemeral distinction exists between health supplements and nutraceuticals another closely similar entrant into the supplement market may bring in new complexities.

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International Alliance of Dietary/  
Food Supplement Associations

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