# IADSA CONNECT

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# New novel food rules in Europe

THE LONG ROAD TO WORKABLE REGULATION IN SOUTH AFRICA

THE INTRODUCTORY GUIDE TO TOLERANCES

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IADSA
International Alliance of Dietary/ Food Supplement Associations

# #02
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Michelle Stout,
Chair, IADSA

# WELCOME TO THIS ISSUE OF IADSA CONNECT

During the course of 2018, we have celebrated the first 20 years of IADSA and looked carefully at what we all need to do across the world to continue to build sound regulation and policy. The 2019 IADSA Workplan has been provided to all members and reflects this discussion, moving us forward into new areas that will become increasingly important over the coming years.

While we have clearly made great progress across the Alliance in securing positive change in regulation, it is only too clear to everyone that we need to continue to remain vigilant to new initiatives and engage with those who draft and inform both regulation and policy. It is also evident that across the Alliance we have the expertise and experience to address just about any challenge that comes our way and we need to continually find ways to share this and apply it effectively.

Connect is a great way for everyone to learn more about what is going well and also what is going not so well, and to learn from those experiences. We hope you will enjoy this latest issue.

Michelle Stout
Chair

# THE IADSA COMPANY COUNCIL: WORKING GLOBALLY, SUPPORTING ASSOCIATIONS LOCALLY

The Company Council is comprised of representatives drawn from IADSA's company members. It meets regularly to address key global topics and priorities. Ken Myers is VP, Product Regulatory Affairs, NuSkin and was elected as Chairman of the Company Council in August 2018. He sat down with Connect to discuss the Council's role and its priorities for the future.

## WHAT IS THE ROLE OF THE COMPANY COUNCIL WITHIN IADSA?

The key function of the Company Council is to identify and understand the global regulatory and policy issues impacting on IADSA's members and help them respond to the challenges they face. If we do that alone, as separate businesses, there are limits to what we can achieve. But, acting together and working closely with the member associations on the ground, we can connect the knowledge that exists between us for the benefit of all. Working side-by-side gives us different perspectives and allows us to leverage the best practices we've learned in one region or category and apply them in another. From the major global developments, right down to the regulatory small print, the Company Council is a rich source of expertise and experience.

## WHO SITS ON THE COMPANY COUNCIL?

Representatives come from IADSA's company members, of which there are currently 20. Many have regulatory or technical experience, but there are others who have expertise in government affairs or business development backgrounds. We are a diverse group, which is important because it helps the Company Council see things from many angles.

Ken Myers, Chairman of the Company Council

### IN WHAT WAY CAN A SUPPLEMENT BUSINESS BENEFIT FROM BEING PART OF IADSA'S COMPANY COUNCIL?

Over the past 20 years, IADSA has built relationships with regulators and policy makers all over the world and, during that time, has earned their respect. It's very difficult for individual companies to achieve that level of engagement and influence, so the core principle of the Company Council is that, as businesses operating in the supplements sector, we are stronger together. Acting collectively will always be more effective than doing so independently. In addition, sitting on the Company Council gives businesses a unique opportunity to sit shoulder-to-shoulder with their peers and some of the industry's greatest strategic minds.

### HOW DOES THE COMPANY COUNCIL WORK WITH IADSA'S MEMBER ASSOCIATIONS?

The Company Council members are closely involved in the work of IADSA's member associations at all levels – national, regional and global. The discussions we hold in the Council enable us to align our activities and help associations achieve their objectives. In addition, when there is a special need for action in a country, this is often reported by a company member to the IADSA Secretariat. The Council can then work out what support is needed to help make progress.

For example, we faced significant issues in the Turkish market a few years back. It was through discussion and combined action, and the combined allocation and action of resources from the Company Council, that we were able to provide the support necessary to overcome what was a significant regulatory barrier for product marketing. A new Turkish association was then created, with the core membership for it coming from the Company Council members.

### WHAT INSPIRED YOU TO STAND FOR ELECTION AS CHAIRMAN OF THE COMPANY COUNCIL?

We live in a complex and rapidly changing world and I was excited by the prospect of chairing the Company Council. In particular, I see opportunities to find new and innovative ways to bring IADSA's company members together and achieve alignment on key issues for the benefit of the supplements sector as whole. It's exciting to be in this role and my aim is to ensure the Company Council continues as a force for positive momentum within the wider IADSA family.

Maria Ascenaco,
Chairperson, HPA

# THE LONG ROAD TO WORKABLE REGULATION

The Health Products Association has been the voice of the South African industry since it was founded in 1976 and strives to establish an ethical, credible, relevant and vibrant health products industry in South Africa. The association has developed Self-regulatory Codes of Practice and Standards, and guides members in correct practice and procedures. It has worked for many years with government to try to establish a workable regulatory system in South Africa. HPA was one of the founder members of IADSA.

The General Regulations pertaining to the Medicines and Related Substances Act, 101 of 1965 (Regulations, 2017) were published on 25 August, 2017. The South African natural health products industry had for five years engaged in extensive collaboration with the South African Department of Health through the Health Products Association of Southern Africa (HPA) and its various alliance partners, and expected a positive outcome for the industry. The new regulations, however, effectively defined 'complementary medicines' and 'health supplements' as medicines.

The years of extensive and constructive engagement by the HPA for fair and appropriate regulations in line with the global harmonisation strategy for Natural Health Products and Food Supplements, were thus not considered.

The new regulations make compliance for many involved in the health products industry very difficult: they challenge the understanding of food and dietary supplements according to global norms.

## CURRENT REGULATORY ENVIRONMENT AS RISK TO SA INDUSTRY AND CONSUMERS

The current regulatory framework demonstrates how the classification of natural health and nutritional products – such as Complementary and Traditional Medicines and Health Supplements – as a subset of drugs will negatively impact the South African industry and consumers. The Department of Health has not undertaken any impact studies to determine the risk of these regulations on the economy and on an industry that provides employment and promotes health and wellness.

The onerous requirements for Licensing, Responsible Pharmacists, the Allopathic-styled CTD Dossier compilation and submission, the Single Exit Pricing Model, and registration timelines, amongst other major concerns, have the potential of not only stifling innovation in South Africa but also enforcing the removal of tens of thousands of supplements, safely accessible for years, from people who chose them for health maintenance. The industry is being dismantled by regulations devised for allopathic medicines.

Since the previous regulations were published in 2013, new product innovation in the industry has come to a virtual standstill. The subsequent 2017 regulations have again failed to take into account the benefits of the natural health products industry to both the South African economy and consumers. Inappropriate regulations are being enforced on both natural substances and traditional medicines. This development will drive up costs and put at risk many quality businesses.

The latest regulatory challenge has inspired advocacy and drawn together several stakeholders in a united cause. A joint strategy has been formulated and the HPA, along with the other alliance partners, will continue working hard to prepare for the challenges ahead – with a clear goal of continued constructive engagement with the Department of Health and Government as a whole.

**It is the HPA's intention to ensure a workable system that is sustainable in developing and implementing a framework that best serves the industry, the Department of Health, Government Health Policies, and the South African consumer.**

HPA
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# THE INTRODUCTORY GUIDE TO TOLERANCES

Over the past few years, there has been an increasing government focus on tolerances for supplements. In order to build a better understanding of the issues surrounding product tolerances and to explain in some detail the many causes of variation that can occur in the raw materials, formulation and processing, IADSA have produced a guide to tolerances with specific relevance to supplements.

Lead authors: Peter Berry Ottaway and Sam Jennings, advisors to the UK Council for Responsible Nutrition

All responsible supplement manufactures use appropriate technology and equipment and constantly strive to ensure that their products maintain all their declared values throughout their shelf lives. Despite these efforts there are a number of factors, both singly and collectively, that will influence the declared values.

Whilst manufacturers are aware of these factors, it is not practically possible to reduce or eliminate all the potential influences on the declared values. As a consequence, the combinations of factors that can occur within a particular product formulation and manufacturing process can result in the analysed values of the active ingredients falling either side of the declared value.

Therefore, it has to be appreciated that the declared value must only be taken as a target and cannot be considered to be an absolute value. This means that as the declared value is not an absolute value, there will be small deviations from this value which can be either above or below the target value. Thus, there will always be a narrow range of values for each declared ingredient and the manufacturer aims to ensure that the variations in the product fall within this range. This defined range is commonly referred to as the 'manufacturing tolerance'.

The recognition of the concept of tolerances by all involved in the manufacture and control of supplements is essential, as it takes into account the differences that often occur between active ingredient values declared by the manufacturer on the label and those found in the course of official controls by the authorities. In both cases the measured values should be within the tolerance adopted for the declared values.

The tolerances ranges for supplements need to include all factors leading to variations, and has to be based on the cumulative effects of all these factors.

Tolerances on the labelling of nutrients in supplements do not mean that the manufacturers are permitted to formulate to less than 100% of the declared value at the end of the shelf life. On the contrary, the tolerances are able to provide some protection to the manufacturer if the analytical result is less than the declared value.

The tolerances allow for batch to batch variations in ingredients, small variations in processing and analytical variance during testing. For example, if a product was found to be as low as 85% of the declared value, the company may be required by the control authorities to demonstrate that the product was correctly formulated for the shelf life. It may be necessary to demonstrate from batch documentation that the lower level was due to for example, analytical variations or a major ingredient being at the lower or higher end of a specification range.

The concept of tolerances and their practical application can be difficult to understand, as tolerances are multifactorial and are influenced by a disparate range of variables.

This IADSA guide is essential reading for both manufacturers and regulators as it explains the concept of product tolerances and gives practical advice on identifying and minimising the variances at all stages in the life of a product.

Patrick Coppens,
Director Scientific/Regulatory Affairs, Food Supplements Europe

# NEW NOVEL FOOD RULES IN EUROPE: THE TRUE IMPACT FOR SUPPLEMENTS

Food Supplements Europe represents the interests of the European food supplement sector. Its membership includes national associations and companies committed to ensuring that future EU legislation and policy reflects the important role that this sector plays in the health of consumers.


In 1997 the European Union adopted its Novel Foods Regulation (Regulation 258/97). It introduced a pre-marketing authorization procedure for foods and food ingredients that had not yet been consumed in the EU to a significant degree. The principle was that the safety of such foods be assessed and authorized by the national authority in one country and then this authorisation would be accepted by the other EU Member States. Unfortunately, since other Member States almost systematically raised objections to the national assessment, the work needed to be repeated at the EU level by the European Food Safety Authority. This meant that a typical timeline for an authorization of a novel food was 2-3 years, but some authorizations were taking more than double that time.

The European Commission has been working on a revision of this Regulation and this finally entered into force on 1 January 2018. This revision included a number of fundamental changes:

- All authorizations have become generic, i.e. useable by all companies, except where a request for the protection of proprietary data is granted.
- The introduction of a simplified procedure for foods that have traditionally been consumed in countries outside the EU.
- The repeal of the 'substantial equivalence' procedure, which was a quicker way to get authorization based on the demonstration that a food is substantially equivalent to an existing food or already authorized novel food regarding its composition, nutritional value, metabolism, intended use and level of undesirable substances.

The new approach to novel foods requires the European Food Safety Authority (EFSA) to carry out a safety assessment, and then a decision is taken whether to authorize the food by the European Commission with the Member States. The process should therefore in principle now be shorter, potentially 1-1.5 years. All authorized novel foods will continue to be included in the Union List of authorized novel foods.

Another key feature of the new law is that it is now a legal obligation for companies to assess the status of all new foods they intend to market in the EU. If they are unsure, they must request an official opinion from a Member State. Foods require novel food authorization if they fall in one of the 10 categories of the definition and have not been used in or as food in the EU before 15 May 1997. This is a case-by-case assessment and since proof of use before 1997 is today often hard to find, this might present a number of challenges.

Because this is such an important aspect of the new law with very important implications for innovation in the EU and beyond, FSE has developed a guide on how to perform this assessment (see www.foodsupplementseurope.org). This guidance document has been welcomed by Member State authorities and other industry groups and has already become a standard reference for the European Commission.

The key challenge for the food supplements sector, which is at the forefront of innovation in new substances and ingredients, would be if the scope was to be widened to cover, for example, all new botanical preparations or that the principles historically applied to decide on novel food status would be changed by new interpretations by the Member States. New officials often come into office without knowing the history both of the regulation and how it is applied.

In this light the principles in the Food Supplements Europe guidance document have already demonstrated their usefulness. When in June the value of QPS (Qualified Presumption of Safety) as a parameter to exclude new bacterial strains from the novel food's scope was questioned by a Member State, our guidance document was critical to indicate why QPS is essential. When in October the Commission authorized a specific cranberry extract as novel food, our guidance document was able to ensure that not all other cranberry extracts would be considered novel.

This demonstrates that the Novel Foods Regulation carries a continuous risk for food supplements and new ingredients and that the proactive development of guidelines are crucial tools to ensure consistency in the application of such legislation.

**Further guidelines can be found at www.foodsupplementseurope.org**

food supplements europe

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