CONGRESS REPORT

1st International Congress on
Food Supplements Safety and Compliance

FSSC-2018

Summary and Reflexion from the Congress Chairman

The 1st International Congress on Food Supplements Safety and Compliance "FSSC-2018" took place in Vienna, Austria on the 25th and 26th of June 2018. The aim of this congress was to present and discuss major regulatory and practical implementation issues that Food Supplements (FS) manufacturers face under the current EU legislative framework and related regulations.

The congress was explicitly not intended to address the current EU policy and harmonisation politics, but rather to address the practical implementation issues and to provide some hands-on examples and best practices. How to best approach the implementation of the legislative requirements, acknowledging the fact that the EU legislation may still be far from harmonised and having to deal with local differences. And more importantly, how to benefit from the rules which are harmonised and how to learn from successful examples from the industry.

Looking back at the two-day event, the numerous positive comments received from the participants and the vivid discussions during the Q&A sessions, we can proudly conclude that the event was successful. We are very much looking forward to meeting you again at the next edition of FSSC, where we intend to further address the safety of FS and their ingredients, related risk assessment and other technical challenges in more dept.

The FSSC-2018 program content was brought to you by The Regulatory Company, with great support from Food Supplements Europe, the Council for Responsible Nutrition UK and our most valued presenters. The congress hosting and logistics were arranged for by Bioevents.

Z. Gavrić

Chairman FSSC-2018

Sessions 1 – Food Supplements EU Legislation

Definition and overview of applicable EU legislation, framework for compliance

Presenter: mr. Zoran Gavrić, The Regulatory Company, The Netherlands

The congress was opened by an informative discussion to purposefully give the participants a perspective and overview of the current EU Food Supplements (FS) legislation. The speaker addressed the regulatory status of the different regulations that apply to FS, the respective guidelines available to the manufacturers and to the authorities, and the roles and responsibilities of the different stakeholders. The speaker gave comprehensive though concise insight into the general EU FS legislation principles and the legal framework and principles of the food law.

EU harmonisation, open issues, and differences between member states

Presenter: mr. Patrick Coppens, Food Supplements Europe, Belgium

This informative and well-structured presentation treated numerous questions in relation to the current EU legislation status and moving forward. The differences between member states (MS) such as the notification system, pre-market authorisation of health claims, labelling law and general labelling rules were discussed to focus on some of the limitations which should be addressed by authorities to achieve improved harmonisation between MS. The presenter briefly discussed the science-based risk management model and database and its current limitations, pointing out that botanicals are not yet included in the safety harmonisation. The speaker emphasised that business owners should take the applicable guidelines and legislation in consideration already during the R&D process and ensure that sufficient resources are available to complete all the required product evaluations as per MS requirements. The conclusion with regards to MS harmonisation was stated as a process far from complete.

Sessions 2 – Food Supplements EU Legislation (continued)

Mutual recognition of Food Supplements - update on new developments

Presenter: mr. Ales Bartl, Jones Day, Belgium

In general, the practical aspects of placing a new product on the market were talked over. The presentation included discussions on the Mutual Recognition (MR) principles, general limits to MR claims based on specific MS notification systems such as Belgian FoodSup. Discrepancies and different national view points of the various MS were illustrated with recent law cases. Practical solutions to resolve or assist with these discrepancies were mentioned. Other problematic areas, such as when a FS risk is being categorised by a particular MS as a health risk, were also briefly highlighted. The recommendation and message for product risk assessments based on recognised database information was conveyed. Overall, the current status and future of MR principles for FS were discussed.

Novel Food regulations requirements and Novel Food issues

Presenter: mr. Klaus Riediger, Austrian Agency for Health and Food Safety, Austria

The presenter gave a comprehensive overview of the EU Novel Food regulations and how it changed over the years. He also addressed in more detail the new Novel Food regulation and its current status, how it works with regards to data protection, the exceptions such as GMO's and food additives and for instance enzymes falling under other regulations. The definition and categories of Novel Food were accompanied by several interesting examples of food substances. The history of consumption and procedures used in the determination of Novel Food status using references to published/available bibliographic data were also reviewed. It was also emphasised that the authorised Novel Food list remains a living document.

Sessions 3 – Food Supplements Compliance

Market trends and major challenges in relation to FS product safety and compliance

Presenter: mr. Patrick Coppens, Food Supplements Europe, Belgium

As from this interesting discussion it was clear that there are various market trends and challenges influencing FS product safety and compliance. The FS markets are dynamic and innovative which promote general growth of this market sector. The role of the European Food Safety Authority (EFSA) was also explained. For both business owners and regulators this was a very useful session with referral to a lot of appropriate websites, guidelines and tools relating to product safety and quality, raw material quality control and the different guides to use for product self-assessments.

Borderline products and conflicts with medicinal products legislation (FS vs HMP)

Presenter: ms. Sam Jennings, Council for Responsible Nutrition, UK

This vivid presentation and respective discussions addressed the question "when is a product considered a medicine and when is it considered a FS", mainly from the UK authorities point of view, but also more generally. Various conflicting product examples and cases were mentioned to demonstrate that the classification is indeed not always a clear decision when assessing borderline products. It was highlighted that a FS should be designed for "support and maintenance" of health and that the product packaging and advertising should not make the FS look like a medicine. Claims stating treatment or imply treatment, prevention or curing diseases should be avoided.
Following this interesting discussion, it was illustrated that in theory food vs medicine should be very clearly categorised and easy to do, but also that there are various products that will require genuine and careful assessments.

Sessions 4 – Food Supplements Compliance (continued)

Surveillance of FS: official inspection and consultation service – the Austrian approach

Presenter: mag. Markus Zsivkovits, AGES, Austria

This presentation pointed out practical examples of FS classification problems and some of the relevant aspects to take into consideration. A historical overview of the development of FS legislation was provided with regards to claims and official control of FS. Legal aspects and definitions associated with the criteria on the sources of vitamins & minerals, maximum amounts allowed, reference sources, the limitations of the definitions and the problematic areas thereof were discussed. The presenter also highlighted that the Austrian government agency AGES can assist manufacturers by pre-evaluating products and providing an expert opinion on product marketability in Austria. For that the requester should provide correct documentation and product specification data to the authority, upon which the authority will in general provide its opinion within 2 weeks.

Sessions 5 – Safety of Food Supplements

Risk assessment, a practical approach for finished products and their ingredients

Presenter: mr. Zoran Gavrić, The Regulatory Company, The Netherlands

This presentation gave an insight in how to practically address the risk assessment of FS products and their ingredients. The presenter emphasized the importance of knowing the exact composition of the products and more importantly ingredients used in manufacturing. A step-wise approach was presented which when integrated in the companies NPD process can provide a powerful tool to evaluate and assess the potential risks for a specific product and to adequately address and eliminate them in the product development phase. The core element of this risk assessment tool is a comprehensive database of potential risks associated with specific ingredients. The output of the proposed risk assessment approach provides a solid basis for risk management and ensuring FS product safety.

Risk management – best practice example from the industry

Presenter: dr. Gert Krabichler, Food-PharmaOTC Consult, Germany

This presentation clarified the difference between FS and medicinal products. General manufacturer responsibilities and obligations to ensure product safety were communicated. The presentation of basic dossier requirements accompanied by examples and a practical approach to compile such a dossier was well appreciated by product owners/business operators.

Sessions 6 – Safety of Food Supplements (continued)

Overview Major Safety Issues of "Natural/Botanical" Ingredients in Food Supplements

Presenter: dr. Hartwig Siever, Phytolab, Germany

The responsibility of food business operators to ensure product safety remains extremely high. Product safety is linked to all food final product development and management processes including quality control, manufacturing and product ingredient composition. An overview of regulatory requirements and guidance documents were provided. Quality and safety of unsafe botanicals such as adulterated products, processing technology, contaminants such as mycotoxins, weeds and residues influencing the extend of toxicity of relevant compounds were reviewed. The conclusions highlighted that identity and purity testing are essential for safety. Botanical FS are increasingly subject to regulation. Intentional adulteration and ignorance are huge challenges. Specifications and methods chosen to ensure safety of these FS must be best suited for the compound. Regulatory guidelines and quality technical standards such as pharmacopoeia monographs may assist in many cases.

Clinical safety evaluation for food supplements – is it a must?

Presenter: dr. Alina Nanu, Eurofins Evic Product Testing, Romania

The presenter delved into delegate opinions by suggesting/questioning a need for clinical evaluation of the safety of FS, comparable to practices under other product frameworks like cosmetics and medicinal products. In most cases higher amounts of individual compounds are ingested than which would have been obtained whilst consuming these "natural" products in their true natural state. Death or serious adverse events are indeed possible and do pose a risk when these "natural" formulated compound products are consumed. Questions about sufficient scientific evidence available to prove the safety of botanicals and FS remain unclear. Although clinical testing is not a common practice for food products (to which food supplements belong), the addressed issues and the proposed approach might be a relevant topic for stakeholders to discuss in the future. The presentation resulted in a vivid debate in the Q&A session.

Sessions 7 – Food Supplements and Nutritional and Health Claims (NHC) Compliance

Enforcement of the nutrition and health claims regulation – the case of food supplements

Presenter: ms. Joanna Jaskolska, the European Consulting Company (ECCO), Belgium

The speaker gave a brief history of the label claim regulations with illustrated "borderline" examples. Aspects of the enforcement and current regulatory status were given. Certain labelling and wording issues were also outlined, for instance when claims risk to be "seen" as botanicals. Informative examples were included to illustrate possible exemptions and when labelling causes misperception i.e. when using a probiotic label claim. It was clear that the regulations should be carefully considered when proposing label claims for a finished product.

Human studies for claim support and scientific data for NHCR-dossiers (best approach examples)

Presenter: prof. David Richardson, DR Nutrition, UK

This very insightful presentation summarised how to prepare a successful Nutritional and Health Claims Regulation (NHCR) application. The presenter emphasized the importance to act in accordance within the current EU regulatory principles and legislation whilst using the scientific and technical tools available for the preparation of a health claim application.
Various challenges, strengths, limitations for researchers and the methodologies required for the assessment of the available data sets, were discussed. The weight of evidence approach should be followed to assess appropriate claims that are truthful and meaningful to consumers.

Sessions 8 – Food Supplements and NHC Compliance (continued)

Health claims affecting consumer decisions and new product development

Presenter: dr. Alie de Boer, Maastricht University, the Netherlands

The presenter described claim perception, as recognised by the average consumer. Different types of consumers and the effects of claims on these consumers were explained.
It was advocated to use claims not merely as a marketing tool, but also as an educational tool to inform and uplift the consumer market. The importance of knowing the consumer target market was highlighted to determine which label claims would be appropriate for a specific product.