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2024 A Pivotal Year For EU Supplements Market

by Tom Gallen

With European Parliament elections on the horizon, the coming 12 months will shape the EU policy agenda for dietary supplements regulation for the foreseeable future. Hylobates Consulting's managing director Luca Bucchini highlights some of the key issues which need addressing if Europe is ever going to achieve a harmonized, single market for supplements.

Could 2024 be the year the European Union starts making real progress towards a harmonized single market for dietary supplements?

After years of much talk but little action on key issues hindering the development of the supplements sector a political shake up at the EU level provides grounds for optimism.

European Parliament elections in June – and the knock on effect on the composition of the European Commission – will see new policy priorities introduced and overlooked issues driven back up the agenda.

For firms operating in Europe's supplements market, "summer 2024 will be a time for reading the tea leaves and planning ahead," Luca Bucchini, managing director of Hylobates Consulting, told HBW Insight.

One of the first tasks of the newly assembled European Parliament – "projected to include many new, inexperienced MEPs with unpredictable views," according to Bucchini – will be to elect a Commission president for a five-year term. While it is a distinct possibility current incumbent Ursula von der Leyen could be handed a second term, there will nevertheless be changes to the composition of the College of Commissioners.

"In summer 2024, it will be clear whether the new Commission will push a balanced agenda for supplements going forward, bring about disproportion regulation, or fall back on inaction for the

next five years up to 2029," Bucchini observed.

"From a practical standpoint, food supplement brands investing in the EU will find out whether they can count on a single market for the same supplement, or whether they will face further national requirements that make an EU-wide strategy pointless."

Bucchini is scathing in his assessment of progress made by the Commission during its current term – which comes to an end on 31 October 2024 – on a number of regulatory issues key to achieving a supplements single market.

"The von der Leyen Commission, which is heading for the exit, did not pay much attention to food supplements, and failed to make much progress in defining proportional rules for these products. Such progress would open up the potential of a market that is, on paper, larger than the US."

Probiotics, botanicals and maximum permitted levels for vitamins and minerals are three of the areas highlighted by Bucchini as examples of the Commission's inaction over the past five years.

Probiotic Labelling

"The Commission has failed to respond to the request of member states to find a solution for probiotics," Bucchini pointed out.

Currently, the use of the term "probiotic" to describe supplements that contain "live microorganisms which when administered in adequate amounts confer a health benefit on the host" is considered by the Commission to be an unapproved health claim.

Despite this, around a third of member states allow use of the term on product labels. The first countries to move away from the Commission's restrictive view of probiotics were Italy and the Czech Republic and since January last year France has given the green light to the probiotic label, as well as the related health claim "contributes to the balance of the intestinal flora." (Also see "*France Becomes Latest EU Member To Allow 'Probiotic' Label For Dietary Supplements*" - HBW Insight, 12 Jan, 2023.)

Fit for Future Platform (F4F) – which describes itself as a "high-level expert group" that advises the Commission on achieving regulatory and cost efficiency – has called for "harmonized implementation and enforcement" when it comes to probiotic labelling.

"We want the internal market to function," F4F group member Lasse Hamilton Heidemann said in April 2023. "We want health claims to be credible and uniform across the EU that everyone knows what we're dealing with." (Also see "*Harmonized Probiotic Labeling In Europe? Not Before 2027, Says EC Expert Advisor*" - HBW Insight, 26 Apr, 2023.)

With an increasing number of member states implementing their own national rules, the International Probiotics Association issued a statement in December asserting that "the current position of the European Commission is no longer fit for purpose and should be reconsidered."

"We advocate for a comprehensive review of the European approach to align with the actual nature of probiotics as a distinct category of substances of food and food supplements," IPA stated, adding that "enhancing clarity is imperative to alleviate the existing confusion among European consumers concerning probiotic labelling."

But not all member states are prepared to accept use of the term probiotic. According to the July 2023 newsletter of the International Alliance of Dietary/Food Supplement Associations (IADSA), at a meeting with the Commission Austria requested clarification from the French authorities on the permission given to use the term. This led the Commission to remind member states to take action to ensure conformity of their market with EU rules. "Noting the divergent views in the room, a suggestion was made to address this topic in a working group," the IADSA newsletter notes.

Max. Levels For Supplements

Alongside probiotics, Bucchini bemoaned a lack of meaningful progress by the Commission towards setting maximum permitted levels (MPLs) for vitamins and minerals in supplements sold in the EU.

With the 2002 Directive on food supplements requiring the setting of MPLs, the von der Leyen Commission was hopeful of completing the work by the end of its mandate. In 2021, it asked the European Food Safety Authority to deliver scientific opinions on tolerable upper intake levels (ULs) for eight nutrients, from which MPLs could later be derived. According to the Directive, MPLs should be set taking into account ULs of vitamins and minerals established by scientific risk assessment, and the intake of vitamins and minerals from other dietary sources.

However, this work is now more than a year behind schedule. To date, EFSA has delivered scientific opinions on ULs for four of the eight nutrients requested by the Commission. The outstanding opinions are expected by 30 June. (Also see "*EU Plan To Set Maximum Levels For Vitamins In Supplements Further Delayed*" - HBW Insight, 20 Oct, 2023.)

In the absence of action by the Commission, some EU member states have set their own MPLs for certain vitamins and minerals in supplements, but these limits differ widely.

In the case of vitamin B6, the Netherlands, Ireland and Poland are at the upper end of the scale with MPLs of 21 mg/day, 20 mg/day and 19 mg/day respectively. Italy falls in the middle with a limit of 9.5 mg/day, while France permits just 2.0 mg/day.

With EFSA's 2023 scientific opinion reducing the UL for vitamin B6 in supplements to 12 mg/day for adults, down from 25 mg/day, industry is facing the introduction of a greatly reduced maximum limit than currently permitted in many countries. "The expectation is that MPLs will be massively lower than those currently applied by the member states, and possibly as low as 5 mg/day for food supplements and 1-2 mg/day in enriched foods," Bucchini told HBW Insight early last year. (Also see "*EU's Proposed Safe Limit For Vitamin B6 In Supplements 8 Times Lower Than US Cap*" - HBW Insight, 14 Feb, 2023.)

Botanicals Deadlock

A lack of action in relation to health claims for botanical supplements is Bucchini's third and final criticism levelled at the Commission. "No progress was made despite the invitation of the previous Commission to act, in a balanced manner, on botanicals," he said.

More than 2,000 health claims relating to botanicals in supplements have been placed on hold by the Commission since 2012 after the European Food Safety Authority rejected over 500 of these which sought to rely on traditional use data for substantiation rather than human intervention studies.

Those on hold may still be used in the EU if they comply with the general principles and conditions of the Regulation and the relevant national provisions.

Emphasizing Bucchini's point, the European Parliament will vote on 18 January on a resolution calling on the Commission and member states to take swift action to break the botanicals deadlock.

The resolution emphasizes Parliament's disapproval of the ongoing suspension of botanical claim evaluation and points out there are significant legal concerns about the continued use of on-hold claims under the transitional measures of the Nutrition and Health claims Regulation (NHCR). (Also see "*European Parliament Looks To Kick-Start Botanical Health Claims Assessment*" - HBW Insight, 9 Jan, 2024.)

In 2020, the Commission published a staff working document which suggested "traditional use" could be explored as a way to resolve the decade-long deadlock. Five years in the making, the Commission's evaluation found that the objectives of the NHCR had not been "fully attained" with regards to botanicals. (Also see "*European Commission Suggests 'Traditional Use' Could Resolve Botanicals Deadlock*" - HBW Insight, 1 Jul, 2020.)

However, just a few months later the Commission revealed that botanicals had once again been kicked into the long grass. "Currently there are so many competing priorities that further work on [this issue] is not the top priority," the Commission's Sabine Jülicher admitted in December 2020. "Reflections are ongoing in the background, but we have no timetable that we could

communicate at this point in time." (Also see "*Resolving Botanicals Deadlock 'Not A Priority' For European Commission*" - HBW Insight, 2 Dec, 2020.)

The lack of progress at EU-level means a harmonized approach for botanical claims across the region is not possible. Recent research commissioned by the European Parliament found that several EU member states have introduced their own positive or negative lists for botanical ingredients in foods, adding to the fragmentation in the EU internal market.

Furthermore, some countries require supplement manufacturers to notify regulators before placing their products on the market. "In this too, however, member states determine their own approach, again leading to different strategies," the researchers note. (Also see "*European Commission Must Decide If 'Traditional Use' Can Break Botanicals Deadlock*" - HBW Insight, 25 Oct, 2023.)

Whether botanicals, probiotics or MPLs – or indeed other issues facing the supplements industry such as CBD product authorizations – are prioritized by the new Commission remains to be seen.

But failure to adequately resolve them will hold back the EU supplements market from reaching its full potential, according to Bucchini.

"These developments will impact on major new players entering the European market where they have done well in far more harmonized sectors," he concluded.