

# HFMA UPDATE

Martin Last, Director General



## Setting maximum permitted levels

Since the Food Supplements Directive came into force in 2002, the question concerning the setting of maximum permitted levels (MPLs) in food supplements under Article 5 has remained a challenging issue for the EU Commission to solve. During those 22 years, there have been several attempts to find a solution that works across all member states but without resolution due to its complexity.

Industry has worked on models to propose solutions and the most notable are the German Federal Institute for Risk Assessment (BfR) model, which suggested rather low levels, and the European Federation of Health Product Manufacturers (EHPM) and Food Supplement Europe (FSE) models, which more reasonably matched current industry practice. The models are based on recognised scientific safety principles that assesses national consumer nutrition data and known upper safe levels of intake, which enables a risk management approach for the setting of maximum levels for use in food supplements.

In December 2023, following liaison between FSE and the EHPM, it became aware that the Commission had instigated meetings with selected member states on a possible new formula that may be applied to set MPLs.

This suggested that the Commission appeared to be considering using arbitrary maximum levels for food supplements by splitting food intake data by 50 per cent at



levels referenced to children's intake only. The effect of this on the EU population would have meant very restrictive MPLs and appeared to be politically motivated to encourage action ahead of the political elections in June 2024.

EHPM and FSE concerns were that this was moving away from recognised scientific models and if implemented would have a devastating effect on our food supplements industry. The feedback received took no account of the economic impact, or the safe regulation by industry for over 20 years with no concerns.

The reaction from industry was a joining of forces of EU associations and high-level lobbying activity, with the Commission calling for an economic impact assessment (EIA) and for proper stakeholder consultation, urging them not to rush their work, giving stakeholders the opportunity to be involved and consulted in a transparent and effective manner.

In the early months of 2024, this lobbying was successful in opening discussions; the Commission's proposals were not implemented before the EU elections, and whilst there has still not been any formal

proposal, the Commission is expected to launch a call for evidence, which will seek industry opinion on setting maximum levels, this autumn.

The International Alliance of Dietary Supplement Associations (IADSA) has now also

joined forces with EHPM and FSE, concerned at what global impact these measures may have. There has been considerable pressure to request the Commission to provide a full EIA, rather than just a call for evidence, but the Commission continually refuses to entertain this. The EIA would provide evidence of the effect that such changes would have on the economic viability of the industry sector, the EU economy, and on the EU population should such changes be introduced and would then influence regulators on the proportionality of any such regulation being enacted.

In industry discussions over the summer, it has been decided that, in the absence of a Commission EIA, it's best that industry conduct its own to defend industry's position. Several management consultant proposals were provided and whilst the process is complex and expensive to conduct, all associations have agreed in principle to proceed with shared costs, which will include an industry call for funds. Details are not yet available but are being finalised. Once final details and adjustments have been made, the assessment is planned to be conducted this autumn and ready by November.

As part of this preparation, discussion has occurred between the EHPM and FSE regarding their two MPL models. Both models follow similar approaches but with some variations. It was discussed that there would be a stronger industry position if these two models could be aligned so that industry could speak with one voice. Over the summer, scientific experts from both associations have agreed a common industry position, with a new paper being drafted to reflect this.

To date, the Commission has not yet published its formal proposals for the setting of MPLs, which is now expected early in 2025. It appears that the EC proposal has already received 'informal agreement' of most member states but no formal discussion with stakeholders has yet begun.

Clearly, given such a possible threat to our industry, it is positive to see all relevant trade associations working together, prepared and ready to defend our industry. The HFMA and I, as Vice President of the EHPM, have played an active part of these discussions and await final confirmation from the joint EU industry group. The HFMA is also aligned with other UK trade associations, The Committee for Responsible Nutrition and the Proprietary Association of Great Britain in support of this EU engagement.

If you would like to know more about the benefits of membership, visit our website, [www.hfma.co.uk](http://www.hfma.co.uk), to learn more or contact me on 020 8481 7100.