HFMA Bulletin

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Monacolin K from red yeast rice

The European Federation of Health Product Associations (EHPM), which the HFMA helped to create over 40 years ago, is extremely active in Europe fighting product issues on multiple fronts. One key effort is in seeking transparency and proportionality of implementation of the Article 8 process related to Regulation number 1925/2006, covering the addition of vitamins and minerals and certain substances to foods.

To briefly explain, Part A of Annex III of the Reg. 1925/2006 contains products that are prohibited, such as Ephedra and yohimbe bark. Part B contains restrictive substances, such as the levels of trans fats that can be used. Part C contains substances under EU scrutiny such as other plants containing hydroxyanthracene derivatives (HADs), ie rhubarb, senna, frangula.

The Article 8 procedure could be triggered if one or multiple member states highlight a safety concern or by the EC on its own initiative. A process involving the EFSA then follows to ascertain risk. Article 8 is being used more and more frequently by the EC and member states to assess the safety of botanicals or other ingredients used in food. This procedure can lead to the banning or restriction of the concerned substance, or the placing of it under EU scrutiny.

Article 8 has already led to the ban of aloe preparations foreseen in Reg. 468/2021 on botanical substances containing hydroxyanthracene derivatives that entered into application in April 2021. Article 8 is also ongoing and will affect restrictions on monacolins from red yeast rice, alpha lipoic acid and green tea catechins.

The part B 'Restrictions' provide a condition that the individual portion of food or food supplement for daily consumption shall provide less than 3mg of monacolins from red yeast rice. However, the dossier provided by the EFSA seemingly uses interchangeable reference of 'monacolins' and 'monacolin K' throughout the dossier with a view to restrict the use of all monacolins, even though the data reviewed is only on monacolin K. Furthermore, there is currently no standard method to analyze monacolins other than monacolin K from red yeast rice, which would raise the issue of how operators, academics and control bodies could possibly analyze and follow the measure.

Monacolin K does have a positive health claim previously agreed by EFSA, although as all dosages ≥3mg of monacolins from red yeast rice are to be banned, the health claim at 10mg would no longer be able to be used. The EFSA dossier also proposes several label warnings, one relating to an age restriction of usage to adults above 70 years old, even though the dossier does not show any prevalence of adverse events to adults, nor is it supported by post-market surveillance data.

The EHPM has highlighted such inconsistencies in its contribution to the feedback mechanism and raised the issue with national authorities in order to seek workable resolutions. The EHPM contribution to the stakeholder consultation is available here: https://rb.gy/sy6rws.