Herbal preparations containing hydroxyanthracene derivatives

Published by AGRINFO on 10 Sep 2024

EU to ban herbal preparations containing hydroxyanthracene derivatives – WTO consultation

Draft Commission Regulation amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards certain botanical species containing hydroxyanthracene derivatives

Update

The European Commission has informed the World Trade Organization Sanitary and Phytosanitary Measures (WTO SPS) Committee that it intends to prohibit herbal preparations containing hydroxyanthracene derivatives from various botanical species (G/SPS/N/EU/794). Comments can be submitted to the EU SPS Enquiry Point until **9 November 2024**.

Impacted products

Botanical products

What is changing?

The European Commission proposes to prohibit preparations containing hydroxyanthracene derivatives obtained from the:

- bark of Rhamnus frangula and Rhamnus purshiana
- leaf or fruit of Cassia senna
- root or rhizome of Rheum palmatum, Rheum officinale, and their hybrids.

“Preparations” means products obtained from botanical materials by various processes (EFSA 2009).

An evaluation by the European Food Safety Authority (EFSA) concluded that it could not exclude genotoxicity concerns related to the hydroxyanthracene derivatives contained in these plant preparations (EFSA 2024).

Timeline

These plant preparations will be prohibited 20 days after the Regulation is published, likely to be in the **first quarter of 2025**.

Recommended Actions

Countries that are members of the WTO can submit comments or concerns about potential impacts, via the National SPS notification authority of the country concerned, to the EU SPS Enquiry Point until **9 November 2024**.

Background

Regulation 1925/2006, Annex III lists substances which are:

- prohibited (Part A)
- restricted (Part B)
- under scrutiny (Part C).

Where a substance is placed on the scrutiny list (Part C), at any time during the scrutiny period food businesses can submit to EFSA scientific data related to the safety of the ingredient. A decision on how to regulate a substance under scrutiny (whether to prohibit, restrict, or allow its use) must be taken within 4 years of the substance being placed on the scrutiny list.

The botanical species above were previously listed under Part C, and will be moved to Part A (prohibited).

Resources

Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

EFSA (2009) Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. EFSA Journal, 7(9): 1249.

EFSA (2024) Scientific opinion on additional scientific data related to the safety of preparations of *Rheum palmatum* L., *Rheum officinale* Baill. and their hybrids, *Rhamnus purshiana* DC., *Rhamnus frangula* L. and *Cassia senna* L. EFSA Journal, 22(5): e8766.

Sources

Draft Commission Regulation amending Annex III to Regulation (EC) No 1925/2006 as regards certain botanical species containing hydroxyanthracene derivatives