

European Union Set to Ban the Use of Aloe Extracts in Food Products and Herbal Supplements

On 4 March 2020, the European Commission **published a draft regulation** prohibiting certain substances obtained from aloe plants from being used as ingredients in food products and supplements. Specifically, the draft regulation proposes that hydroxyanthracene derivatives including aloe-emodin and emodin, a structurally-related substance called danthron, and aloe extracts that contain these substances should be added to the list of prohibited substances and ingredients set out in Annex III, Part A of **Regulation (EC) No 1925/2006**, which governs the addition of vitamins and minerals and certain other substances to foods.

This prohibition could affect aloe growers, producers of materials derived from aloe, and businesses that use these materials as ingredients in food products and herbal medicinal supplements that are exported to the EU market.

The European Commission is currently accepting public feedback on the draft regulation. Stakeholders have until 1st April 2020 to **provide their comments** through the EC website.

The aloe extracts subject to the prohibition contain hydroxyanthracene derivatives, which are botanical substances commonly used in food and herbal medicinal supplements for their laxative effect. On 22nd November 2019, the European Food Safety Authority (EFSA) adopted a **scientific opinion** concerning the **safety of hydroxyanthracene derivatives for use in food**. The opinion concluded that hydroxyanthracene derivatives in aloe extracts are genotoxic (i.e., they damage DNA) and that whole-leaf aloe extracts are carcinogenic (i.e., they were shown to cause cancer of the intestine in animal trials). The EFSA was unable to determine a safe daily intake amount that would not give rise to health concerns. The proposed prohibition is based on these findings.

The proposed wording of the draft regulation prohibits aloe extracts in which hydroxyanthracene derivatives, including aloe-emodin and emodin, and the structurally-related danthron are present. Presumably, the prohibition would not cover aloe extracts that have been processed to remove these substances, although there is not yet any guidance available on this point.

The draft regulation has come to the attention of the U.S. Department of Agriculture (USDA) Foreign Agriculture Services, which published a **GAIN Report** on 17 March 2020 to inform U.S. stakeholders in the aloe industry. Aloe is a commercially important agricultural product in the United States, Mexico, Australia, China, and other countries, where its extracts are used in the production of food, herbal medicinal supplements, and cosmetic products.

Tereposky & DeRose regularly provides advice on international trade barriers and trade-restrictive measures. Should you have any questions regarding this matter, we are at your disposal.

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