

Regulatory status in different fields of use and geographic regions -

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This is a discussion paper. It does not reflect the views of the Committee. It should not be cited.

United States

36. Several clinical trials had not revealed any health risks, and *G. cambogia* Desr., was used as an ingredient in food supplements, most notably in the Hydroxycut® range sold in the U.S. in the early 2000s. However, shortly after they were marketed, reports of hepatic, muscular, cardiac and neurological damage, sometimes serious, were reported in the United States and Canada. In 2009, the United States Food and Drug Administration (US FDA) requested the withdrawal of *G. cambogia* Desr., from Hydroxycut® preparations. It should be noted that consumers continued to use these products for several years following withdrawal from the market, due to remaining stock or illegal sales.

Europe

37. Several European Union member states, including Belgium, Italy, and Hungary, have authorised the use of *Garcinia cambogia* Desr., in food supplements. Between 2008 and 2010, applicants submitted requests to the European Food Safety Authority (EFSA) for the evaluation of health claims related to the species *G. cambogia* Desr., including in extract form. These health claims relate to weight control, reducing fat storage and hunger, controlling blood sugar and cholesterol levels. These are said to still be awaiting assessments. In addition, HCA is also the subject of a health risk assessment by EFSA, which is yet to be published.

France

38. The French National Agency for the Safety of Medicines and Health Products (ANSM), classifies *G. cambogia* Desr., as a medical product due to its hypoglycaemic and lipid-lowering effects associated with HCA. However, given the lack of proven therapeutic benefit and an unfavourable benefit/risk ratio due to adverse effects reported in the U.S. and Canada, the ANSM Director General issued a ban on 12 April 2012. The decision prohibits the import, preparation, prescription, and dispensing of preparations containing *G. cambogia*, as well as its use in humans.

39. The French “plants” decree which establishes the list of plants authorised for use in food supplements and their conditions of use, does not include *G. cambogia* Desr.; however, the General Directorate for Competition, Consumer Affairs and Fraud Control (DGCCRF) registered it by mutual recognition under the incorrect name *G. gummi-gutta* (L.) Roxb. The latter appears on the list of plants permitted in food supplements.

40. Data from the Télécare database show that the DGCCRF registered 340 food supplements containing *G. cambogia* Desr., between April 2016 and January 2023. Based on the information gathered from these products, the average HCA intake was 752 mg/day for products that contained only *G. cambogia* Desr. The range was 1.25 – 2,850 mg/day, with 747 mg/day as the median. For multi-ingredient dietary supplements (MIDS) containing HCA, the average HCA intake was 255 mg/day. The range was 0 – 2,070 mg/day, with 150 mg/day as the median.

41. HCA analyses were conducted separately by Service commun des laboratoires and shared between the DGCCRF and customs. The HCA intake was calculated to consider the manufacturer’s advice for use. The average daily intake was 412 mg/day. The range was 21 – 2,000 mg/day, with a median of 203 mg/day.

42. Seventy-four percent [of the registered 340 food supplement products] combined *G. cambogia* with other ingredients that are known to cause liver toxicity in experimental models and clinical studies. These included: green tea containing epigallocatechin gallate; curcuma containing curcumin; red yeast rice containing monacolin K and coumarin. The Plants Working Group (WG) identified other substances that were suspected to be hepatotoxic (as suggested by the literature). These included: conjugated linoleic acid (unspecified isomers), hydroxyanthracene derivatives, forskolin, salicin, methyl salicylate and salicylated derivatives, *Equisetum arvense* [horsetail], gingerol, ginsenosides, gymnemic acid, and parsley. The Plants WG and Human Nutrition Expert Committee further noted that 89% [of the registered 340 food supplement products] contained at least one other ingredient that is known to be hepatotoxic: chromium, caffeine or piperine.