

Adverse effects linked to the consumption of *G. cambogia* Desr.

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

Data from French vigilance systems

43. Since launching in 2009 and up to March 2024, ANSES has received 38 reports of adverse reactions likely linked to food supplements containing *G. cambogia* (or *G. gummi-gutta*), the products labels did not display the full scientific names. All admissible cases (n=35/38) were hepatic, cardiovascular and digestive. Of the 35 reported cases, 18 had sufficient information to assess the product's causal relationship with the observed adverse effects. The number of reports where the causal relationship of the product was very likely was (n = 1/18), likely (n = 7/18), possible (n = 8/18), doubtful (n = 1/18) or excluded (n = 1/18). It should be noted that the majority of the products are MIDS (n=16/18), with the remaining 2 stated to contain *G. cambogia* only.

44. The reported cases with a possible causal relationship associated with hepatic effects were further analysed by ANSES. Five of the six reported liver damage cases involved cytolytic hepatitis. In each case, the person either took *G. cambogia* alongside another potentially hepatotoxic ingredients in the supplement or used a hepatotoxic drug at the same time. In addition, all consumers have co-morbidities, or even risk factors for liver damage (obesity, significant and rapid weight loss).

45. Six additional case reports from the pharmacovigilance system were provided by the French ANSM. Three of which had enough information for the Nutrивigilance WG to assess the causal relationship of *G. cambogia* consumption with the observed adverse effects. The Nutrивigilance WG determined that 2 of the 6 cases had a possible or a very likely causal relationship.

46. Twenty out of 30 additional case reports from the toxicovigilance system were reviewed by the Nutrивigilance WG, they identified that the adverse effects were mostly cardiovascular (n=8/20; tachycardia) and digestive effects (n=6/20; abdominal pain, vomiting). Other effects included general symptoms (n=5/20; dizziness, malaise, fatigue, excessive sweating, dilated pupils) and skin reactions (itchy erythema).

Data from other vigilance system

Europe

47. In October 2020, ANSES contacted its European counterparts to gather more data on adverse effects potentially linked to the consumption of food supplements containing *G. cambogia* or *G. gummi-gutta* (under their truncated names). Of the 37 countries contacted, 21 responded. In brief, most of the 21 respondents (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Hungary, Iceland, Ireland, Latvia, Lithuania, Malta, Slovakia, Spain, Switzerland) were not aware of any cases of adverse reactions related to *G. cambogia* (truncated names).

48. In Belgium, the Federal Public Service for Public Health, Food Chain Safety and the Environment authorises the use of "gum-resin (from the whole fruit or the pericarp)" of *Garcinia* in food supplements. Companies have currently notified and obtained authorisation for over 300 such products on the Belgian market. In Hungary, manufacturers have used this plant in food supplements on the market for over 20 years, and in 2020, they notified 152 products containing it. Some of these contain HCA at a dose higher than the 1,000 mg considered acceptable in Hungary. In these two countries, despite the notification of several hundred dietary supplements containing *G. cambogia*, authorities have not received any reports of adverse reactions.

49. In contrast, Germany (which recorded at least 167 notified products containing *G. cambogia* in 2020), along with Italy, Norway, Slovenia, and the Netherlands, have reported cases. The effects were primarily hepatic (n=13), followed by cardiovascular (n=8), psychiatric (n=6), and neurological issues (n=6).

50. In 2018, the Slovenian National Institute of Public Health published information relating to dietary supplements for weight control, specifying the risks and benefits of the ingredients frequently used in their composition. Regarding *G. cambogia*, liver damage is mentioned.

51. In 2019, the Spanish Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) published a report on the risks linked to consuming dietary supplements containing *G. gummi-gutta* (AESAN, 2019). The report emphasised the existence of sufficient clinical evidence connecting the consumption of *G. gummi-gutta* to the occurrence of hepatic events. This agency also stressed the need to monitor psychiatric disorders (manic attacks, psychoses) reported in the literature in connection with the consumption of this plant.

Canada

52. From the 1st of January 1965 to 31st of August 2023, 93 reports involving at least one product containing one of the following ingredients: '*garcinia*', '*garcinia gummi-guta*', '*garcinia gummigutta*', '*garcinia gummi- guta extract*', '*garcinia gummi-guta fruit*', '*garcinia gummi-gutta gum resin*' (names registered in the database), were recorded. The average age was 42 [note that 12% of the data did not have information on age], and over 80% were women. The mean BMI where available (62% missing data) was 29.9 (\pm 5.2) kg/m². The commonly reported adverse reactions included general symptoms (headache, dizziness), digestive issues (abdominal pain, nausea, vomiting), cardiovascular problems (palpitations, high blood pressure), and psychiatric or neurological effects. Of these 93 reports, 4 were reports of liver damage.

United States

53. According to the US FDA-Medwatch database, authorities had received 40 adverse reaction reports up until the 14th of December 2023 [the start date was not provided]. Of these 40 adverse reaction reports, 35 involved women. The average age (with 17% of data missing) was 43 years (\pm 12.9). The adverse effects reported were mainly of a hepatic, digestive and cardiovascular nature. The Plants WG and the Human Nutrition Expert Committee reviewed the cases submitted by all foreign vigilance systems but could not establish a causal relationship due to a lack of information.