EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10400/2021
(POOL/E1/2021/10400/10400-EN.docx)
[…](2021) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards green tea extract containing (-)-epigallocatechin-3-gallate

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards green tea extract containing (-)-epigallocatechin-3-gallate

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[1], and in particular Article 8(2)(a)(ii) and (b) thereof,

Whereas:

(1) Pursuant to Article 8(2) of Regulation (EC) No 1925/2006, on its own initiative or on the basis of information provided by Member States, the Commission may initiate a procedure to include a substance or an ingredient containing a substance other than a vitamin or a mineral in Annex III to that Regulation listing the substances whose use in foods is prohibited, restricted or under Union scrutiny, if that substance is associated with a potential risk to consumers as provided for in Article 8(1) of Regulation (EC) No 1925/2006.

(2) On 12 October 2015, Norway, Sweden and Denmark sent a request to the Commission to initiate the procedure under Article 8 of Regulation (EC) No 1925/2006 as a potential risk to consumers was associated with the intake of green tea extracts found in food.

(3) The request by Norway, Sweden and Denmark fulfilled the necessary conditions and requirements laid down in Articles 3 and 4 of Commission Implementing Regulation (EU) No 307/2012[2]. The available information, on which the request was based, included a scientific opinion on green tea extracts by the National Food Institute of the Technical University of Denmark[3], and a safety assessment on levels of (-)-epigallocatechin-3-gallate in green tea extracts used in food supplements carried out by the Norwegian Institute of Public Health[4].

(4) The Commission therefore requested the European Food Safety Authority ('the Authority') to deliver a scientific opinion on the evaluation of the safety of green tea catechins from all food sources in accordance with Article 8 of Regulation (EC) No 1925/2006.

---

1 OJ L 404, 30.12.2006, p. 26.

2 Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (OJ L 102, 12.4.2012, p. 2).

3 Opinion on green tea extracts and green tea infusion – Danish Technical University (2015).

4 Safety assessment on levels of (-)-Epigallocatechin-3-gallate (EGCG) in green tea extracts used in food supplements, Norwegian Institute of Public Health (2015).

(5) On 14 March 2018, the Authority adopted a scientific opinion on the safety of green tea catechins[5]. Green tea is produced from the leaves of *Camellia sinensis* (L.) Kuntze, without fermentation, which results in the presence of flavanols commonly known as catechins, the most relevant of which is (-)-epigallocatechin-3-gallate. Green tea catechins can be consumed as traditional green tea infusion, reconstituted tea drinks or as food supplements containing concentrated green tea extracts with widely differing levels of (-)-epigallocatechin-3-gallate. In response to a public 'Call for data' launched by the Authority, no data were received from interested parties on the levels of catechins in green tea extracts used for the manufacturing of food supplement.

(6) The Authority concluded in that opinion that catechins from green tea infusions prepared in a traditional way, and reconstituted drinks with an equivalent composition to traditional green tea infusions, are in general considered to be safe according to the presumption of safety approach, provided the intake corresponds to reported intakes in Member States. The mean daily intake of (-)-epigallocatechin-3-gallate resulting from the consumption of green tea infusions ranges from 90 to 300 mg/day.

(7) The Authority concluded in that opinion that, based on the available data on the potential adverse effects of green tea catechins on the liver, there is evidence from interventional clinical trials that intake of doses equal to or above 800 mg of (-)-epigallocatechin-3-gallate per day taken as a food supplement has been shown to induce a statistically significant increase of serum transaminases in treated subjects compared to control subjects, which is indicative of liver injury.

(8) In the opinion, the Authority explained that there were a number of uncertainties regarding exposure to green tea catechins, and the biological and toxicological effects. Therefore, it was unable to provide advice on a dietary intake of green tea catechins that does not give rise to concerns about harmful effects to health, for the general population, and as appropriate, for vulnerable subgroups of the population. The chemical composition, including the content of (-)-epigallocatechin-3-gallate, varies widely due to plant variety, growing environment, season, age of leaves and manufacturing conditions, and there are uncertainties on how the composition of extracted catechins and other substances used to prepare green tea extracts is influenced by manufacturing procedures. The Authority noted the limited data on dose–response relationships between doses of (-)-epigallocatechin-3-gallate and abnormal liver parameters that is needed for the assessment of a dose of (-)-epigallocatechin-3-gallate that will not cause an effect on liver parameters. Furthermore, uncertainties exist as to whether more serious liver effects may develop after long-term use of green tea extracts, as well as uncertainties on the mechanisms leading to dose-dependent hepatotoxicity of (-)-epigallocatechin-3-gallate. The mechanism leading to hepatotoxicity in rare cases of liver injury that have been reported after consumption of green tea infusions, is not certain, and the Authority stated that such cases are probably due to an idiosyncratic reaction, therefore there is no clear relation to the dose, route or duration of administration of the substance.

(9) Considering that no daily intake of green tea catechins in foods that does not give rise to concerns for human health could be set, and considering the significant harmful effect on health associated with the intake of (-)-epigallocatechin-3-gallate at a daily intake level equal to or above 800 mg, the use of green tea extracts containing 800 mg or more of (-)-epigallocatechin-3-gallate in foods including food supplements, should be prohibited. Green tea extract containing (-)- epigallocatechin-3-gallate should

[5] EFSA Journal 2018;16(4):5239.

therefore be placed in Part B of Annex III to Regulation (EC) No 1925/2006 and its addition to foods or its use in the manufacture of foods should only be allowed under the conditions specified in that Annex.

(10) As the Authority could not identify, in its 14 March 2018 opinion, a dietary intake of green tea catechins that does not give rise to concerns about harmful effects to health, for the general population, and as appropriate, for vulnerable subgroups of the population, and as, therefore, there remains the possibility of harmful effects on health associated with the use of green tea extracts containing less than 800 mg of (-)-epigallocatechin-3-gallate, but scientific uncertainty in this regard persists, the use of green tea extracts containing ()- epigallocatechin-3-gallate in foods and food supplements, should be placed under Union scrutiny and therefore, should be included in Part C of Annex III to Regulation (EC) No 1925/2006. Considering the uncertainties outlined by the Authority in its 14 March 2018 opinion and its recommendation that studies should be performed to determine a dose–response of hepatotoxicity of green tea catechins and examine inter and intra species variability, interested parties may submit, under Article 8(4) of Regulation (EC) No 1925/2006, the data necessary to demonstrate the safety of green tea extracts used in foods including food supplements in accordance with Article 5 of Commission Implementing Regulation (EU) No 307/2012. In accordance with Article 8(5), the Commission should take a decision, within four years from the entry into force of this Regulation, whether to include green tea extract containing (-)- epigallocatechin-3-gallate in Annex III, Part A or Part B, to Regulation (EC) No 1925/2006, as appropriate, taking into account the opinion of the Authority on any submitted data.

(11) The Authority recommended, in its 14 March 2018 opinion, that labels of green tea products, with particular reference to food supplements, should include the content of catechins and the proportion of (-)-epigallocatechin-3-gallate. It is important to ensure effectively and verifiably that consumers cannot be exposed to equal or higher levels of green tea extract containing (-)-epigallocatechin-3-gallate that the Authority considered harmful for human health. It is therefore necessary to provide for appropriate labelling requirements for all foods containing green tea extracts containing (-)- epigallocatechin-3-gallate.

(12) Article 6(3) of Directive 2002/46/EC of the European Parliament and of the Council[6] requires the labelling of food supplements with the portion of the product that is recommended for daily consumption together with a warning not to exceed the stated recommended daily dose. As different foods or food supplements containing green tea extracts may be consumed simultaneously, there is a risk of exceeding the daily dose of (-)- epigallocatechin-3-gallate laid down in the Annex to this Regulation. Therefore, it is necessary to provide for appropriate labelling requirements for all foods containing green tea extract containing (-)-epigallocatechin-3-gallate.

(13) The Authority also noted, in its 14 March 2018 opinion, that the administration of green tea extract under fasting conditions, and as a bolus, leads to a significant increase in the area under the plasma concentration-time curve of (-)- epigallocatechin-3-gallate compared to administration with food and in split doses, and that fasting has been demonstrated to increase the toxicity of green tea catechins in experimental

[6] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183 12.7.2002, p. 51).

animals. Therefore, it is necessary to warn consumers not to consume green tea extract preparations in foods, including food supplements, under fasting conditions.

(14) The Authority further noted, in its 14 March 2018 opinion, that none of the intervention studies addressed pregnant and lactating women, breast-fed infants and children below 18 years old, and thus there remains the possibility of harmful effects on health associated with the use of green tea catechins. It is therefore appropriate to include a warning as regards the use of foods and food supplements containing green tea extracts in certain vulnerable groups of consumers. Furthermore, considering the uncertainties outlined by the Authority in that opinion, it is appropriate to warn persons to seek medical advice if they experience any health problems.

(15) (-)-Epigallocatechin-3-gallate as a highly purified extract from the leaves of green tea (*Camellia sinensis* (L.) Kuntze) containing a minimum of 90% (-) -epigallocatechin-3-gallate has a defined CAS registry number and manufacturing process and is authorised for use as a novel food under the Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods,[7] and in accordance with the conditions of use and specifications laid down by Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods[8]. The use of highly purified extracts of (-)-epigallocatechin-3- gallate in fortified foods and food supplements that fall within the conditions of use and specifications of the novel food in Regulation (EU) 2017/2470 should continue to be used in accordance with that regulation.

(16) Regulation (EC) No 1925/2006 should therefore be amended accordingly.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1925/2006 is amended as follows:

1. The following entry is inserted in the table in Part B, in alphabetical order:

‘

Restricted substance	**Conditions of use**	**Additional requirements**
Green tea extract containing (-)-epigallocatechin-3-gallate used in foods including	Individual portion of food or food supplement for daily consumption shall contain less than 800 mg of	The label shall provide the maximum number of portions of the product for daily consumption and a

[7] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327, 11.12.2015, p. 1.

[8] Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

beverages*, and food supplements as defined by Directive 2002/46/EC * excluding green tea infusions prepared in a traditional way and reconstituted drinks (containing at least 0.12 g dry mass of extracts from tea in 100 mL) with an equivalent composition to traditional green tea infusions.	(-)-epigallocatechin-3-gallate	warning not to consume a daily amount of 800 mg of (-)-epigallocatechin-3-gallate or more. The label shall indicate the content of catechins and the proportion of (-)-epigallocatechin-3-gallate per portion of the product. The label shall include the following warnings: "Should not be consumed if you are already consuming other products containing green tea". "Should not be consumed by pregnant or lactating women, children below 18 years old." "Seek advice from a doctor on consumption of this product if you experience health problems". "Should not be consumed under fasting conditions".

,

2. The following entry is inserted in Part C, in alphabetical order:

'Green tea extracts containing (-)- epigallocatechin-3-gallate used in foods including beverages*, and in food supplements as defined by Directive 2002/46/EC

*excluding green tea infusions prepared in a traditional way and reconstituted drinks (containing at least 0.12 g dry mass of extracts from tea in 100 mL) with an equivalent composition to traditional green tea infusions.'

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN