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Delegations will find attached document D082021/01.

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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 extracts containing (-)-epigallocatechin-3-gallate

(Text with EEA relevance)

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 extracts 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 catechins, and in particular of (-)-epigallocatechin-3-gallate in green tea extracts used in the manufacture of food.

(3) The request of 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

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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).

catechins from all food sources in accordance with Article 8 of Regulation (EC) No 1925/2006.

(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 infusions, reconstituted tea drinks or as a food supplement containing concentrated green tea extracts with widely differing levels of (-)-epigallocatechin-3-gallate.

(6) On 10 April 2017, the Authority launched a public 'Call for data' on new scientific information as regards the use of green tea catechins to retrieve from interested parties documented information relevant to the evaluation of those substances from all sources in foods, including preparations such as food supplements and infusions. However, no data were received from interested parties on the levels of catechins in green tea extracts used for the manufacturing of food supplements.

(7) On 14 March 2018, the Authority adopted a scientific opinion on the safety of green tea catechins[5]. 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.

(8) The Authority also concluded 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 in the form of 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.

(9) In that opinion, the Authority explained that there were a number of uncertainties regarding exposure to green tea catechins and their 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 depending on the plant variety, the growing environment, the season, the age of leaves and the 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, which is needed for the assessment of a dose of (-)-epigallocatechin-3-gallate that would not cause an effect on liver parameters. Furthermore, there are uncertainties as to whether more serious liver effects may develop after long-term use of green tea extracts, as well as regarding the mechanisms leading to dose-dependent hepatotoxicity of (-)-epigallocatechin-3-gallate. The mechanism leading to hepatotoxicity in the rare cases of liver injury that have been reported after consumption of green tea infusions is not certain, and the Authority

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

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.

(10) Considering that the Authority could not determine a daily intake of green tea catechins in foods that does not give rise to concerns for human health, and considering the significant harmful effect on health associated with a daily intake level of (-)-epigallocatechin-3-gallate equal to or above 800 mg, the addition to foods or use in the manufacture of foods of (-)-epigallocatechin-3-gallate from green tea extracts at levels of 800 mg or more per daily portion of food should be prohibited. Green tea extracts containing (-)- epigallocatechin-3-gallate should therefore be included 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.

(11) The Authority in its opinion of 14 March 2018 could not identify 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. As there is still a possibility of harmful effects on health associated with a daily intake level of less than 800 mg of (-)-epigallocatechin-3-gallate from green tea extracts, but scientific uncertainty in this regard persists, green tea extracts containing (-)- epigallocatechin-3-gallate should be placed under Union scrutiny and 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 in accordance with Article 5 of Commission Implementing Regulation (EU) No 307/2012.

(12) 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 extracts 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.

(13) 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 over one day, there is a risk that the consumer's intake exceeds the maximum daily dose of (-)- epigallocatechin-3-gallate. Therefore, it is necessary to provide for appropriate labelling requirements for all foods containing green tea extracts containing (-)-epigallocatechin-3-gallate.

(14) The Authority recommended, in its 14 March 2018 opinion, that labelling of green tea products, with particular reference to food supplements, should include the content of (-)-epigallocatechin-3-gallate. It is important to ensure effectively and verifiably that consumers cannot be exposed to levels of (-)-epigallocatechin-3-gallate from green tea extracts that the Authority considers harmful for human health. It is therefore

[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).

necessary to provide for appropriate labelling requirement indicating the content of (-)-epigallocatechin-3-gallate per portion of the food.

(15) The Authority also noted, in its 14 March 2018 opinion, that the administration of green tea extracts 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 animals. Therefore, it is necessary to warn consumers not to consume green tea extract preparations in foods on an empty stomach.

(16) 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 in those vulnerable groups of consumers. It is therefore appropriate to include a warning as regards the use of foods containing green tea extracts in those vulnerable groups of consumers.

(17) This Regulation should not affect the use in fortified foods and food supplements of (-)-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. That substance is safe and authorised for use as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council[7], and is subject to the conditions of use and specifications laid down by Commission Implementing Regulation (EU) 2017/2470[8].

(18) A reasonable period should be provided to allow food business operators to adapt to the new requirements set out in this Regulation. Considering the safety concerns such period should concern only products already lawfully placed on the market before the entry into force of this Regulation.

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

(20) 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) in Part B, the following entry is inserted in the table, in alphabetical order:

Restricted substance	**Conditions of use**	**Additional requirements**
'Green tea extracts containing (-)-epigallocatechin-3-gallate*	Daily portion of food shall contain less than 800 mg of (-)-epigallocatechin-3-	The label shall provide the maximum number of portions of the food for

[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).

*excluding aqueous green tea extracts containing (-)-epigallocatechin-3-gallate which after reconstitution in beverages have a composition comparable to traditional green tea infusions.	gallate	daily consumption and a warning not to consume a daily amount of 800 mg of (-)-epigallocatechin-3-gallate or more. The label shall indicate the content of (-)-epigallocatechin-3-gallate per portion of the food. The label shall include the following warnings: "Should not be consumed if you are consuming other products containing green tea on the same day". "Should not be consumed by pregnant or lactating women and children below 18 years old". "Should not be consumed on an empty stomach".'

(2) in Part C, the following entry is inserted, in alphabetical order:

'Green tea extracts containing (-)- epigallocatechin-3-gallate*

*excluding aqueous green tea extracts containing (-)- epigallocatechin-3-gallate which after reconstitution in beverages have a composition comparable to traditional green tea infusions.'

Article 2

Foodstuffs containing green tea extracts containing (-)- epigallocatechin-3-gallate, which do not comply with the requirements of this Regulation and were lawfully placed on the market before the entry into force of this Regulation may remain on the market until [*OP: indicate specific date corresponding to 6 months after the entry into force*)].

Article 3

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