Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Notice of final decision to amend (or not amend) the current Poisons Standard

19 February 2025

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Notice of final decision to amend (or not amend) the current Poisons Standard

This web publication constitutes a notice for the purposes of regulation 42ZCZS of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulation 42ZCZS, this notice publishes:

- the decision made by a delegate[1] of the Secretary of the Department of Health and Aged Care (the **Delegate**) pursuant to regulation 42ZCZR
- the reasons for the final decision and
- the date of effect of the decision.

Defined terms

In this notice the following defined terms are used in addition to those above:

- the Therapeutic Goods Act 1989 (Cth) (the **Act**)
- the Scheduling Policy Framework 2018 (the **SPF**)
- the Scheduling handbook, Guidance for amending the Poisons Standard (the **Handbook**) and
- the Therapeutic Goods Administration (the **TGA**).

Note: additional terms are also defined for individual decisions.

Final decision on a proposed amendment referred to the Advisory Committees on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #32, November 2022)

Final decision in relation to *Camellia sinensis* extract (green tea extract)

Proposal

The Delegate received a proposal to create a Schedule 2 entry for *Camellia sinensis* extract (green tea extract) in the Poisons Standard in preparations for internal use, unless they are labelled with specific warning statements (the Proposal). Under the proposal preparations containing green tea extract not carrying the specific warnings would be removed from general sale.

Interim decision

The Delegate made an interim decision to not amend the Poisons Standard in relation to *Camellia sinensis* extract which was published on 3 February 2023. Public consultation on the interim decision was undertaken during 3 February to 3 March 2023. Following discussion with internal and external stakeholders, an additional public consultation regarding the scheduling of *Camellia sinensis* extract was conducted from 1 March 2024 to 12 April 2024.

[1] For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth).

Final decision

Pursuant to regulation 42ZCZR of the Regulations, the Delegate has made a final decision to set aside the interim decision and amend the current Poisons Standard in relation to *Camellia sinensis* extract as follows:

Schedule 5 – New entry

CAMELLIA SINENSIS EXTRACT (GREEN TEA EXTRACT) for oral use **except**:

- in preparations for human therapeutic use when compliant with the required advisory statements for medicine labels, or
- in preparations containing 300 mg or less of epigallocatechin-3-gallate per maximum recommended daily dose.

Appendix F, Clause 1 – New entries

113 – Stop use and see a doctor if you have yellowing skin or eyes, unusual fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.

114 – To be taken with food.

Appendix F, Clause 4 – New entry

Item	Poison	Warning statement item number	Safety direction item number
57a	CAMELLIA SINENSIS EXTRACT (GREEN TEA EXTRACT)	113, 114	

Index – New entry

CAMELLIA SINENSIS EXTRACT
Cross reference: GREEN TEA EXTRACT
Schedule 5
Appendix F, clause 4

Materials considered

In making this final decision, the Delegate considered the following material:

- the application to amend the current Poisons Standard with respect to *Camellia sinensis* extract (green tea extract) (the **Application**)
- the 8 public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations
- the advice received from the 32nd meeting of the Advisory Committees on Medicines and Chemicals Scheduling in joint session (the **Committee**)
- the interim decision relating to *Camellia sinensis* extract and the materials considered as part of the interim decision, as published on 3 February 2023
- the 5 public submissions received in response to the interim decision consultation under regulation 42ZCZP of the Regulations
- the 10 public submissions received in response to the additional consultation conducted in March and April 2024
- the changes to the Permissible Ingredients Determination with regards to *Camellia sinensis* extract, as published on 27 February 2024
- subsection 52E(1) of *the Therapeutic Goods Act 1989*, in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use

of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (e) the potential for abuse of a substance; and (f) any other matters considered necessary to protect public health.

- pursuant to paragraph 52E(2)(a) of the Act, the SPF, and
- the Handbook.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to set aside my interim decision to not amend the current Poisons Standard in relation to *Camellia sinensis* extract (green tea extract), and instead amend the Poisons Standard in the manner set out above. In making my final decision, I have taken into account the material considered in making the interim decision, the 8 public submissions received in response to the interim decision, and the 10 public submissions received in response to the additional consultation on the scheduling of *Camellia sinensis* extract.

I note that in the additional consultation, 8 of the submissions received were either supportive or partially supportive of the suggested entry for *Camellia sinensis* extract outlined in the consultation. The one written submission opposing the new scheduling entry expressed uncertainty regarding the scope and practical effect that the new entry may have on currently marketed products containing *Camellia sinensis* extract.

The proposal to include *Camellia sinensis* extract (green tea extract) in the Poisons Standard was initiated in response to the rare but serious incidence of adverse hepatic events related to ingestion of this extract. *Camellia sinensis* extract is used in a variety of preparations including foods, medicines, cosmetics, and over-the-counter supplements for weight loss and general health. The extract is often concentrated, with various ingredients present at high concentrations. Ingestion of concentrated *Camellia sinensis* extracts has resulted in adverse events eventuating in liver transplants in some cases, including at least one case in Australia.[2] While the long history of consumption of *Camellia sinensis* by humans is a reasonable indicator of the safety of this substance and adverse events are relatively rare, the severity of these adverse events combined with the variety of preparations and uses of *Camellia sinensis* extract, necessitate implementation of further controls on this substance through the Poisons Standard.

Further, I have considered the TGA's recent review and subsequent changes[3] to the listing for *Camellia sinensis* extract in the Therapeutic Goods (Permissible Ingredients) Determination (No.1) 2024 (the Determination), a legislative instrument which outlines the requirements for listed medicines in the Australian Register of Therapeutic Goods (ARTG, referred as the Register in the Poisons Standard). I am of the view that the final decision on changes to the Determination in relation to *Camellia sinensis* extract accurately reflect the serious consequences that can arise from ingestion of this substance, especially concentrated extracts of this plant species.

The adverse effects of *Camellia sinensis* extract on the liver can be minimised or reversed with early identification of symptoms. The symptoms are typical of liver injury and include yellowing skin/eyes, fatigue, nausea, appetite loss, abdominal pain, dark urine, and/or itching, all of which can be readily identified by the consumer. Consistent with factor 4 in the SPF for Schedule 5 substances, these risks can be adequately mitigated through labelling with warning statements. The new warning statements in Appendix F will inform consumers of the rare but still significant risks associated with the use of *Camellia sinensis* extract, as well as appropriate actions should they experience any of the associated symptoms. I am satisfied that the risks can be mitigated through these simple warnings.

I agree with the decision relating to *Camellia sinensis* extract in the Determination that products containing 300 mg or less of epigallocatechin-3-gallate (EGCG) – the primary biomarker in *Camellia sinensis* – are unlikely to present a significant risk to human health. While research indicates that adverse reactions to extracts of *Camellia sinensis* are somewhat idiosyncratic in nature and dependent on a range of factors, there is clear evidence that dosage can play a significant role. Data

[2] I note that this case did involve the use of other supplements by the consumer and therefore causality is not clear.

[3] Final decision on green tea extract in the Permissible Ingredients Determination

from interventional clinical trials show that intake of doses equal or above 800 mg EGCG/day taken as a food supplement induce a statistically significant increase of serum transaminases in treated subjects compared to control (European Food Safety Authority Panel on EFSA Panel on Food Additives and Nutrient Sources added to Food)[4]. Based on the human studies of healthy populations, Health Canada identified a no observed adverse effect level for *Camellia sinensis* extract equivalent to 600 mg EGCG per day and a recommended maximum daily intake (RMDI) of 300 mg EGCG per day when used as a supplemental ingredient in food[5]. Considering the information available in literature and the findings of international regulators, I have decided that low-dose preparations present sufficiently low risk to health such that they can be exempted from the requirements of the new Schedule 5 entry. EGCG is the most abundant flavonoid in *Camellia sinensis* and therefore is the most useful for establishing a suitable cut-off for exemption from scheduling. After reviewing all the available data, I consider that the exemption limit that is included in the new entry, which is based on the daily dose of EGCG when the product is used as labelled, is appropriate.

The new Schedule 5 entry for *Camellia sinensis* extract and the exemptions will apply to preparations containing *Camellia sinensis* extract regardless of how that extract was obtained. This is in contrast with the Determination which exempts aqueous extracts of *Camellia sinensis*, a decision that was based on the available toxicity data being limited to extracts obtained in this way. However, I find it is not practical to extend this exemption for aqueous extracts to preparations other than those for therapeutic use. The manner of extraction, including the solvent used, is often unknown for this ingredient, for example, when used as a food additive. Therefore, the new Schedule 5 entry for *Camellia sinensis* extract, including the specified exemptions from scheduling, applies to the substance independent of the way it was obtained from the plant material.

After considering the limited labelling space available for many products that may be affected by this decision, I have decided to abbreviate the required Appendix F warning statements compared to those included in the Determination. These statements are to be applied to all applicable products and outline the symptoms of liver toxicity that may arise from consumption of *Camellia sinensis* extract, as well as actions the consumer should take if they experience these symptoms.

However, care must be exercised in the implementation of the new entry in the Poisons Standard to ensure only products that present sufficient risk of adverse events are affected, and undue regulatory burden is not placed on the manufacturers and sponsors of those products which present a low risk. Therefore, in introducing a new entry for *Camellia sinensis* extract to Schedule 5 of the Poisons Standard, I have considered each of the known uses of this substance in turn.

Preparations administered by means other than the oral route, e.g. topical including cosmetics: I agree with the reasoning provided in the relevant final decision on changes to the Determination that there is presently insufficient evidence to link non-oral preparations containing *Camellia sinensis* extract to adverse health events. Despite the Register listing several topical products that contain *Camellia sinensis* extract as an excipient, such as sunscreens, there have been no safety concerns identified with this route of administration for the substance. There have also been no concerns raised regarding the use of *Camellia sinensis* extract in cosmetic preparations. Therefore, I have decided to limit the scheduling entry to *Camellia sinensis* extract in preparations for oral use, where a considerable body of evidence indicates a risk to public health.

Preparations for therapeutic use: I recognise that currently all medicines containing *Camellia sinensis* extract on the Register are listed medicines which must comply with the Determination including the requirements for warning labels where applicable. Therefore, any entry in the Poisons Standard that applies to therapeutic products containing *Camellia sinensis* extract will either duplicate or, in future, potentially contradict the requirements imposed by the Determination. By exempting *Camellia sinensis* extracts in human therapeutic preparations from the Schedule 5 entry, the Determination remains the sole applicable legislative instrument for the regulation of *Camellia sinensis* extract in listed medicines. Some listed medicines may also require advisory statements about specific

[4] EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2018. Scientific Opinion on the safety of green tea catechins. EFSA Journal 2018;16(4):5239, 89 pp. https://doi.org/10.2903/j.efsa.2018.5239

[5] https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/notice-modification-list-permitted-supplemental-ingredients-permit-use-green-tea-extract-supplemental-ingredient-foods/document.html

risks related to use of the medicines as set out in the Required Advisory Statements for Medicine Labels (RASML). While the most recent version of RASML (Therapeutic Goods (Medicines Advisory Statements) Specification 2021) does not include any warning statements for *Camellia sinensis* extract, the Poisons Standard entry covers any future changes to RASML. As the Register currently does not include any therapeutic preparations containing *Camellia sinensis* extract other than listed medicines, there is no impact from amending the wordings as suggested in the additional consultation to those in in my final decision (above).

Supplements: I observe that *Camellia sinensis* is a popular ingredient in numerous health supplements that are available for over-the-counter sale in Australia. The substance is frequently included in weight loss supplements either as a sole ingredient, or in combination, due to its thermogenic properties. Some supplements are now defined as therapeutic goods[6] under the *Therapeutic Goods (Declared Goods) Order 2019*,[7] and therefore are subject to inclusion on the Register and are required to comply with the requirements of the Determination. Examples include supplements containing *Camellia sinensis* extracts that are used, advertised or presented for the improvement or maintenance of physical or mental performance in sport, exercise or recreational activity or weight loss. However, there is a range of marketed products containing *Camellia sinensis* extract that fall outside the scope of this Order, whether due to a lack of health claims on the product labelling or the dosage form of the product itself (usually bulk powders). The presence of *Camellia sinensis* extract in these products presents a genuine risk to public health, and I find that is appropriate that they are included in the scope of the new Schedule 5 entry for this substance. The potential for background dietary exposure of *Camellia sinensis* extracts, in addition to the risk of liver injury, supports cautionary labelling for the supplemental use of *Camellia sinensis* extracts to prevent overconsumption.

Food: The new Schedule 5 entry for *Camellia sinensis* extracts intends to capture the concentrated extracts that pose a risk of liver toxicity due to high EGCG content. The Poisons Standard's Appendix A entry exempts all products defined as food, but not food additives, from the requirements of the Poisons Standard. Given the wide use of *Camellia sinensis* both as a food itself (e.g. in the preparation of brewed beverages), and as an ingredient used in food for its flavouring, colouring and antioxidant properties, it is important to be clear that *no products regarded as foods per se are affected by the new Schedule 5 entry*. The new scheduling entry allows for further dietary exposures to EGCG for example through consumption of brewed green tea and the use of *Camellia sinensis* in foods remains wholly regulated by Food Standards Australia New Zealand (FSANZ) under the Food Standards Code. However, any food containing *Camellia sinensis* extract with ECGC above the maximum recommended daily dose will be considered a Schedule 5 substance and will require warning statements.

Food additives: I am aware that bulk powders containing *Camellia sinensis* extract that can provide more than 300 mg EGCG per day are available as food additives. I find that this presents a risk to public health and these preparations should be included among those that are subject to controls under the Poisons Standard. The Poisons Standard's Appendix A entry does not exempt food additives before incorporation into food. The new Schedule 5 entry ensures that any food additive providing more than 300 mg EGCG per day is classified as a Schedule 5 substance. Risk mitigation measures such as appropriate packaging and including warning labels will apply to such products.

Given the potential scope of this decision and the range of products that may be affected, I have elected to extend the implementation period of this decision. This extended lead time should allow manufacturers to make the necessary alterations to the labelling for their products prior to the implementation date.

Implementation date

1 October 2026

[6] https://www.tga.gov.au/resources/resource/guidance/changes-regulation-sports-supplements-australia

[7] https://www.legislation.gov.au/F2019L01352/latest/text

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au