

SCIENTIFIC OPINION

Inability to assess the safety of beta-, gamma- and delta- tocopherol and alpha-, beta-, gamma-, delta- and desmethyl-tocotrienol added for nutritional purposes as sources of beta-, gamma- and delta-tocopherol and alpha-, beta-, gamma-, delta- and desmethyl-tocotrienol in food supplements and the bioavailability of beta-, gamma-, delta- tocopherol and alpha-, beta-, gamma-, delta- and desmethyl-tocotrienol from the different sources, based on the supporting dossiers ¹

Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food (ANS)

(Questions No EFSA-2006-262, EFSA-Q-2006-263, EFSA-Q-2006-264, EFSA-Q-2006-266, EFSA-Q-2006-267, EFSA-Q-2006-268, EFSA-Q-2006-269, EFSA-Q-2006-270)

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PANEL MEMBERS

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

The European Community legislation lists nutritional substances that may be used for nutritional purposes in certain categories of foods as sources of certain nutrients.

The Commission has received a request for the evaluation of beta-, gamma- and delta-tocopherol, alpha-, beta-, gamma-, delta- and desmethyl-tocotrienol added for nutritional purposes to food supplements. The relevant Community legislative measure is:

- Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements².

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide a scientific opinion, based on its consideration of the safety and bioavailability of beta-, gamma- and delta-tocopherol, alpha-, beta-, gamma-, delta- and desmethyl-tocotrienol added for nutritional purposes in food supplements.

² OJ L 183, 12.7.2002, p. 51.

STATEMENT

1. Summary of information provided on beta-, gamma- and delta-tocopherol, alpha-, beta-, gamma-, delta- and desmethyl-tocotrienol

The petitioner submitted 8 scientific dossiers on vitamin E preparations including dossiers on beta-, gamma- and delta-tocopherol, and on alpha-, beta-, gamma-, delta- and desmethyl-tocotrienol.

Forms that lack methyl groups are desmethyl-tocotrienols.

The petitioner does not provide information on the chemical nature of the various tocopherol and tocotrienol preparations to be evaluated. The petitioner stated that Annato bean contains 10% gamma-tocotrienol and 90% delta-tocotrienol and also provided a table of tocopherol and tocotrienol contents of other commercial sources (Table 1).

Table 1. Overview of commercial sources of tocopherols and tocotrienols as provided by the petitioner.

	Rice bran oil	Palm oil	Annato bean
Alpha-tocopherol	42%	22%	0%
Other tocopherols	6%	0%	0%
Alpha-tocotrienol	<2%	22%	0%
Delta-tocotrienol	0%	10%	90%
Gamma-tocotrienol	51%	46%	10%

The petitioner did not provide chemical characteristics or specifications of the tocopherol sources to be evaluated.

The petitioner did not provide information on the manufacturing process.

Use levels for the various tocopherol and tocotrienol preparations were not provided.

No data were provided on the bioavailability of the tocopherols or tocotrienols from the sources.

Referring to a literature study (Nakamura *et al.*, 2001) the petitioner states that tocotrienols are safe and that no side effects have been reported.

No data were provided on the safety of the tocopherols or tocotrienol sources.

2. Assessment

The Panel notes that on the tocopherol and tocotrienol preparations no information has been provided by the petitioner on the following:

- The chemical characterisation, properties and the manufacturing process of the beta-, gamma- and delta-tocopherol, alpha-, beta-, gamma-, delta- and desmethyl-tocotrienol sources.

- The bioavailability of beta-, gamma- and delta-tocopherol, alpha-, beta-, gamma-, delta- and desmethyl-tocotrienol from the sources.
- The toxicity of the beta-, gamma- and delta-tocopherol, alpha-, beta-, gamma-, delta-, and desmethyl-tocotrienol sources.

In a previous opinion the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) evaluated the safety and bioavailability of mixed tocopherols, tocotrienol tocopherol and tocotrienols as a source for vitamin E when added for nutritional purposes in food supplements (EFSA, 2008).

It was concluded that bioavailability studies indicate that mixed tocopherols and tocotrienols are bioavailable although tocotrienols are bioavailable with shorter plasma half-lives and probably different tissue distribution than alpha-tocopherol. The AFC Panel also concluded that the use of mixed tocopherols and tocotrienol tocopherol as a source of vitamin E in food supplements for the general population at the proposed levels of use is not of safety concern, but that the available data were insufficient to conclude on the safety of the proposed use and use levels of the tocotrienol preparation.

Mixed tocopherols evaluated in this previous AFC opinion were obtained by vacuum steam distillation of edible vegetable oil products. The tocotrienol tocopherol preparation evaluated was prepared by distillation of rice bran oil distillate. The source for production of tocotrienols evaluated was palm oil. Rice bran oil and palm oil were listed by the petitioner as possible commercial sources of the tocopherol and tocotrienols. If the tocopherol and tocotrienol preparations of the present dossiers match the specifications of the tocopherol and tocotrienol sources evaluated in the AFC opinion the conclusions of the AFC opinion would apply.

However, the Panel notes that the petitioner has insufficiently characterised the products and therefore has not demonstrated that the tocopherol and tocotrienol preparations are similar to those evaluated previously.

The Panel notes that it was not possible to assess the bioavailability of the tocopherols and tocotrienols from the various uncharacterised sources since no data on the bioavailability of the tocopherols and tocotrienols from these sources were provided.

The Panel notes that it was not possible to assess the safety of the tocopherols and tocotrienols from the various uncharacterised sources since no data on the safety of these sources were provided.

CONCLUSIONS

The Panel concludes that due to the lack of adequate dossiers supporting the use of beta-, gamma- and delta-tocopherol, alpha-, beta-, gamma-, delta-, and desmethyl-tocotrienol in food supplements, the safety and bioavailability of beta-, gamma- and delta-tocopherol, alpha-, beta-, delta-, gamma- and desmethyl-tocotrienol cannot be assessed.

Key words:

Food supplements, beta-, gamma- and delta-tocopherol, alpha-, beta-, delta-, gamma- and desmethyl-tocotrienol.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on beta-tocopherol for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. July 2005. Submitted by David Maddock (UK).
2. Dossier on gamma-tocopherol for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. July 2005. Submitted by David Maddock (UK).
3. Dossier on delta-tocopherol for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. July 2005. Submitted by David Maddock (UK).
4. Dossier on alpha-tocotrienol for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. July 2005. Submitted by David Maddock (UK).
5. Dossier on beta-tocotrienol for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. July 2005. Submitted by David Maddock (UK).
6. Dossier on gamma-tocotrienol for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. July 2005. Submitted by David Maddock (UK).
7. Dossier on delta-tocotrienol for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. July 2005. Submitted by David Maddock (UK).
8. Dossier on desmethyl-tocotrienol for addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. July 2005. Submitted by David Maddock (UK).

REFERENCES

- EFSA, 2008. Opinion on mixed tocopherols, tocotrienol tocopherol and tocotrienols as sources for vitamin E added as a nutritional substance in food supplements - Scientific Opinion of the Panel on Food Additives, Flavourings, Processing aids and Materials in Contact with Food (AFC). The EFSA Journal 640, 1-34.
- Nakamura H, Furukawa F, Nishikawa A, 2001. Oral toxicity of a tocotrienol preparation in rats. Food Chemical Toxicology 39, 799- 805.

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GLOSSARY / ABBREVIATIONS

AFC	Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
ANS	Panel on Food Additives and Nutrient Sources added to Food
EC	European Commission
EFSA	European Food Safety Authority