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**Animal and vegetable fats and oils —  
Determination of sterols and stanols  
in foods and dietary supplements  
containing added phytosterols**

*Corps gras d'origines végétale et animale — Dosage des stérols et des  
stanols dans les aliments et les compléments alimentaires contenant  
des phytostérols ajoutés*

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Published in Switzerland

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## Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 11, *Animal and vegetable fats and oils*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

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## Introduction

Plant sterols and plant stanols, collectively referred to as phytosterols, are increasingly recognized for their role in reducing the risk of coronary heart disease by lowering serum total and low-density lipoprotein cholesterol. Because of these potential health benefits, health claim regulations authorizing the addition of phytosterols and phytosterol esters to foods and dietary supplements now exist in countries throughout Europe, North and South America, Asia, New Zealand and Australia.

This document was developed in response to the worldwide demand for a reference method for quantifying total and individual phytosterols in foods and dietary supplements containing added phytosterols, and in the phytosterol food additive concentrates used to prepare such products. This reference method is based on the single-laboratory validated methods of Clement et al.<sup>[1]</sup> and Srigley and Haile<sup>[2]</sup> for the preparation and gas chromatographic separation of phytosterol trimethylsilyl ether derivatives, respectively.

In 2016 to 2017, an international collaborative study co-organized by the United States Food and Drug Administration (FDA), Cargill (USA) and the American Oil Chemists' Society (AOCS) was carried out to evaluate the performance of this method for the determination of total and individual phytosterols in foods, dietary supplements and phytosterol concentrates.<sup>[3]</sup> A total of 14 laboratories from 6 countries successfully completed the analysis of 18 test materials, upon which the method was approved as AOCS Official Method Ce 12-16<sup>[4]</sup>.

This reference method is appropriate for the determination of the five major phytosterols (i.e. campesterol, campestanol, stigmasterol,  $\beta$ -sitosterol and sitostanol) that are the subject of FDA's health claim regulation for phytosterols and the reduced risk of coronary heart disease<sup>[5]</sup>.

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