

# Evaluation of certain food additives

Eighty-second report of the Joint  
FAO/WHO Expert Committee on  
Food Additives



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization



World Health  
Organization

The World Health Organization was established in 1948 as a specialized agency of the United Nations serving as the directing and coordinating authority for international health matters and public health. One of WHO's constitutional functions is to provide objective and reliable information and advice in the field of human health, a responsibility that it fulfils in part through its extensive programme of publications. The Organization seeks through its publications to support national health strategies and address the most pressing public health concerns of populations around the world. To respond to the needs of Member States at all levels of development, WHO publishes practical manuals, handbooks and training material for specific categories of health workers; internationally applicable guidelines and standards; reviews and analyses of health policies, programmes and research; and state-of-the-art consensus reports that offer technical advice and recommendations for decision-makers. These books are closely tied to the Organization's priority activities, encompassing disease prevention and control, the development of equitable health systems based on primary health care, and health promotion for individuals and communities. Progress towards better health for all also demands the global dissemination and exchange of information that draws on the knowledge and experience of all WHO's Member countries and the collaboration of world leaders in public health and the biomedical sciences. To ensure the widest possible availability of authoritative information and guidance on health matters, WHO secures the broad international distribution of its publications and encourages their translation and adaptation. By helping to promote and protect health and prevent and control disease throughout the world, WHO's books contribute to achieving the Organization's principal objective – the attainment by all people of the highest possible level of health.

The WHO Technical Report Series makes available the findings of various international groups of experts that provide WHO with the latest scientific and technical advice on a broad range of medical and public health subjects. Members of such expert groups serve without remuneration in their personal capacities rather than as representatives of governments or other bodies; their views do not necessarily reflect the decisions or the stated policy of WHO. An annual subscription to this series, comprising about four to six such reports, costs CHF 150.00 / US\$ 180.00 (CHF 105.00/US\$ 126.00 in developing countries). For further information, please contact: WHO Press, World Health Organization, 20 avenue Appia, 1211 Geneva 27, Switzerland (tel. +41 22 791 3264; fax: +41 22 791 4857; email: [bookorders@who.int](mailto:bookorders@who.int); order online: <http://www.who.int/bookorders>).

W H O T e c h n i c a l R e p o r t S e r i e s  
1 0 0 0

# Evaluation of certain food additives

---

Eighty-second report of the Joint  
FAO/WHO Expert Committee on  
Food Additives

*This report contains the collective views of an international groups of experts and  
does not necessarily represent the decisions or the stated policy of the World Health Organization*



**Food and Agriculture  
Organization of the  
United Nations**



**World Health  
Organization**

WHO Library Cataloguing-in-Publication Data

Evaluation of certain food additives: eighty-second report of the Joint FAO/WHO Expert Committee on Food Additives.

(WHO technical report series ; no. 1000)

1.Food Additives - analysis. 2.Food Additives - toxicity. 3.Flavoring Agents. 4.Risk Assessment. I.World Health Organization. II.Food and Agriculture Organization of the United Nations. III.Joint FAO/WHO Expert Committee on Food Additives. Meeting (82nd: 2016, Geneva, Switzerland). IV.Series.

ISBN 978 92 4 121000 3

(NLM classification: WA 712)

ISBN 978 92 4 069586 3 (PDF)

ISSN 0512-3054

**© World Health Organization 2016**

All rights reserved. Publications of the World Health Organization are available on the WHO website ([www.who.int](http://www.who.int)) or can be purchased from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; email: [bookorders@who.int](mailto:bookorders@who.int)).

Requests for permission to reproduce or translate WHO publications – whether for sale or for non-commercial distribution – should be addressed to WHO Press through the WHO website ([www.who.int/about/licensing/copyright\\_form/en/index.html](http://www.who.int/about/licensing/copyright_form/en/index.html)).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

This publication contains the collective views of an international group of experts and does not necessarily represent the decisions or the policies of the World Health Organization.

Design: Rania Spatha ([www.raniaspatha.com](http://www.raniaspatha.com))

**Printed in Malta**

# Contents

<b>List of participants</b>	v
<b>List of abbreviations</b>	viii
<b>1. Introduction</b>	1
1.1 Declarations of interests	2
1.2 Modification of the agenda	2
<b>2. General considerations</b>	5
2.1 Report from the Forty-eighth Session of the Codex Committee on Food Additives (CCFA)	5
2.2 Principles governing the toxicological evaluation of compounds on the agenda	6
2.2.1 Revisions of the Procedure for the Safety Evaluation of Flavouring Agents	6
2.2.2 Approach for prioritizing flavouring agents for re-evaluation	9
2.3 Food additive specifications and analytical methods	9
2.3.1 Replacement of packed column gas chromatographic methods in the specifications monographs	9
2.3.2 Revision of the FAO JECFA Monographs 1, Combined Compendium of Food Additive Specifications, Vol. 4	9
2.3.3 Limits for lead in specifications of food additives for use in infant formula	10
2.3.4 Use of chloroform as solvent in the test methods associated with specifications monographs for synthetic colours	11
2.4 Flavour specifications	12
2.4.1 General inclusion of infrared spectra	12
2.4.2 Inclusion of chemical structures in the JECFA flavourings database	12
<b>3. Specific food additives (other than flavouring agents)</b>	13
3.1 Safety evaluations	13
3.1.1 Allura Red AC	13
3.1.2 Carob bean gum <sup>1</sup>	21
3.1.3 Lutein esters from <i>Tagetes erecta</i>	28
3.1.4 Octenyl succinic acid (OSA)-modified gum arabic	30
3.1.5 Pectin <sup>1</sup>	34
3.1.6 Quinoline Yellow	39
3.1.7 Rosemary extract	45
3.1.8 Steviol glycosides	54
3.1.9 Tartrazine	63
3.1.10 Xanthan gum <sup>1</sup>	72
3.2 Revision of specifications and analytical methods	81
3.2.1 Aspartame	81
3.2.2 Cassia gum	81
3.2.3 Citric and fatty acid esters of glycerol (CITREM)	82
3.2.4 Modified starches	83
3.2.5 Octanoic acid	84

<sup>1</sup> For use in infant formula and formula for special medical purposes intended for infants.

3.2.6 Starch sodium octenyl succinate	84
3.2.7 Total colouring matters	84
<b>4. Flavouring agents</b>	<b>87</b>
4.1 Flavouring agents evaluated by the Procedure for the Safety Evaluation of Flavouring Agents	87
4.1.1 Alicyclic, alicyclic-fused and aromatic-fused ring lactones	90
4.1.2 Aliphatic and aromatic amines and amides	94
4.1.3 Aliphatic secondary alcohols, ketones and related esters	105
4.1.4 Cinnamyl alcohol and related substances	111
4.1.5 Tetrahydrofuran and furanone derivatives	119
4.2 Specifications of identity and purity of flavouring agents	126
4.2.1 New specifications	126
4.2.2 Revised specifications	126
<b>5. Future work and recommendations</b>	<b>129</b>
<b>Acknowledgements</b>	<b>135</b>
<b>References</b>	<b>137</b>
<b>Annex 1</b>	
Reports and other documents resulting from previous meetings of the Joint FAO/WHO Expert Committee on Food Additives	139
<b>Annex 2</b>	
Toxicological information and information on specifications	151
<b>Annex 3</b>	
Summary of the safety evaluation of the secondary components of flavouring agents with minimum assay values of less than 95%	159
<b>Annex 4</b>	
Meeting agenda	161

# List of participants

## Eighty-second meeting of the Joint FAO/WHO Expert Committee on Food Additives Geneva, 7–16 June 2016

### Members

- Ms J. Baines, Food Standards Australia New Zealand, Canberra, Australian Capital Territory (ACT), Australia
- Dr S. Barlow, Brighton, East Sussex, England, United Kingdom
- Dr D. Benford, Risk Assessment Unit, Food Standards Agency, London, England, United Kingdom
- Dr M. DiNovi, Division of Biotechnology and GRAS Notice Review, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, College Park, Maryland, United States of America (USA)
- Dr D. Folmer, Division of Petition Review, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, College Park, Maryland, USA
- Dr Y. Kawamura, Division of Food Additives, National Institute of Health Sciences, Tokyo, Japan
- Dr A. Mattia, Division of Biotechnology and GRAS Notice Review, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, College Park, Maryland, USA (*Chairperson*)
- Ms I. Meyland, Birkerød, Denmark (*Vice-Chairperson*)
- Dr U. Mueller, Food Standards Australia New Zealand, Barton, ACT, Australia (*Joint Rapporteur*)
- Dr G. Pascal, Le Breuil, Saint Alyre d'Arlanc, France
- Dr J. Schlatter, Zurich, Switzerland
- Dr M. Veerabhadra Rao, Department of the President's Affairs, Al Ain, United Arab Emirates
- Ms H.C. Wallin, Helsinki, Finland (*Joint Rapporteur*)
- Professor G.M. Williams, Department of Pathology, New York Medical College, Valhalla, New York, USA

## Secretariat

Dr J.N. Barrows, United States Food and Drug Administration, College Park, Maryland, USA  
(*FAO Expert*)

Dr R. Cantrill, AOCS, Urbana, IL, USA (*FAO Expert*)

Dr E. Dessipri, General Chemical State Laboratory, Athens, Greece (*FAO Expert*)

Mr M. Feeley, Bureau of Chemical Safety, Food Directorate, Health Canada, Ottawa, Ontario, Canada (*WHO Expert*)

Dr B. Fields, Food Standards Australia New Zealand, Barton, ACT, Australia (*WHO Expert*)

Ms Z. Gillespie, Bureau of Chemical Safety, Food Directorate, Health Canada, Ottawa, Ontario, Canada (*WHO Expert*)

Mrs F. Hill, Food Standards Agency, London, England, United Kingdom (*WHO Expert*)

Dr X. Jia, Laboratory of Toxicology, National Center for Food Safety Risk Assessment, Beijing, China (*WHO Expert*)

Dr J.C. Leblanc, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Secretariat*)

Dr M. Lipp, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Joint Secretary*)

Dr J. Moore, United States Pharmacopeia, Rockville, Maryland, USA (*FAO Expert*)

Dr K. Muldoon Jacobs, Division of Food Contact Notifications, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, College Park, Maryland, USA (*WHO Expert*)

Professor F. Paumgartten, National School of Public Health, Oswaldo Cruz Foundation, Rio de Janeiro, Brazil (*WHO Expert*)

Ms M. Pronk, National Institute for Public Health and the Environment (RIVM), Bilthoven, the Netherlands (*WHO Expert*)

Ms M. Sheffer, Orleans, Ontario, Canada (*WHO Technical Editor and Co-rapporteur*)

预览已结束，完整报告链接和二维码如下：

[https://www.yunbaogao.cn/report/index/report?reportId=5\\_26798](https://www.yunbaogao.cn/report/index/report?reportId=5_26798)

