

WHO STUDY GROUP ON TOBACCO PRODUCT REGULATION

Report on the Scientific Basis
of Tobacco Product Regulation:
Third Report of a WHO Study Group



**World Health
Organization**

WHO STUDY GROUP ON TOBACCO PRODUCT REGULATION

report on the scientific basis of
tobacco product regulation: third report
of a WHO study group



World Health
Organization

WHO Library Cataloguing-in-Publication Data

WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: third report of a WHO study group.

(WHO technical report series ; no. 955)

1.Tobacco use disorder - prevention and control. 2.Tobacco industry - legislation. 3.Tobacco control campaigns. 4. Tobacco-derived products labelling. 5.Tobacco-derived products packing. I.World Health Organization. II.Series.

ISBN 978 92 4 120955 7

(NLM classification: QV 137)

ISSN 0512-3054

© World Health Organization 2009

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

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 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.

Typeset in India
Printed in Switzerland

Contents

1. Introduction	1
1.1 Background	2
2. TobReg Scientific Recommendation: Devices designed for the purpose of nicotine delivery to the respiratory system in which tobacco is not necessary for their operation	3
2.1 Preface	3
2.2 Definition of ENDS	4
2.3 Types and distribution	5
2.4 Substances in addition to nicotine	5
2.5 Concern about lung delivery	6
2.6 Nicotine addiction as the basis for ENDS marketing	6
2.7 ENDS are not nicotine replacement therapy	7
2.8 Capacity of ENDS to serve as nicotine replacement therapy	8
2.9 Regulatory status	8
2.10 Other concerns	9
2.11 Conclusions	10
2.12 Recommendations for regulatory policy	10
2.13 Recommendations for clinical trials and other research required for regulatory approval	11
2.14 References	11
Annex 1. International regulatory measures for electronic nicotine delivery systems (ENDS)	13
3. Report on setting regulatory limits for carcinogens in smokeless tobacco	23
3.1 Background	23
3.2 Carcinogens present in smokeless tobacco	24
3.3 Tobacco-specific nitrosamines and polycyclic aromatic hydrocarbons	25
Table 1. Concentrations of tobacco-specific <i>N</i> -nitrosamines in selected smokeless tobacco products ($\mu\text{g/g}$ dry weight of tobacco)	27
Table 2. Concentrations of tobacco-specific nitrosamines (TSNA) and benzo[<i>a</i>]pyrene in smokeless tobacco products purchased in the United Kingdom and elsewhere	28
Table 3. Concentrations of tobacco-specific nitrosamines (TSNA) and benzo[<i>a</i>]pyrene in smokeless tobacco products sold in the United States	29
3.4 Differences in carcinogens present in smokeless tobacco by region	26
3.5 Targets for regulation	30
3.6 Selection of metric for regulation	30
3.7 Selection of achievable levels for tobacco-specific <i>N</i> -nitrosamines and benzo[<i>a</i>]pyrene in smokeless tobacco	32
3.8 Regulatory considerations and communication of regulatory values and testing results to the public	34

3.9	Recommendations	36
3.10	Acknowledgement	36
3.11	References	37
4.	Overall recommendations	39
4.1	Electronic nicotine delivery systems (ENDS): regulatory recommendations and research needs	39
4.2	Smokeless tobacco: setting regulatory limits for carcinogenic components	40

WHO Study Group on Tobacco Product Regulation

Durban, South Africa, 12–14 November 2008

Members

- Dr D.L. Ashley, Chief, Emergency Response and Air Toxicants Branch, Centers for Disease Control and Prevention, Atlanta, Georgia, United States of America
- Dr O.A. Ayo-Yusuf, Associate Professor, School of Dentistry, University of Pretoria, South Africa
- Dr D. M. Burns, Professor Emeritus of Family and Preventive Medicine, School of Medicine, University of California at San Diego, San Diego, California, United States of America
- Dr Vera Luiza da Costa e Silva, Independent Consultant, Senior Public Health Specialist, Rio de Janeiro, Brazil
- Dr M. Djordjevic, Program Director, National Cancer Institute, Division of Cancer Control and Population Sciences, Tobacco Control Research Branch, Bethesda, Maryland, United States of America
- Dr N. Gray, Honorary Senior Associate, Cancer Council Victoria, Melbourne, Australia
- Dr S.K. Hammond, Professor of Environmental Health Sciences, School of Public Health, University of California at Berkeley, Berkeley, California, United States of America
- Dr J. Henningfield, Professor (Adjunct), Behavioral Biology, Johns Hopkins University School of Medicine; Vice President, Research and Health Policy, Pinney Associates, Bethesda, Maryland, United States of America
- Dr M. Jarvis, Principal Scientist, Cancer Research UK, Health Behaviour Unit, Royal Free and University College London Medical School, London, England

Dr A. Opperhuizen, Head of the Laboratory for Health Protection Research, National Institute for Public Health and the Environment, Bilthoven, The Netherlands

Dr K.S. Reddy, Professor of Cardiology, All India Institute of Medical Sciences, New Delhi, India

Dr C. Robertson, Ruth G. and William K. Bowes Professor in the School of Engineering, Department of Chemical Engineering, Stanford University, Stanford, California, United States of America

Dr G. Zaatari (*Chair*), Professor, Department of Pathology and Laboratory Medicine, American University of Beirut, Beirut, Lebanon

Secretariat

Dr D.W. Bettcher, Director, Tobacco Free Initiative, WHO, Geneva, Switzerland

Mr R. Minhas, Technical Officer, Tobacco Free Initiative, WHO, Geneva, Switzerland

Ms E. Tecson, Administrative Assistant, Tobacco Free Initiative, WHO, Geneva, Switzerland

Ms G. Vestal, Technical Officer, Tobacco Free Initiative, WHO, Geneva, Switzerland

1. Introduction

The fifth meeting of the WHO Study Group on Tobacco Product Regulation (TobReg) was held in Durban, South Africa on 12–14 November 2008. TobReg is mandated to provide the WHO Director-General with scientifically sound, evidence-based recommendations to Member States about tobacco product regulation. In line with the provisions of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control, TobReg identifies approaches for regulating tobacco products that pose significant public health issues and raise questions for tobacco control policy.

At its fifth meeting, the Study Group addressed regulation of electronic cigarettes, smokeless tobacco toxicants, ‘roll-your-own’ products, products marketed as cessation aids, particles in smoke and menthol. The meeting followed a WHO press release on 19 September 2008, which asserted that WHO does not consider electronic cigarettes to be a legitimate tobacco cessation therapy. The press release stressed that, as no rigorous, peer-reviewed studies have been conducted to show that electronic cigarettes are a safe, effective nicotine replacement therapy (NRT), there is no evidence to support marketing of these products for tobacco cessation.

This report presents the conclusions and recommendations of the Study Group at its fifth meeting on two products, both of which represent potential harm to public health and the promotion, sale and use of which are inad-

云报告
<https://www.yunbaogao.cn>
预览已结束，完整报告链接

<https://www.yunbaogao.cn/report/index/re>