



Influence of measurement uncertainty on the world health organization recommended regulation for mainstream cigarette smoke constituents



Huimin Deng, Zhonghao Li^{*}, Zhaoyang Bian, Fei Yang, Shanshan Liu, Ziyang Fan, Ying Wang, Gangling Tang

China National Tobacco Quality Supervision and Test Center, No.2 Fengyang Street, Zhengzhou High and New Technology Industries Development Zone, Zhengzhou 450001, China

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ABSTRACT

The World Health Organization Study Group on Tobacco Product Regulation (WHO TobReg) proposed mandated ceilings on 9 prioritized mainstream cigarette smoke constituents determined from the market-specific median of nicotine-normalized yield distributions. Considering the requirements for assessing and reporting of compliance with ceilings, it is of great importance to estimate the measurement uncertainty. To have a better understanding of influence of measurement uncertainty on the WHO recommended regulation for cigarette smoke constituents, in the present study, the measurement uncertainties were evaluated systematically based on series of collaborative studies reported by three different authorities over the years from 2012 to 2016, according to the approaches guided in ISO/TS 21748. Furthermore, the compliance assessment of 20 representative cigarette samples with proposed ceilings was conducted by taking measurement uncertainty into account. This work demonstrated that measurement uncertainty had great influence on the implementation of the regulated mandated lowering of toxic smoke constituents, both on the setting of ceilings and the compliance assessment as well.

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1. Introduction

Tobacco has long been subject to regulatory controls over the quantity and quality production due to its recognized health hazards. Cigarette smoke toxicants have become a global regulatory issue, maximum permissible limits on tar, nicotine and carbon monoxide (TNCO) were set in many countries since 1990s. Mandated measurement and reporting of toxicant emissions of cigarette smoke has become a regulatory requirement in Canada, Brazil and the U.S., and is now spreading to other countries (Health Canada, 2000; Brazil National Health Surveillance Agency ANVISA, 2007; FDA, 2010). Several cigarette smoke constituent lists have been proposed, such as the Hoffman list, Health Canada list and the U.S. Food and Drug Administration proposed HPHCs list (Hoffmann and Hoffmann, 1998; Health Canada, 2012; FDA, 2012). Both in the 2008 and 2014 report (WHO, 2008; WHO, 2014a), the World Health

Organization (WHO) Study Group on Tobacco Product Regulation (TobReg) recommended a strategy for regulation based on product performance measures. The proposed regulation aims to reduce toxicant levels in mainstream smoke and prevent the introduction onto a market of cigarette with higher levels of smoke toxicants than those already on the market. It recommends establishing maximum limits for selected priority list mainstream smoke toxicants per milligram of nicotine obtained under a modified machine-testing regimen with more intense puffing parameters (WHO, 2012), and TobReg recommended use of that regimen (Intense regimen) by regulators in implementing the proposed regulatory strategy. The mandated lowering for NNK and NNN was set at below the median of the data set analyzed. An initial level of 125% of the median value was recommended for the other toxicants. The priority toxicants recommended for mandatory lowering and the proposed ceilings based on existing data reported by Counts et al. (2005), and Health Canada (Health Canada, 2004) are listed in Table 1.

To achieve the goal of the regulation of tobacco product

^{*} Corresponding author.

E-mail address: lee_zhonghao@sina.com (Z. Li).

Abbreviations			
APLAC	Asia Pacific Laboratory Accreditation Cooperation	ILAC	International Laboratory Accreditation Cooperation
CEC	Commission of the European Communities	ISO	International Standardized Organization
CNAS	China National Accreditation Service for Conformity Assessment	NNK	4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone
CNTC	China National Tobacco Cooperation	NNN	N'-nitrososornicotine
CORESTA	Cooperation Center for Scientific Research Relative to Tobacco	R	Reproducibility
CRMs	CORESTA Recommended Methods	R	Repeatability
CTQTC	China National Tobacco Quality Supervision and Test Center	RSD _R	Relative Standard Deviation for Reproducibility
CV	Coefficient Variation	SAC	Standardization Administration of the People's Republic of China
EU	European Union	SASG	Special Analytes Sub Group
FCTC	Framework Convention on Tobacco Control	SD	Standard Deviation
FCV	Flue Cured Virginia	SOP	Standard Operating Procedure
GUM	Guide to the Expression of Uncertainty in Measurements	TNCO	Tar, Nicotine and Carbon Monoxide
		TSNAs	Tobacco-specific nitrosamines
		WHO TobReg	World Health Organization Study Group on Tobacco Product Regulation

constituents, the first recommendation was formulated by TobReg in 2004 (WHO, 2004). The purpose of this recommendation is to promulgate the principles that should guide the development of the laboratory capacity required to enable implementation of Articles 9 (*Regulation of the contents of tobacco products*) and 10 (*Regulation of tobacco product disclosures*) of the WHO Framework Convention on Tobacco Control (FCTC) and the initiation of tobacco product testing. In the test guidance section of this document, it was required that the laboratories selected for the analysis of tobacco products or smoke constituents must be accredited by the ISO 17025. In order to satisfy the requirements of ISO/IEC 17025, laboratories accredited under ISO/IEC 17025 must estimate the measurement uncertainty of the results they submit (ISO, 2005).

Measurement uncertainty is a parameter characterizing the dispersion of the quantity values being attributed to a measurand based on the information used (ISO, 2008; Mari, 2006). It is considered very important in two issues, the first concerns the problem of whether a result constitutes evidence of noncompliance with some limit, particularly when the limit is within the uncertainty quoted; the second issue is the use of uncertainty information in the setting of limits (Ellison et al., 1997). Detection of compliance samples is linked to measurement uncertainty consideration as presented in Fig. 1. A well-accepted fixed measurement uncertainty applied in laboratories will facilitate trade worldwide (Medina-Pastor et al., 2011). Therefore, in the implementation of mandated lowering of toxic smoke constituents based on the upper ceilings, it is of great importance to evaluate the

influence of measurement uncertainty both on the setting of ceilings and on the compliance assessment of tobacco products based on ceilings.

The GUM guideline (JCGM, 2008) describes extensively the “bottom-up” approach or strict mathematical calculation based on the estimation of all separately measured uncertainty components which are subsequently combined by applying the propagation law to obtain the overall measurement uncertainty. However, separate evaluations of all the measurement uncertainty components in different complex testing methods are extraordinarily tedious. As one of the “top-down” approaches, ISO/TS 21748:2004 gives guidance to the evaluation of measurement uncertainties using data obtained from studies conducted in accordance with ISO 5725-2 (ISO, 1994b), and to the comparison of collaborative study results with measurement uncertainty obtained using formal principles of uncertainty propagation (ISO, 2010). This approach is clearly more easily accepted by laboratories considering the recent trend that different classes of cigarette smoke analytes are required to be analyzed and reported by using series of analysis Standard Operating Procedures (SOPs) (WHO, 2014b; WHO, 2015; WHO, 2014c), in which the repeatability and reproducibility information that could be used for measurement uncertainty estimation are available.

Regarding the implementation of the regulatory control recommended by WHO TobReg, lots of work had been published to address this issue from different perspective of views, including the standardized analysis methods (Purkis et al., 2010a; Wright, 2015),

Table 1
Toxicants recommended for mandated lowering.

Toxicant	Level in µg/mg nicotine		Value
	International brands	Canadian brands	
NNK	0.072	0.047	Median value of data set
NNN	0.114	0.027	Median value of data set
Acetaldehyde	860	670	125% of median value of data set
Acrolein	83	97	125% of median value of data set
Benzene	48	50	125% of median value of data set
Benzo[<i>a</i>]pyrene	0.011	0.011	125% of median value of data set
1,3-Butadiene	67	53	125% of median value of data set
Carbon monoxide	18400	15400	125% of median value of data set
Formaldehyde	47	97	125% of median value of data set

NNK, 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone; NNN, N'-nitrososornicotine.

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