

THE PERCEIVED RISK CONTINUUM FOR TOBACCO- AND NICOTINE-CONTAINING PRODUCTS

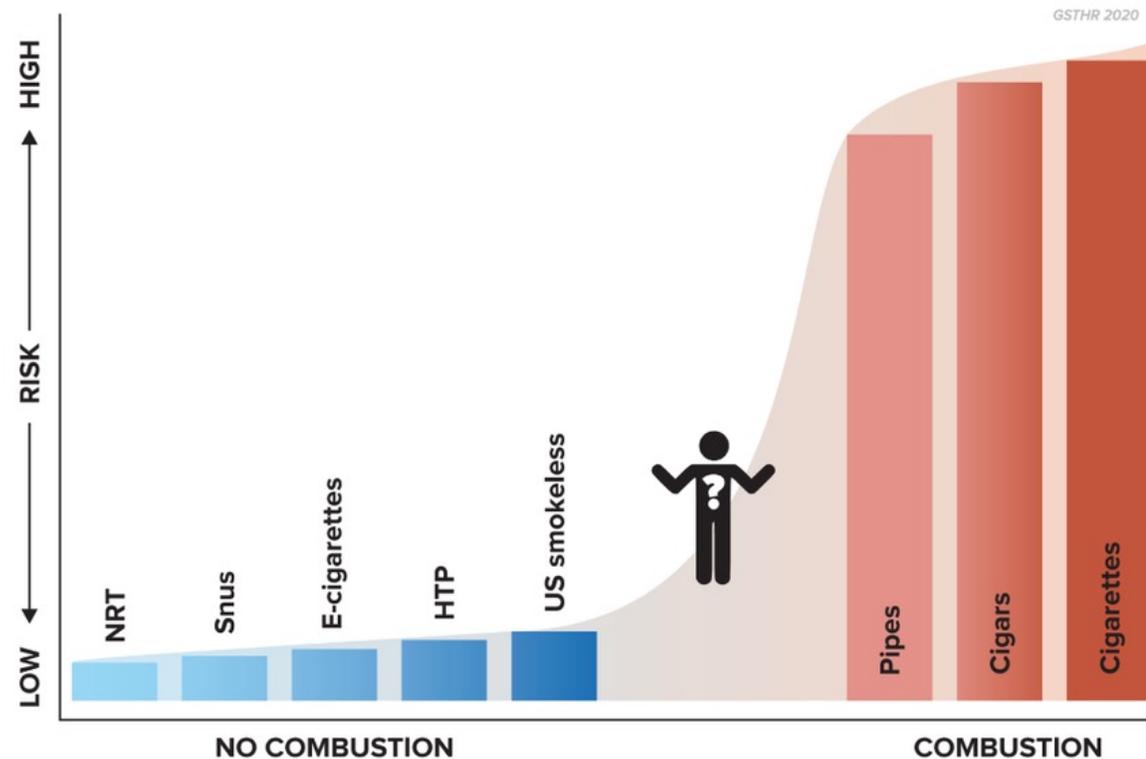
DOES MEASUREMENT MATTER?

Christelle Chrea, PhD

Philip Morris Products SA

Risk Continuum for Tobacco and Nicotine-Containing Products

- Risk continuum is **based on the premise that nicotine and tobacco products fall along a spectrum from most to least risk**, which denotes the impact of tobacco use on human health at the individual and population levels.



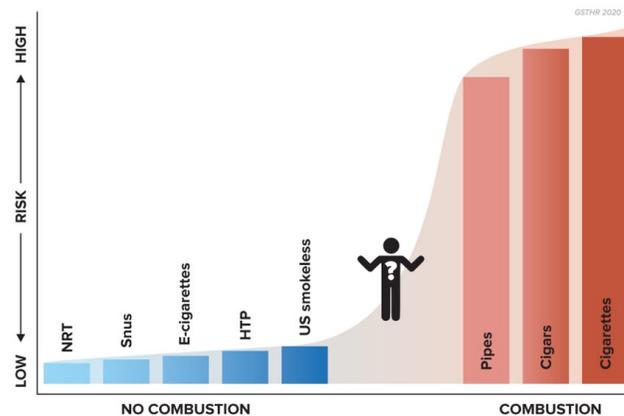
Source: *Burning Issues: The Global State of Tobacco Harm Reduction 2020*



Risk Perception is a Key Construct in Tobacco Regulatory Research

Risk perceptions are defined as the **subjective judgments** about the **potential harms to health from using tobacco and nicotine-containing products**.

- Pre-market: To help demonstrate that the **product's labeling or advertising enables the public to understand the modified risk information** and the relative significance of the information in the **context of total health**.
- Post-market: To provide data regarding how consumers **perceive the risks to health from using the marketed product** and how this perception **predicts use behavior**



Regulatory Requirements for Risk Perception Data

- Perceptions about the **absolute health risks of specific tobacco-related diseases**, including **addiction** and other principal **diseases causally associated** with use of the product (e.g., heart disease)
- Perceptions about the **health risks of using the product relative to:**
 - Using **other products** in the same product category or using products in a different product category
 - Using cessation aids such as FDA-approved **nicotine replacement therapy products**
 - **Quitting all tobacco use**
- Perceptions of the **health risks of using the product** that is the subject of the application **concurrently with the comparison product (i.e., dual use), relative both to exclusive use of the proposed product and to exclusive use of the comparison product.**

-> **Valid and reliable CROM** that quantifies **relevant domains of perceived risk**, to allow **comparable measurement** across a range of **tobacco- and nicotine-containing products** (including past use), and a range of **product use behaviors**



Tobacco Products: Principles for Designing and Conducting Tobacco Product Perception and Intention Studies

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <https://www.regulations.gov>. Alternatively, submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with the docket number FDA-2019-D-4188.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at <http://www.fda.gov/TobaccoProductsLabelingRulesRegulationsGuidance/default.htm>. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

August 2022

Best Practices Based on Advances in Risk Perception Research

- ✓ Focusing on a **variety of specific risks and outcomes**
- ✓ Prioritize asking questions in **first-person**
- ✓ Identifying a **risk timeframe**
- ✓ Use **Likert-type response scales**

→ Goal of these best practices is to standardize **the risk that people are evaluating**



Problems with the Current Measures of Perceived Risks

- Mainly product-specific (e.g., for cigarettes, e-cigarettes, smokeless tobacco)¹⁻⁴
- Rely on a single statement of comparative perceived harm between a pair of products³⁻⁵
- Often comprise a very small number of items⁶
- Not developed to account for various use behaviors (e.g., dual use)¹⁻⁶

To get the risk measurement RIGHT matters to establish the continuum of perceived risk

¹ Rindfleisch A, Crockett DX. Cigarette smoking and perceived risk : a multidimensional investigation. *J Public Policy Mark.* 1999;18:159–71.

² Budd GM, Preston DB. College student's attitudes and beliefs about the consequences of smoking: development and normative scores of a new scale. *J Am Acad Nurse Pract.* 2001;13:421–7.

³ O'Brien EK, Baig SA, Persoskie A. Developing and Validating Measures of Absolute and Relative E-Cigarette Product Risk Perceptions: Single Items Can Be Surprisingly Comprehensive. *Nicotine Tob Res.* 2022 Feb 14;24(3):316–23.

⁴ O'Brien EK, Baig SA, Persoskie A. Absolute and Relative Smokeless Tobacco Product Risk Perceptions: Developing and Validating New Measures that are Up-to-Snuff. *Nicotine Tob Res.* 2022 Feb 1;24(2):265-269.

⁵ Smith SY, Curbow B, Stillman FA. Harm perception of nicotine products in college freshmen. *Nicotine Tob Res.* 2007;9:977v82.

⁶ O'Brien EK, Persoskie A, Tam J. Multi-item measures of tobacco health perceptions: a review. *Am J Health Behav.* 2019;43(2):266–78.

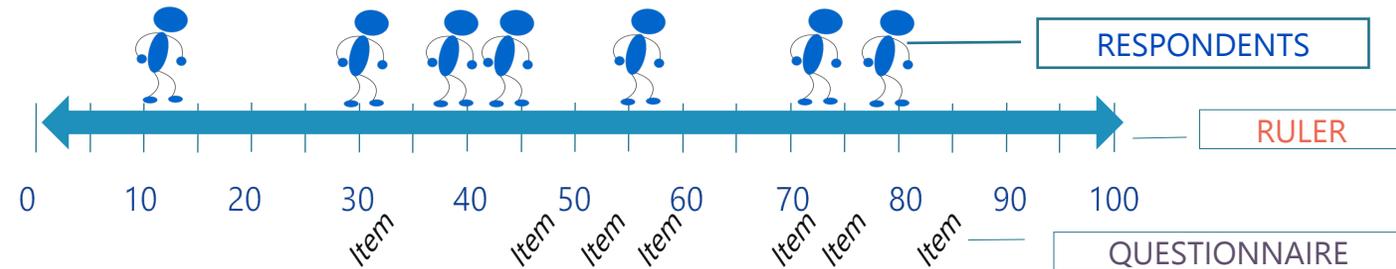


Benefits of Modern Psychometrics: Rasch Model Theory

- Philosophy that attempts to put **social measurement under a degree of scrutiny** that can help us achieve **metrological advances**
- Unique inherent **properties of the Rasch model**
 - ✓ **Parameter separability**
 - ✓ **Statistical sufficiency**
 - ✓ **Invariant comparison**

Concept-Driven...

Conceptual clarity with hierarchy of unique concepts
Covering the range of consumers' experience in context of use



...Measurement

Simple stochastic measurement model providing improved interpretability of data



Emergence of this Approach in Tobacco Regulatory Research

RESEARCH

Open Access

Development and validation of a new instrument to measure perceived risks associated with the use of tobacco and nicotine-containing products



Stefan Cano¹, Christelle Chrea², Thomas Salzberger^{3*}, Thomas Alfieri⁴, Gerard Emilien², Nelly Mainy², Antonio Ramazzotti⁵, Frank ...

METHOD ARTICLE

Developing fit-for-purpose self-report instruments for assessing consumer responses to tobacco and nicotine products: the ABOUT™ Toolbox initiative [version 1; referees: 2 approved]

Christelle Chrea¹, Catherine Acquadro², Esther F. Afolalu¹, Erica Spies¹, Thomas Salzberger³, Linda Abetz-Webb⁴, Stefan Cano⁵, Benoit Arnould², Nelly Mainy¹, Jed Rose⁶, Rolf Weitkunat¹

McCaffrey et al. *Health Qual Life Outcomes* (2021) 19:123
<https://doi.org/10.1186/s12955-021-01764-2>

Health and Quality
of Life Outcomes

RESEARCH

Open Access

Development and validation of behavioral intention measures of an E-vapor product: intention to try, use, dual use, and switch



Stacey A. McCaffrey¹, Jessica Parker Zdinak², Stephanie Plunkett², Elizabeth Becker^{2*}, Jennifer N. Lewis² and Ryan A. Black¹

Measurement 181 (2021) 109593

Contents lists available at [ScienceDirect](#)

Measurement

journal homepage: www.elsevier.com/locate/measurement



Addressing traceability of self-reported dependence measurement through the use of crosswalks



Thomas Salzberger^{a,*}, Stefan Cano^b, Linda Abetz-Webb^c, Esther Afolalu^d, Christelle Chrea^d, Rolf Weitkunat^e, Jed Rose^{f,g}



Roadmap to Measuring Perceived Risk

- To address regulatory requirements, a CROM assessing perceived risk should be:
 1. Appropriate to capture the individual perspective and include relevant and meaningful domains
 2. Applicable across a wide range of tobacco- and nicotine-containing products
 3. Suitable for a range of respondent groups such as users and non-users
 4. Underpinned by an appropriate psychometric measurement model
 5. Straightforward to administer and score
 6. Applicable for clinical and population-based studies

- Following best practice qualitative and quantitative scale development research methods to ensure the final item set is:
 - ✓ The most fit for purpose
 - ✓ Easily understood and completed
 - ✓ Reliable and valid



T h a n k y o u f o r y o u r
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