SRNT Policy and Regulatory Science Network Product Standard Summary Documents

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TOBACCO SCIENCE AND REGULATION

David L. Ashley has received funds for serving as an investigator and consultant on Food and Drug Administration and National Institutes of Health-funded research grants at Georgia State University. He has also received funds as a consultant for Westat, McKing Consulting, Inc. (Atlanta, GA, USA), Cherokee National Operational Systems, and Wake Forest University. He received honoraria for presentations at Roswell Park Cancer Institute, Georgetown University, the University of Southern California, the Ohio State University, Wake Forest University, and the University of Minnesota. He received funds for attending meetings, writing papers, and serving as part of the World Health Organization Tobacco-Free Initiative Study Group for Tobacco Regulation and for serving on Study Sections of the National Institutes of Health. He has received funds for serving on the expert advisory board of research projects at Yale University; the Medical University of South Carolina; the University of California, San Francisco; and Virginia Commonwealth University.

Please add “yes” or “no” to each table cell. If “yes”, please turn cell background color to yellow.	Tobacco Industry	E-cigarette & nicotine product industry (excluding pharma)	Pharma Industry
The work being presented has received funding or other means of support from any of the following sources:	No	No	No
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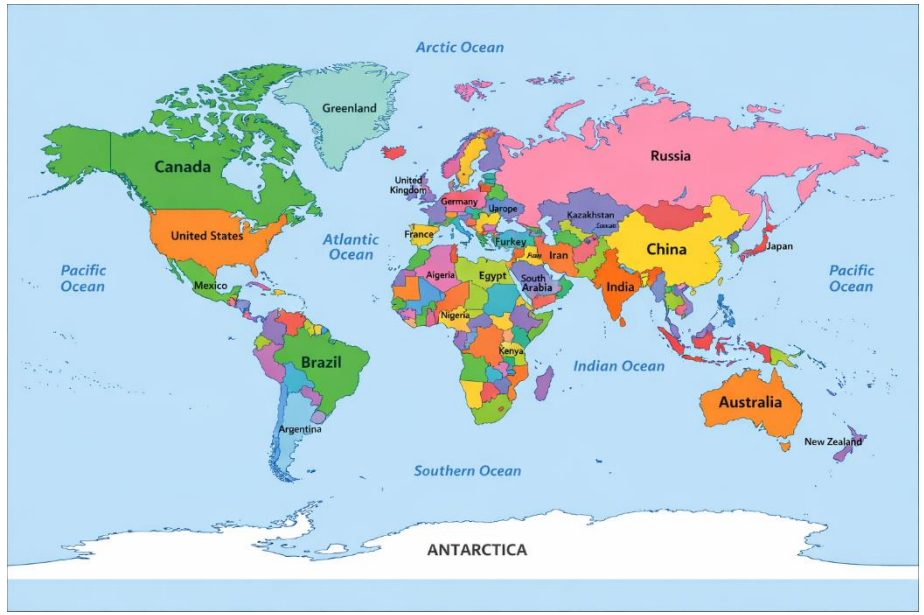
What are Product Standards?

- Product standards are requirements which must be met before products can be legally marketed.
- May include design, ingredients, additives and any other characteristics of the consumed product, packaging and labeling.
- Authority is given through the Framework Convention on Tobacco Control Article 9 and various countries' laws
- Powerful tools that can be used by regulatory agencies to reduce the adverse outcomes from tobacco/nicotine product use by, for example, prohibiting or capping the allowable levels of particular compounds.

Why were Summary Documents developed?

- Intended to aid in reducing the appeal, addictiveness, or toxicity of products
- To inform national (particularly low-and-middle-income countries) and subnational legislation or regulations on the state of the science
- Can also benefit members of SRNT as they formulate project proposals by identifying important scientific research gaps.



SOCIETY FOR RESEARCH ON NICOTINE & TOBACCO

How were Summary Documents developed?

- Members of the Policy and Regulatory Science Network identified three priority product standards based on their possible public health impact and estimates of the extent of scientific evidence available
- PRSN members were identified with expertise in these scientific issues
- Teams worked together to review the science and write draft documents
- PRSN leadership reviewed and provided feedback
- SRNT Board reviewed and provided feedback
- Documents will be published on the SRNT website.

Cigarette Nicotine Content Product Standard Summary Document Team

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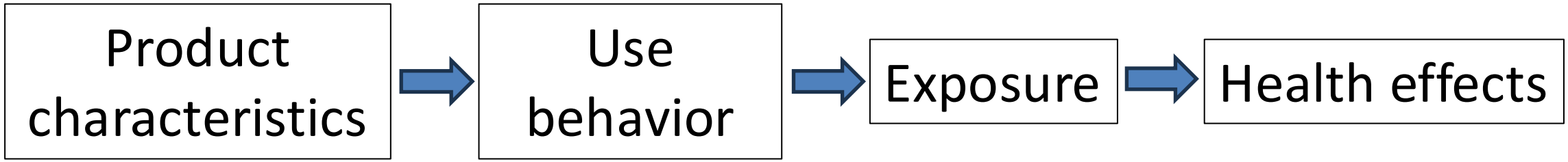
What's included in these documents?

- **Background Summary**
  - Broad description of the proposed standard
  - Purpose of the standard
  - Expected health outcome
  - Description of the relevant facts



What's included in these documents?

- **Scientific Evidence supporting a standard and gaps in the available research**
- Primary evidence
  - Evidence that the current product characteristic is causing the adverse impact on public health
  - Evidence that the specific quantitative standard would end or reduce the adverse the adverse impact
  - Estimate of the public health benefit that would be achieved by meeting the standard
  - Evidence of the impact on the product standard on vulnerable populations and health equality

What is included in these documents?

- Secondary evidence
  - Evidence of likely changes to population dynamics (e.g., initiation, cessation, product switching)
  - Evidence that meeting the proposed standard is achievable
  - Evidence that there are adequate analytical methods to differentiate products that meet the requirement from products that do not
  - Possible unintended/secondary consequences of the requirement
  - Scientific evaluation of other changes that might result from the standard that might limit the public health benefit
  - Scientific evaluation of alternative ways which were considered that may achieve the same public health benefit

What's included in these documents?

- **Regulatory considerations**
  - Steps required to address marketed products (e.g., storage time, manufacturer claims)
  - Methods for ensuring compliance (e.g., industry reports, sampling plans and procedures)
  - Methods for evaluating the resulting outcome of the standard on public health
  - Limits on industry steps that could reduce the positive outcome of the standard

What's included in these documents?

- **Additional information, where appropriate**
  - Addressing common questions and concerns about a standard
  - Other consequences of a mandate
  - Loopholes to address
  - Steps to take to maximize the public health benefits
  - Implementation issues
  - Further research which would support a standard and address evidence gaps

How are these different from reviews carried out by government regulatory agencies?

- In addition to addressing the science that supports product standards
  - Possible loopholes which should be addressed
  - Likely industry strategy intended to minimize or counter the public health benefits of enacting a product standard
  - Any limitations in the science that may be strengthened through research by SRNT scientists.

How will these documents be disseminated?

- Located on the SRNT website and available to the public
- Additional peer-reviewed publication summaries
- Other subcommittees of PRSN
- Other networks of SRNT
- SRNT email list
- Other organizations – CASEL, CTFK, WHO
- Direct interactions with country regulatory organizations

- The first of these documents is available at https://srnt.org/education/ …