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A large, stylized brushstroke graphic on the left side of the slide. It consists of a thick yellow stroke at the top that curves downwards and to the left, and a thick dark blue stroke below it that curves upwards and to the right, meeting the yellow stroke's path. The strokes have a textured, hand-painted appearance with some white highlights and darker shadows.

Policy making at the American Chemical Society (ACS) - developing a statement on scientific integrity

Chris Proctor and Sarah Cooney
CINF seminar, Boston, August 18,
2015

A decorative horizontal band at the bottom of the slide, consisting of several parallel stripes in yellow, white, and dark blue, creating a layered, brushstroke-like effect.



Overview

- Why scientific integrity matters to the ACS
- Developing the public policy message (with thanks to Ray Garant)
- The essence of the position
- Observations on the process
- Is the policy applicable to tobacco harm reduction?



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Why scientific integrity matters to the ACS?

- ACS recognises that government faces a wide range of critical and complex issues that involve significant technical challenges, as well as important economic, legal, and political components, that can create tension between technical and nontechnical stakeholders.
- Most scientists and engineers understand that complex policy decisions are not made on technical grounds alone. However, without up-to-date, accurate scientific and technical information, the decision-making process will not lead to the most effective public policies.
- Scientists and engineers have an obligation to provide comprehensive, transparent, unbiased, and understandable technical analyses. Policymakers have the responsibility to consider these analyses and any other relevant technical input in a comprehensive, transparent, and unbiased manner.
- The ACS strongly supports the use of insightful, comprehensive, scientific and engineering input to the development and evaluation of policy options. ACS also encourages scientific integrity policies that help the federal government obtain and integrate scientific assessments into policy development and implementation.

Developing the ACS Public Policy Message

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The ACS Public Policy Message



- Public Policy Priorities
- Public Policy Statements
- Letters, Press Releases, Advertising
- Coalition Positions

The collage features several documents and advertisements from the American Chemical Society. On the left is a document titled "STEM Education Coalition" dated November 9, 2007, signed by Barbara A. Mikulski and Richard C. Shelby. In the center is a letter from the ACS dated December 3, 2007, addressed to Chairman Dingell and Ranking Member Barton, discussing energy policy. On the right is an advertisement for the ACS Green Chemistry Institute with the slogan "Green Chemistry Good for Business. Good for the Environment." and a photograph of scientists in a laboratory.

ACS Policy Statements

- Observations and recommendations on specific policy matters
- Intended for policymakers, most of whom have minimal science background
- Currently 24 active
- One paragraph to six pages
- Collectively represent the broad interests of ACS and our members as a unified agenda



Public Policy Statement
2008-2011

SUSTAINABILITY AND THE CHEMICAL ENTERPRISE

ACS POSITION

The American Chemical Society (ACS) is committed to policies that advance environmental and resource sustainability and the application of the chemical sciences and engineering to global challenges in areas such as energy, food, and water. The Society endorses research support, tax incentives, patent policy, government purchasing policy, awards, voluntary environmental management programs, and other efforts to encourage the adoption of green and sustainable chemistry and engineering.

BACKGROUND

Preserving the habitability of the Earth and its ability to provide the resources required for future generations to thrive is a basic human obligation. It is now necessary for society to address the challenges of limited resources, an expanding population, and the unintended impacts of technological achievements on human health and ecosystem viability. The best way to handle these challenges is by redirecting human development toward sustainability, which would allow humanity "to meet current environmental and human health, economic, and societal needs without compromising the progress and success of future generations" (WCED, 1987; NRC, 1999; NRC, 2005).

The chemical enterprise—consisting of the chemical and allied industries, their trade associations, and the educational and professional organizations (schools, colleges, universities, research institutions, government laboratories, professional societies) that produce both the enabling scientific knowledge and the necessary scientific and engineering workforce—has a crucial role to play in sustainable development.

ACS Policy Issues–2015

Tier 1

- Climate Change
- Energy
- Funding of S&T
- Innovation and Entrepreneurship
- Science Education

Tier 2

- Access to High Quality Science
- Chemicals Risk/Regulation
- Peer Review
- Scientific Insight and Integrity
- Sustainability
- U.S. Business Climate

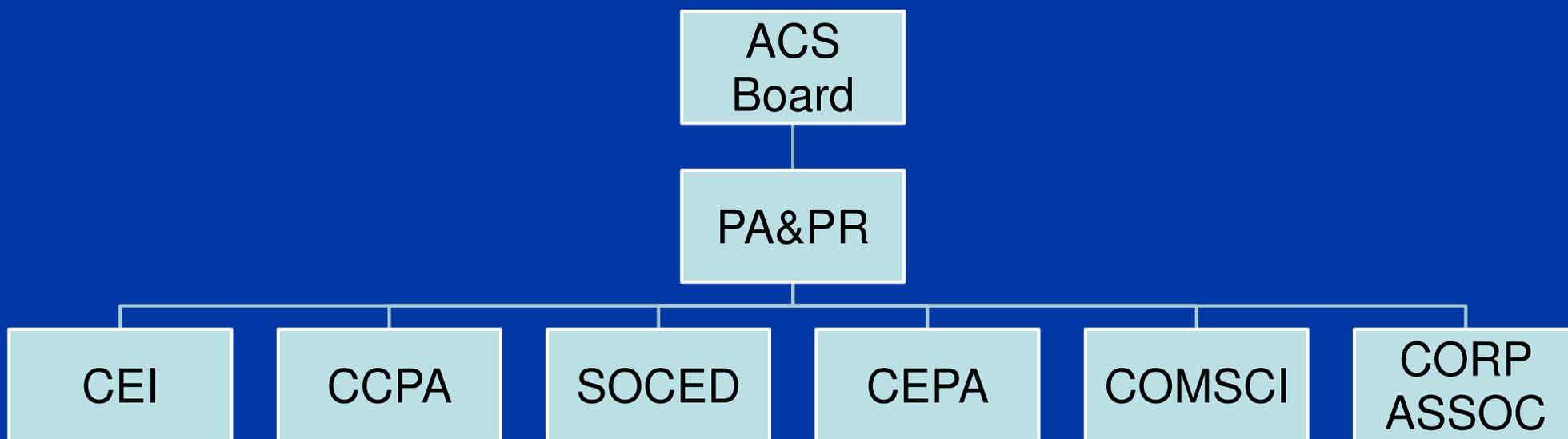
Tier 3

- Forensic Science
- Freedom of Scientific Exchange
- Inherently Safer Technology
- Regulation of Laboratory Waste
- Visa Restrictions

Tier 4

- Biomonitoring
- Charitable Donations
- Endocrine Disruption
- Employment Non-Discrimination
- Hands-On Science
- Healthcare
- Retirement Security
- Teaching of Evolution

ACS Governance



“How a draft becomes an ACS statement”

Committees-or other ACS units

- Recommends drafts to PA&PR
- Maintains policy expertise
- Works with ACS OPA
- Coordinates with other committees, divisions, etc.
- Helps advocate issues
- Reviews statements every third year

PA&PR-delegated by Board

- Approves, declines, or returns drafts for further work
- Develops biennial ACS Public Policy Priorities
- Provides overall guidance to committees
- Leads statement reviews every third year

Improving the Process

Recent Improvements

- Guidelines for Statement Development
- Better preparation of writing team leads
- More cooperation between committees
- More Division Involvement

This Year's Improvement Focus

- More outreach for individual member input
- More checkpoints for committees throughout the year
- Helping writing team representatives involve committees



Updating the policy on Scientific Integrity



- This policy defines the inter-relationship between the scientists (industrial and academic) and the policy-maker
- It sets out best practice on how to use scientific knowledge to inform good policy decision making



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Key sections

- **Government – Congress and Federal Agencies**
 - Calls on Federal Agencies to use unbiased science in a transparent way, and to use scientists outside of the agencies, while protecting commercially sensitive information
 - Calls on Congress to have direct access to technical expertise from qualified professionals

- **Scientific processes and procedures**
 - Scientific discourse should be encouraged, leading to honest differences in interpretations. Conflict of interest should be transparent
 - The use of scientific input to Congressional hearings should be encouraged to determine the nature and uncertainty of knowledge



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Key sections

- Data quality and review
 - All relevant peer-reviewed sources should be used, and quantitative scientific input with careful uncertainty and sensitivity analysis should be the norm. Conflicting results should be documented and, if possible, reconciled
 - Agencies should communicate between themselves
- Scientific Access and Advice
 - Government scientists should be encouraged to publish and present their research, and if not transparent reasons for not doing so should be given
 - Advisory committees should comprise an appropriate mix of technical expertise and breadth of experience. Employer, professional or political affiliations, and prior policy positions should not preclude anyone from serving on advisory committees.

Appendix to Policy statement

- Transparency and selection of scientific review panellists
- The National Academies' definitions of conflict of interest and bias
- Scientific integrity
 - Credibility Assessment
 - Weighing Evidence and Drawing Conclusions
 - Example: One Framework for Assessing the Totality of Evidence in a Systematic Review for Evaluating Hypotheses of Causality (Bradford Hill criteria)
 - Example of a Classification System for Weighing Evidence and Drawing Conclusions (USSG on tobacco and disease)



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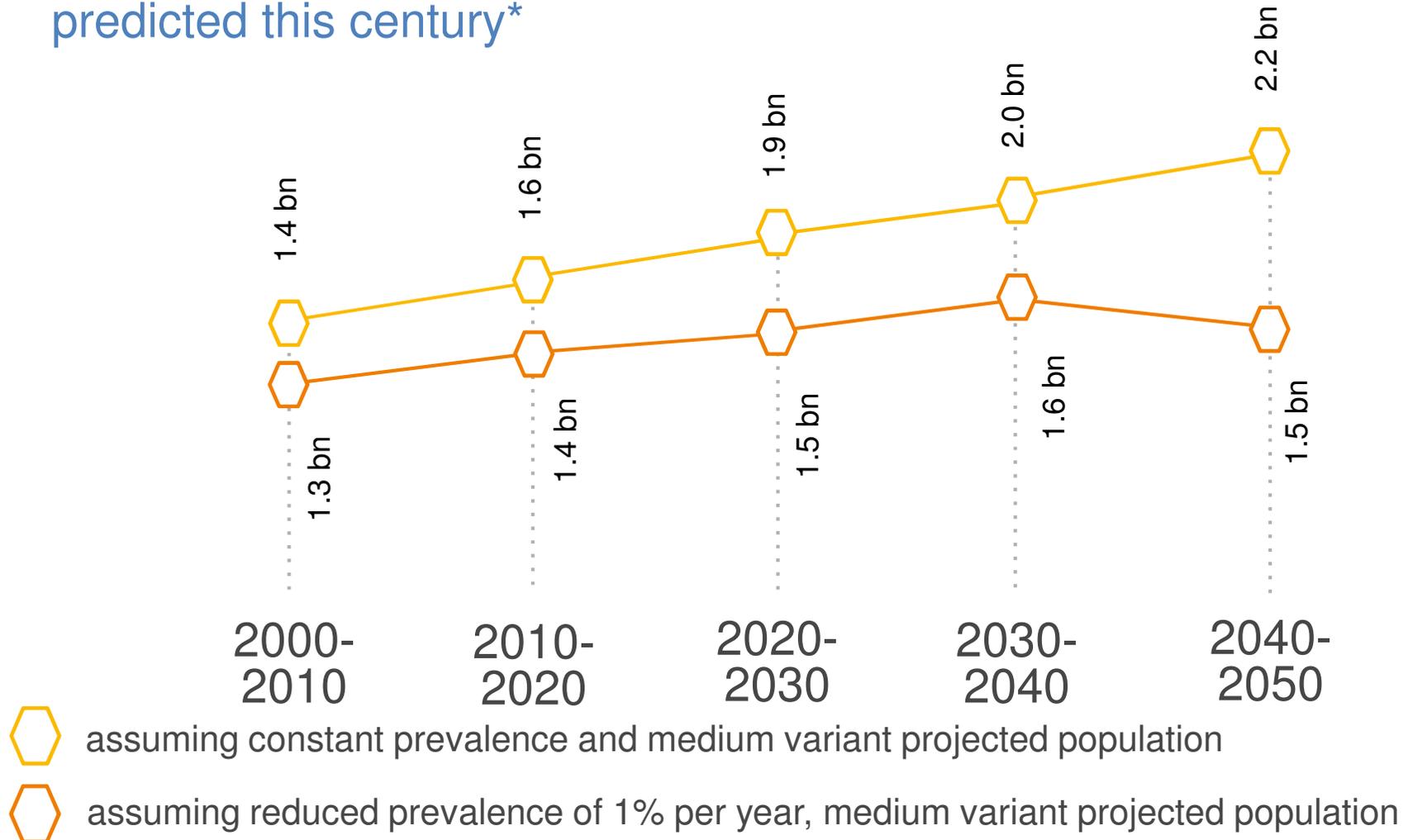
Observations on the process

- This was an update, and having a starting point helps
 - Choose a lead writer
 - Frequent conference calls allow the policy to iterate to consensus
 - Inclusive
 - Strong governance
-
- Now, a case study

The WHO estimates...

...the number of smokers will rise to between 1.5 and 2.2 bn by 2050 and ~1,000,000,000 smoking-related deaths predicted this century*

Deaths from tobacco use are predicted to double between 2005 and 2020, from 5 million to 10 million a year.



*Source: The Tobacco Atlas, WHO, MacKay, Eriksen & Shafey, 2006

The public health impact of tobacco and nicotine use



“Over the course of the 21st Century, tobacco use could kill a billion people or more unless urgent action is taken” *WHO report on the global tobacco epidemic, 2011: warning about the dangers of tobacco*

Professor Michael Russell wrote in the British Medical Journal in 1976: "People smoke for nicotine but they die from the tar." *M. Russell, Brit. Med. J, 1, 1430-33, 1976*

“Extensive experience with nicotine replacement therapy in clinical trial and observational study settings demonstrates that medicinal nicotine is a very safe drug.” *Royal College of Physicians, Harm reduction in nicotine addiction, 2007*

“Nicotine inhaled from smoking tobacco is highly addictive. But it is primarily the toxins and carcinogens in tobacco smoke – not the nicotine – that cause illness and death.” *UK National Institute for Health and Care Excellence (NICE): Tobacco: Harm reduction approaches to smoking, June 2013*



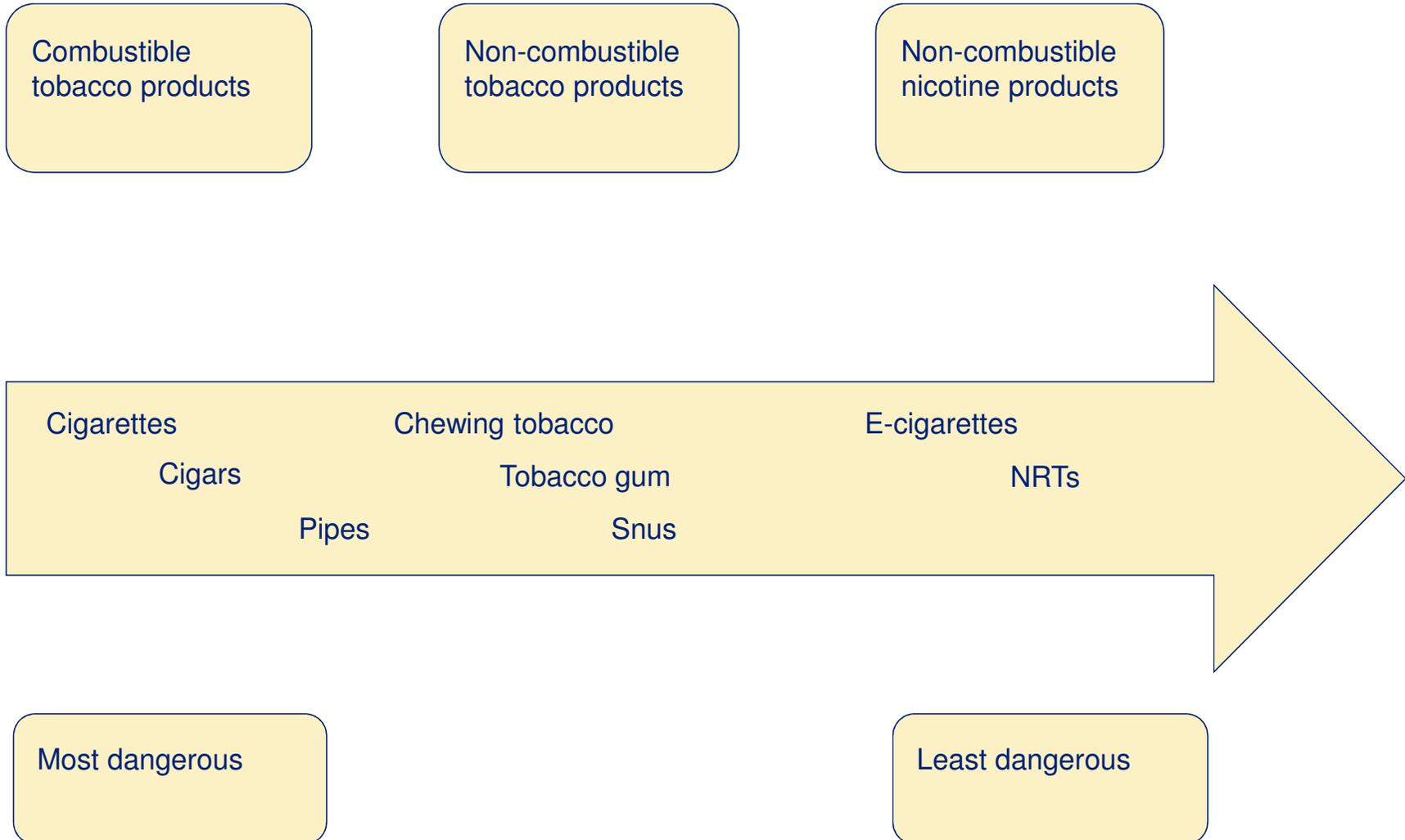
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‘The basic proposition of harm reduction is not that alternative nicotine products are harmless but that they offer reductions in risk of 95% or more compared to cigarettes, and provide a viable alternative to smokers who cannot or do not wish to quit using nicotine.’

The importance of dispassionate presentation and interpretation of evidence, open letter to the World Health Organisation (WHO) signed by 53 leading scientists and public health experts, June 2014



Reducing harm from tobacco use, Professor Ann McNeil and Professor Marcus Munafò, Journal of Psychopharmacology, October 3, 2012





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Reduced risk tobacco and nicotine products and the FDA

- Family Smoking and Tobacco Control Act includes provisions on Modified Risk Tobacco Products
- Products can, if they are approved, be marketed as having reduced exposure to toxicants or reduced risk
- Population health standards
- Applications subject to public comments and review by Tobacco Products Scientific Advisory Panel

FDA Center for Tobacco Products and scientific inclusivity



DAY 1: August 25, 2011
Afternoon session

Panel 2: Comparisons of MRTPs to other Products

David Burns, M.D.

Timothy McAfee, M.D., M.P.H.

Christopher Proctor, Ph.D.

Lars E. Rutqvist, M.D., Ph.D.

Karla Sneegas, M.P.H.



EU and scientific integrity



- Swedish snus is a strong example of the potential for tobacco harm reduction
- UK Royal College of Physicians (2007) noted “On toxicological and epidemiological grounds, some of the Swedish smokeless products appear to be associated with the lowest potential for harm to health.”
- Scientific Committee on New and Emerging Health Risks was more precautionary
- Snus still banned in the EU outside of Sweden

E-Cigarette Standards

European approaches to e-cigarettes are more inclusive in standards setting, less so in regulation setting

- **Standards**

- AFNOR (France)
- BSI (UK)
- CEN (Europe Wide)

- **Regulations**

- Tobacco Products Directive, subject to national implementation and variance

afnor





Application of the policy to tobacco harm reduction



Some regulators acting on the precautionary principle, despite the available science

A classic example in Swedish snus in Europe, and e-cigarettes may be destined to be a further example

Opinions of expert groups often divided, and rarely reconciled

FDA strong on scientific capability and scientific inclusivity, EU less so

Applying the principles of scientific integrity as set out in the ACS policy may help