

Relevance of the Precautionary Principle in Regulating ENDS/ENNDS

Asian Center for WTO & International Health Law and Policy

I. Difficulties with Regulating ENDS/ENNDS

(1) Uncertainty regarding the health risks of ENDS/ENNDS

- Some studies have reported that the emission of ENDS contains various toxicants harmful to human health, while others have regarded ENDS and/or ENNDS as “harm-reduction” alternatives.¹
- In light of the inconclusiveness of relevant scientific evidence, the health risks of using ENDS/ENNDS remain uncertain.
- Therefore, policymakers have faced a dilemma in regulating ENDS/ENNDS, puzzled in the debate between applying existing regulation on conventional tobacco products or imposing a comprehensive ban on ENDS/ENNDS.

(2) Diverse policies adopted by governments

- To cope with the said dilemma, governments have adopted diverse policies and measures based on different evidences and circumstances.
- For example, the United States has extended its regulation over conventional tobacco products to ENDS and fashioned out new categories such as “New Tobacco Products” and “Modified Risk Tobacco Products.”² By contrast, the United Kingdom has released a licensing procedure for using ENDS as medicines; and the first license was issued in 2016.³
- Given the significant discrepancies between existing regulatory actions taken by different governments, effective standard harmonization in this issue area may not be readily achievable. Nevertheless, FCTC Parties shall continue to work on consensus building, information sharing, and best practice exchange to facilitate international cooperation.

¹ See FCTC, *Report by WHO: Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS)*, ¶¶7-11, FCTC/COP/7/11 (Aug. 2016). For a more developed reference, see also FCTC, *Report by the Convention Secretariat: Progress Report on Regulatory and Market Developments on Electronic Nicotine Delivery Systems (ENDS) and Electronic Non-Nicotine Delivery Systems (ENNDS)*, ¶25, FCTC/COP/8/10 (June 27, 2018).

² Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule, 81(90) Fed. Reg. 28987, 29091 (May 10, 2016) (revising 21 CFR §§ 1100, 1140 & 1143).

³ MED. & HEALTHCARE PROD. REGULATORY AGENCY, GUIDANCE: LICENSING PROCEDURE FOR ELECTRONIC CIGARETTES AS MEDICINES (2017).

II. The Relevance of the Precautionary Principle

(1) The Precautionary Principle helps address risks in uncertain circumstances

- First advocated in Principle 15 of the 1992 Rio Declaration on Environment and Development as the precautionary approach,⁴ the notion of taking cost-effective actions before degradation hazards realize has been embraced by *inter alia* the Convention on Biological Diversity, Framework Convention on Climate Change, and Convention for the Protection of the Marine Environment of the North-East Atlantic. International lawmaking initiatives as such have ultimately distilled into the Precautionary Principle.
- Beyond the environmental protection context, the Precautionary Principle may well extend to other issue areas such as human health and food safety. For example, EU has incorporated the Precautionary Principle into Regulation (EC) No 178/2002 as one of the general principles of food law EU member may adopt.⁵

(2) Key elements regarding the application of the Precautionary Principle

- The lack of full scientific certainty;
- The existence of serious threats or irreversible damages; and
- The need for taking cost effectiveness into account when developing regulatory responses.

(3) The Precautionary Principle may be applied to regulate ENDS/ENNDS

- The health risks of using ENDS/ENNDS, as noted, remain scientifically uncertain, conflicting, or insufficient.
- The health hazards and potential adverse impacts on global health as well as tobacco control efforts may be deemed as serious and irreversible damages.
- Therefore, the Parties of the FCTC are urged to consider the relevance of the Precautionary Principle and to reach consensus on taking cost-effective actions commensurate to their respective resources and capabilities to cope with the challenges posed by ENDS/ENNDS.

⁴ United Nations Conference on Environment and Development, Rio de Janeiro, Braz., June 3-14, 1992, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26 (Vol. I), Annex I, Principle 15, (Aug. 12, 1992): "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

⁵ Parliament and Council Regulation (EC) No 178/2002, Laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, 2002 O. J. (L 31) 9, Art. 7.