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WHO Framework Convention on Tobacco Control
Key issues for the INB-4
A briefing for the Government of Malaysia

Regulation and disclosure

Regulation of tobacco products

There is at present no satisfactory regulation of the actual composition and performance of tobacco products in use anywhere in the world. A single paragraph G1(b) – is devoted to the subject in the working texts. At present, what little regulation there is, is based on maximum machine measured yields according to an ISO standard smoking regime (or variations on this) or disclosures of yields.

The ISO standards

The International Organisation for Standardisation (ISO) defines a series of standards for measuring the emissions from cigarettes.

- ISO 4387 covers tar yields. Tar is the sticky particles in smoke comprised of thousands of chemicals created by burning tobacco.
- ISO 10315 covers nicotine yield. Nicotine is the most active and addictive drug in tobacco.
- ISO 8454 covers carbon monoxide (CO) yield. Carbon monoxide is a colourless odourless gas.

These standards govern the specifications of mechanical smoking machines, and the puffing regime that is used for comparative measurements. The standard smoking regime requires one 35-millilitre puff every minute until a predetermined length of tobacco rod has been smoked. The smoke is drawn through an aperture (a mechanical 'mouth') and the residues are trapped on a filter or gases held in a closed container. The residues are dried and weighed. These weights are then presented as 'yields'. Tar yields are typically 1mg to 25mg, nicotine 0.1mg to 2mg, and CO 1mg to 30mg.

'Tar content' – no such thing

The FCTC texts have contained references to 'tar content' – this implies that the cigarette has a certain quantity of tar that it is able to be released during smoking. However, there is no such thing as tar content – the tar is formed during combustion of the tobacco, and the tar yield is only the amount trapped in the filter during standardised smoking.

Low tar cigarettes

Cigarettes with lower tar yield are those that leave a smaller tar deposit on the filter when smoked in the standard way. Most low tar cigarettes work through 'filter ventilation'. Porous paper or tiny ventilation holes are drilled with lasers in the filter, so that when the smoker draws on the cigarette, air is sucked in to dilute the smoke. The effect of doing this with a standard smoking regime is to draw in the same quantity of smoke, but diluted by air. That means less tar, CO or nicotine is deposited on the filter and a lower yield recorded. These lower yields have become the basis for 'light' and 'low' branding, and implied claims of lower risk.

The weakness in the ISO standards – why 'low-tar' is a consumer fraud

The standard smoking regime ignores the single most important aspect of smoking – the addictive nature of nicotine. Machines are not addicted to nicotine and do not modify their smoking when different products are smoked. But humans are different. Tobacco users are trying to achieve a sufficient dose of nicotine to satisfy their cravings for nicotine and they will adjust their smoking accordingly – a process known as 'compensation'. Compensation takes many forms: the smoker may take deeper or longer puffs, more puffs, or subconsciously block ventilation holes with fingers, lips or saliva to prevent dilution of the smoke. An in-depth study of this phenomenon concluded¹:

Smokers' tendency to regulate nicotine intake vitiates potential health gains from lower tar and nicotine cigarettes. Current approaches to characterizing tar and nicotine yields of cigarettes provide a simplistic guide to smokers' exposure that is misleading to consumers and regulators alike and should be abandoned.

In effect, smokers achieve the nicotine dose they want whatever the machine yields say. It follows that such measurements are no use at all for health regulation and that branding based on 'yields' is dangerously misleading. The FCTC working text (G1(d)(ii)) bans misleading descriptors based on these measurements for these reasons.

ISO standards work for the tobacco industry but not for health

The measurements say nothing useful about the health impact of the cigarettes and are not a useful basis for comparison between different brands. A major critique of the ISO methodology – co-authored by the Director of the WHO Tobacco Free Initiative (Dr. Derek Yach) drew attention to the domination of the tobacco industry in Technical Committee 126, the committee responsible for setting tobacco product standards.²:

The tobacco industry dominates the process of tobacco and tobacco products standard setting to advance its political and commercial needs, therefore pre-empting the passage of regulatory policies that would indeed protect the health of the public. In the area of cigarettes and other tobacco products, the establishment of international standards has failed to protect consumers' health and safety, due largely to the influence of the tobacco industry.

The regulation of tobacco for health purposes should be in the hands of health authorities, such as the WHO. The ISO may have a role in specifying technical standards, but this should be subordinate to a body whose main mandate is protection of public health.

How could meaningful regulation work?

In theory, it should be possible to set standards for the ingredients used in tobacco products, the 'engineering' and design of tobacco products, and the emissions – both inhaled mainstream smoke and the sidestream smoke that drifts from the burning tip of a smoked tobacco product. In fact, there are many difficulties with doing this – the chemistry is complex and measurement is complicated further by the 'nicotine seeking' behaviour of tobacco users, which differs dramatically between smokers according to the extent of their nicotine dependence. It may be possible to measure toxins in smoke per unit of nicotine, and there are some potentially useful voluntary standards for smokeless tobacco already in existence specifying maximum limits for known irritants, carcinogens, heavy metals etc.³ However, at this stage, it is premature to establish a regulatory regime in the FCTC – so the option of developing a protocol later might be considered, as in G1(b). It will also be important to recognise that ISO standards do not work for health and reject them.

Disclosures

Disclosure is essential to inform regulatory standards and should come first. Costs for measurements necessary for disclosure should be carried by tobacco companies and reported to the health authorities. While it is tempting to want to specify extremely broad disclosure requirements, this does have costs to governments in processing and understanding the data. Data should be made publicly available so that independent researchers can draw conclusions and test hypotheses. There are probably around 1,000 ingredients that are used or can be used in manufactured cigarettes – though each product will use far fewer. When tobacco is burnt, there are around 4,000 detectable products of combustion – far too many for full disclosure. The aim should be to have comprehensive disclosure of all ingredients in tobacco, papers and filters, and disclosure of a representative set of important emissions. These may be measured by standard methodologies such as the ISO standards – but the use to which this data is put should be under the control of health authorities.

¹ Jarvis MJ, Boreham R, Primatesta P, Feyerabend C, Bryant A. Nicotine yield from machine-smoked cigarettes and nicotine intakes in smokers: evidence from a representative population survey. *J Natl. Cancer Inst.* 2001;**93**:134-8.

² Bialous SA, Yach D. Whose standard is it, anyway? How the tobacco industry determines the International Organization for Standardization (ISO) standards for tobacco and tobacco products. *Tob. Control* 2001;**10**:96-104

³ Swedish Match. GothiaTek® limits for undesired components (www.gothiatek.com).