WHO plans e-cigarette offensive

The Financial Times reports on the World Health Organisation's strategy for undermining e-cigarettes and diminishing the potential for tobacco harm reduction [WHO plans to regulate e-cigarettes in the same way as normal tobacco (£)]. I have now obtained a copy of the leaked document the FT refers to. This document is the WHO FCTC Bureau minutes from November 2013 and it reveals a great deal about this remote and unaccountable organisation. It shows how it is planning to use the WHO Framework Convention on Tobacco Control to apply the same sort of restrictions to non-combustible nicotine products like e-cigarettes that are applied to the far more dangerous smoking products. This is a continuation of an attitude that WHO displayed at the last Conference of the Parties (COP-5) in 2012: see my Open letter to COP-5 delegates, which includes links to WHO's papers on what they call Electronic Nicotine Deliver Systems (ENDS) and smokeless tobacco (SLT). That open letter to delegates also attracted many comments from tobacco and nicotine experts expressing concern about WHO's negative approach. So far, WHO appears to have had no change of heart.

Update 22 April. An excoriating FT leader followed a week later: *Follow the science on e-cigarettes*.

Harm reduction as a public health strategy

WHO itself projects one billion avoidable deaths from smoking in the 21st Century. If WHO manages to engineer the FCTC into over-regulation of safer alternatives to smoking, it will be denying potentially hundreds of millions of smokers an opportunity to avoid cancer, cardiovascular and respiratory disease. We will have the bizarre situation of WHO emerging as one of the most serious causes of preventable death in the 21st Century – it would be preventing the prevention of preventable deaths – the exact opposite of what it is supposed to do.

Not only that, it would disempower millions of ordinary people, as Gerry Stimson highlights in conflict with WHO's own Ottawa charter on public health.

> *Health promotion is the process of enabling people to increase control over, and to improve, their health.*

This is exactly what ENDS and SLT do… they allow people to control the risk associated with taking nicotine and reduce it down to very low or negligible levels. The fact that authorities like WHO think it would be better if they quit nicotine use completely is of little consequence. It is up to people using nicotine to decide, and a decision to switch to SLT or ENDS has two beneficial effects: a dramatic reduction in risk, and a staging post for complete nicotine cessation, *if the user wishes to take that step*. If they conclude they want to keep the nicotine without the harm, we – the coffee and wine drinkers – should not sit in judgement of the use of a different recreational drug.

Inappropriate culture of secrecy

Notice that these minutes are *leaked*, and not simply routinely published as we now expect from 21st Century transparent government. There is no reason to keep them secret and every reason to publish them – other than how embarrassing they are to the participants. But then one gets an idea of this institution's interest in openness in Agenda item 8: para 57-60, where they discuss screening and excluding members of the public who are associated with the tobacco industry – note this isn't about granting 'observer status' (the right to sit in the negotiating room and occasionally make statements when invited by the chair), it is about the right to sit *in the public gallery, when the public gallery is open*. Then they discuss holding closed sessions: why? This is not a place where anything needs to be secret – no operational security details are discussed – and the sunlight of public scrutiny is always valuable. The idea that WHO chooses which stakeholders are granted access to a process that may significantly affect them is reinforced at para 34-36, where they (correctly) note tobacco growers have a legitimate interest in Article 17 and 18 of the FCTC (economic diversification and environment), but then decide to shut the ITGA (International Tobacco Growers Association) out of the proceedings all the same. One wonders about the integrity of a process that is so fragile that it cannot tolerate dissenting voices.

Biases revealed

The people involved in the bureau and secretariat are supposed to be neutral civil servants serving the decision makers, who are national governments and 'state parties' to the FCTC. But on this evidence and all that has come before, they are not acting that way, but betraying crude ideological biases of politicised officials with a little self-serving power but no accountability. Take for example this aside:

> *23. The Head of the Secretariat [Dr Haik Nikogosian] felt that more importance should be given to the threat posed by electronic cigarettes and other smokeless products, which in his view could result in a new wave of the tobacco epidemic. This item should in his view be given a special attention at COP6.*

How these products will create '*a new wave of the tobacco epidemic*' is not explained, and there is no evidence anywhere in the world to support that contention that they will. Nor is the characterisation of ENDS or SLT as a 'threat' appropriate. The huge *opportunity* to reduce the billion deaths that WHO estimates from smoking in the 21st Century is not even mentioned. Like so many public health organisations, WHO lacks a coherent intellectual framework for discussing and negotiating the 'risk politics' of harm reduction. In the risk politics of harm reduction, the appropriate comparator is smoking; the primary concern is reducing disease and premature death; and the regulatory balancing act is to mitigate minor (or implausible) risks of unintended consequences without squandering potentially huge opportunities to reduce smoking related disease through excessive restrictions and red tape. Unless and until the WHO and FCTC can provide a more sophisticated framework for managing these products, it is not a suitable instrument for regulating them. According to its objective (Article 3), the FCTC exists to reduce the "*devastating health, social, environmental and economic consequences of tobacco consumption*". ENDS and SLT do not produce devastating consequences.

Anti-scientific policy making

As a sign of how remote from the evidence the WHO and its leading international representatives are, turn to paragraph 13.

> *13. Ms Dorcas J. Kiptui (Kenya, Africa Region) raised a concern at the strong*

> *and aggressive interference of the tobacco industry in her Region, in particular with regard to the threat posed by the introduction of SLT products and ENDS and the claims made by the industry that these products were safer than cigarettes. It was important in her view that a decision be taken by COP6 on this matter to help countries regulate these products as soon as possible.*

Strangely, no-one is recorded pointing out that, even if the tobacco industry is saying this, *it is absolutely right – and by a very large margin indeed*. If the representative of the Africa region and those who let this remark go unchallenged do not know this, then they really should not be so closely involved in setting a world-wide regulatory framework for ENDS and SLT. It would be helpful if WHO and its policy function would say in broadly clear terms what they think the relative risks are. One of the principles (Article 4) of the FCTC is that:

> *Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption*

So, what's the plan for informing people about risk? It certainly would help if those involved in running the FCTC were more informed. Here is one analysis that might help from Nutt D.et al (2014), and it is broadly consistent with other estimates, it suggests that SLT and ENDS are one to two orders of magnitude (10-100x) less harmful than smoking. If we focus only on disease, then the risk reductions are greater still – probably 99% or more for ENDS and almost as much for snus. This picture should awaken WHO to huge possibilities, but they appear unaware or unconcerned and without an alternative analysis.

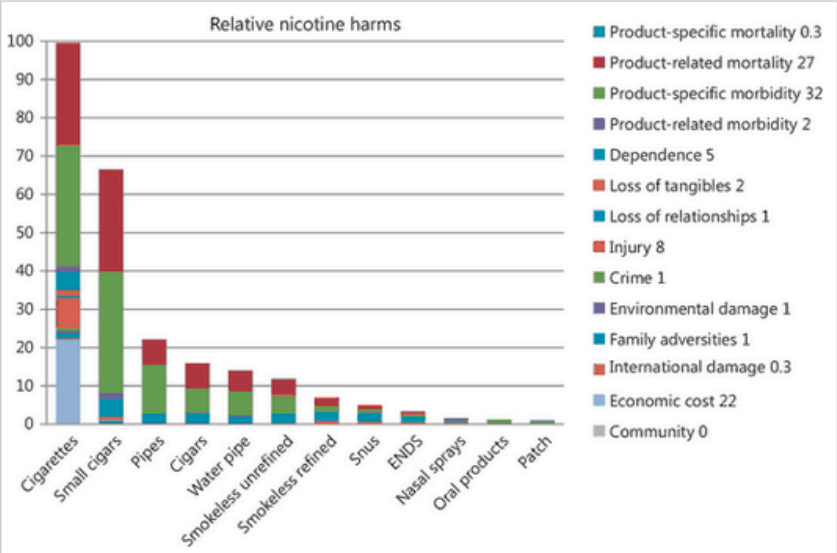


Fig. 2. Overall weighted scores for each of the products. Cigarettes, with an overall harm score of 99.6, are judged to be most harmful, and followed by small cigars at 67. The heights of the coloured portions indicate the part scores on each of the criteria. Product-related mortality, the upper dark red sections, are substantial contributors to those two products, and they also contribute moderately to cigars, pipes, water pipes, and smokeless unrefined. The numbers in the legend show the normalized weights on the criteria. Higher weights mean larger differences that matter between most and least harmful products on each criterion.

Nutt DJ, Phillips LD, Balfour D, et al. Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach. Eur Addict Res 2014;20:218–25. doi:10.1159/000360220

The game plan – making e-cigarettes a tobacco product

This is all work in progress in the run up to COP-6 of the FCTC, which is to be held in Moscow from 13-18 October, nationalist aggression permitting.

The plan for dealing with harm reduction approaches is set out in Agenda item 11, para 69-75. First commission a one-sided background paper focussed on minor concerns, and make that the big issue. The fact that these non-combustible substitute for the vastly more toxic combustible smoking products does not seem to be part of the thinking.

> *71. WHO/PND had prepared a draft background paper on ENDS to be submitted to COP6. […] The paper to COP 6 would address the scientific evidence on toxicity and addictiveness of ENDS and would hopefully contain policy options for the prevention and control of ENDS as requested by the COP.*

So there we have it: the problem is 'toxicity and addictiveness', and the solution is 'prevention and control'. There then follows the critical tactic: to define these products as tobacco products and treat them as if they were as hazardous as smoking:

> *72. The Bureau felt that it was important to include scientific evidence as to whether ENDS contained nicotine from tobacco leaves – and not synthetic nicotine as claimed by the tobacco industry – in which case they would be considered as tobacco products as per the WHO FCTC. The Bureau also referred to Articles 5, 8, 13, and 16 of the WHO FCTC that contained provisions to allow the COP to make recommendations on regulations of SLT products and ENDS.*

The Bureau text above refers to FCTC articles (5, 8, 13, 16) – these are as follows:
Art 5. Would define e-cig companies as tobacco companies and (and so exclude them from most policy deliberation and bestow official pariah status on them, which is completely unjustified).
Art 5. Would require FCTC Parties to 'prevent or reduce' use of SLT/ENDS – this defines them as a problem to be reduced, rather than a solution to be advanced. See the discussion below on including e-cigarettes in a tobacco target.
Art 8. Deals with second hand smoke – which would potentially include vapour (why mention it otherwise?) and so could apply the same situational restrictions to vaping as smoking by default. The is no basis to use the law at all to determine whether someone can use ENDS in a given place, let alone an international treaty. Unless there is material risk to others, it should be a matter for the owners or operators of public spaces. See more views on vaping in public places.
Art 13. Deals with banning advertising, sponsorship and promotion – if applied fully, it would protect cigarettes from competition and inhibit development of a benign consumer nicotine industry. The bans on advertising in, for example the EU, are justified with reference to many thousands of deaths. No such justification exists for ENDS or SLT. In both cases, they are likely to *reduce* the death toll. There should be controls on advertising, but this should be proportionate and more like those applied to alcohol advertising in many countries. See more views on e-cigarette advertising.
Art 16. Relates to sales to minors – almost all involved are content to have the product exclusively aimed at adults and no jurisdiction needs FCTC to do this.
I doubt it would stop there. Once defined as part of the 'tobacco epidemic', e-cigarettes become officially part of the problem, not part of the solution. Further consequences might include:
– applying unnecessarily alarmist warnings (Art 11) or even standardised

packaging
– encouraging excise duties at comparable rates to tobacco (Art 6)
– include ecigs in targets for reducing tobacco (eg, the UN/WHO non-communicable disease target to reduce tobacco consumption by 30% by 2025. E-cigs should be used to *meet* this target, not be part of it.
All of this would be highly counterproductive and damaging to health. It's a kind of double negative: getting tough on e-cigarettes and harm reduction is just the same as protecting cigarettes and causing harm.

Are e-cigarettes a tobacco product?

> *…and not synthetic nicotine as claimed by the tobacco industry*

See what they did there? No company to my knowledge claims synthetic nicotine is used in ENDS (because it isn't), but WHO asserts that the correct test of whether these products are considered to be 'tobacco products' and therefore fall under the FCTC is whether the nicotine in them comes from tobacco. The WHO FCTC definition of tobacco product is at best ambiguous:

> *(f) "tobacco products" means products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing;*

There is no leaf tobacco in e-cigarettes. How about 'contains tobacco' as a test of whether something is a tobacco product? It is really only in the United States that anyone takes seriously the idea that because a product contains nicotine derived from tobacco plants it must be a tobacco product (unless it is a pharmaceutical). The only reason for this, is that legal action stopped the FDA defining e-cigs and e-liquids as drugs, and the FDA doesn't know what to do unless it can define the products as tobacco products. The United States is not a party to the FCTC

Whatever the definitions, the main problem with defining them as tobacco is that they are automatically classed *as part of the problem*, although they are already emerging as an *important part of the solution*.

Smokeless tobacco

Even the definition 'contains tobacco' is unsatisfactory if you take a forward

looking view because it fails to differentiate between combustible and non-combustible tobacco. Non-combustible tobacco can have similar risk characteristic to e-cigs, and has minimal risk relative to smoking. Again it is part of the solution not part of the problem, as argued many times on this blog – how can they just ignore among the best tobacco and health results in the world in Sweden see: Why is the EU banning Europe's most effective anti strategy? – in which several experts set out the evidence and experience of SLT in harm reduction, and so-called experts from WHO made fools of themselves.

Global goals – WHO already acting as though e-cigarettes are tobacco

Although decisions in the FCTC are taken by the Conference of the Parties, not WHO, it appears WHO is already trying to bounce this approach into the international architecture, notably into the Sustainable Development Goals that will replace the Millennium Development Goals when these expire in 2015. These goals and supporting indicators are under negotiation at the moment but once set they will assume pervasive international significance and become a standard definition. WHO reveals its approach in a consultation undertaken by the UN's Sustainable Development Solutions Network: see Public Consultation on Indicators for Sustainable Development. In the consultation document, on page 79 indicator 47 is defined thus:

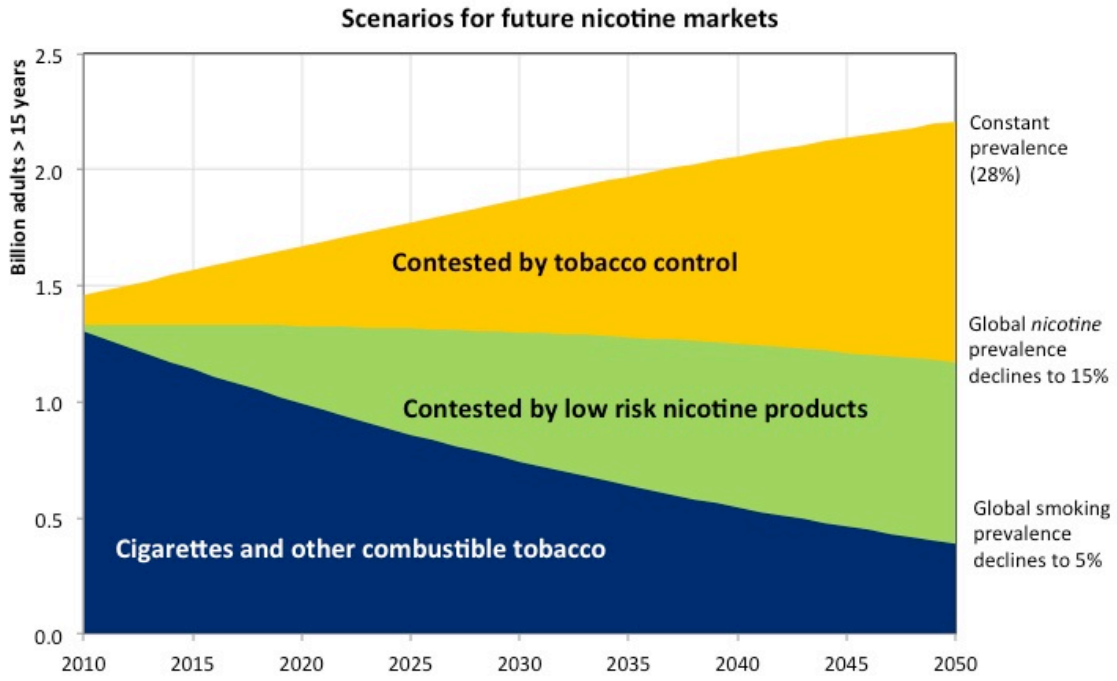
Indicator 47: Current use of any tobacco product (age-standardized rate)

> *Rationale and definition: Tobacco use is a leading cause of preventable death in many developed countries, and is a growing problem and contributor to the burden of disease in developing countries. This indicator measures the prevalence of current smoking (daily, non-daily, or occasional) of any tobacco product, including cigarettes, cigars, pipes, etc., for adults aged 15 years and over.[72] 15 It expands upon the WHO's recommendation to further track use of smokeless tobacco products (**including chewing, snuff, and electronic cigarettes**). The age-standardized prevalence rate of tobacco use (adjusted according to the WHO regression method) allows for comparisons across countries and across time periods to determine trends.[73] (**emphasis** added)*

Source 72 and 73 are: WHO Indicator and Measurement Registry (2011). But

these do not, at present, mention e-cigarettes. So WHO is anticipating the definition of e-cigarettes as a tobacco product later in the year, and in advance of any agreement on this from the Conference of the Parties. If agreed, this would be an extremely serious and negative development – defining ENDS and SLT as part of the problem rather than part of the solution, based on no evidence at all. See my response to the consultation (now closed) here.

It is totally wrong to include ENDS in this target, and inappropriate to include SLT. If the focus is on disease, it would be far better to use of the crude rate of current smoking of any tobacco product, to characterise the risk. This is a standard WHO indicator, and deserves greater attention. Measuring daily smoking rate has some merits – it is a precise definition and it reflects the part of the tobacco using population at greater risk, excluding those who smoke only occasionally. However on balance, a more complete indicator is preferable as non-daily use can still be risky. What they should be trying to achieve is something more like this:



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In summary

- E-cigarettes and smokeless tobacco are part of the solution to the 'epidemic' of disease and premature death caused by smoking, they are not part of the problem
- The WHO is in danger of becoming an agent in causing the very harms it is trying to prevent and obstructing people's personal efforts to control their own risks.
- If the WHO is serious about tackling the one billion smoking related deaths it needs to find a way to encourage ENDS and SLT with enlightened regulation, not suffocate them with regulation – *or step aside*
- To extent it suppresses demand for ENDS and SLT, WHO is providing *de facto* protection for cigarette sales and so prolonging and deepening the smoking epidemic
- If the WHO wishes to meet the non-communicable diseases (NCD) target to reduce tobacco use by 30% by 2025 – a laudable but ambitious goal – it needs to include ENDS and SLT as part of the solution, not part of the problem. The target is there to reduce disease, and that is what matters to WHO's broader mission. If ENDS *are included in this reduction target*, it will not be met – and will be missed by some distance. If ENDS are used *to meet the target*, there is a chance of success.
- The risks of ENDS and SLT are not just a little lower than smoking, they are 95-100% lower. So far we see little risk from e-cigarettes or modern smokeless tobacco products – at least risks that are comparable with everyday hazards, like consuming coffee. WHO does itself, global health and ordinary citizens no service by commissioning research from sources that will reflect its own biases. We will return to this.