Bills Committee on Smoking (Public Health) (Amendment) Bill 2019 (2020-2021 session)

List of follow-up actions required of the Administration arising from the discussion at the meeting on 19 January 2021

The Administration's response on the items raised by Members is set out as follows.

Premarket review mechanism of the Food and Drug Administration ("FDA") for new tobacco products

2. In the United States, the Federal Food, Drug, and Cosmetic Act ("FFDCA") requires that any tobacco product that is not commercially marketed on or before February 2007[1] must be granted marketing authorisation by FDA through one of the following pathways before it can be legally marketed - (i) Substantial Equivalence, which applies to a tobacco product that, when compared to tobacco products that are already commercially available in the United States market, has the same characteristics, or has different characteristics but does not raise different questions of public health; (ii) exemption from Substantial Equivalence, which applies to a tobacco product that is a modification of another tobacco product legally marketed by the same organisation and the modification is minor; or (iii) Premarket Tobacco Product Application ("PMTA"), which applies to new tobacco products[2]. To legally market a new product with a reduced risk claim, or to modify a legally marketed product to make a reduced risk claim, the manufacturer must also apply for a modified risk tobacco product order.

3. PMTA applicants are required to submit, among others, full reports of health risk investigation; a full statement of what is in the product (e.g. components, ingredients, additives, properties, and principles of operation); full description of methods, facilities, and controls for manufacture, processing, packing and/or installation of the product; compliance with tobacco product standards; samples of components of the product; and proposed labelling of the product[3]. The FFDCA requires FDA to consider the risks and benefits of the product to the population as a whole, including users and non-users of tobacco products, and taking into account the increased or decreased likelihood that existing tobacco users will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using them[4].

4. FDA considers PMTAs on a product-by-product basis. The Agency had admitted that it was still gaining experience in applying statutory authorisation standard to PMTAs. In September 2019, FDA published a proposed rule for PMTA of new tobacco

[1] https://www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product
[2]https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications
[3] FFDCA section 910(b)(1)
[4] FFDCA section 910 (c)(4)

products, which sets out the minimum requirements for the content and format of PMTAs for the FDA's evaluation. The rule would also formalize the general procedures that FDA would follow when evaluating PMTAs and the post-market record-retention and reporting requirements for manufacturers that receive marketing authorization. To date, the finalised rule has not been published by FDA yet.

Modified Risk Tobacco Product ("MRTP") Application[5]

5. MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Before an MRTP can be introduced or delivered for introduction into interstate commerce, an order from FDA (a risk modification order or exposure modification order) must be obtained[6].

6. FDA must make MRTP applications available for public comment and also refer the applications for review of the Tobacco Product Scientific Advisory Committee ("TPSAC"). FDA will evaluate the information in an MRTP application, recommendations from the TPSAC, public comments, and other information made available to FDA. After evaluation, FDA may grant a risk modification order or an exposure modification order to a product under MRTP application.

7. FDA will issue a risk modification order if, and only if, it determines that the applicant has demonstrated that the product, as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users, and benefit the health of the population as a whole taking account both users of tobacco products and persons who do not currently use tobacco products[7].

8. For a product that cannot receive a risk modification order, FDA may issue an exposure modification order if the product reduces or eliminates exposure to a harmful substance and the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity and mortality among individual users is reasonably likely in future studies. The labeling and advertising of product with exposure modification order must be limited to a representation that:

(i) the tobacco product or its smoke does not contain or is free of a substance;
(ii) the tobacco product or its smoke contains a reduced level of a substance; or
(iii) the tobacco product presents a reduced exposure to a substance in tobacco smoke.

[5] https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products
[6] FFDCA section 911(g)
[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modified-risk-tobacco-product-applications

9. An MRTP order is valid only for the fixed time period specified in the order. To continue marketing an MRTP after the specified term, the company may submit a new application for FDA to determine that the product still satisfies the requirements. Besides, the company is required to conduct post-market surveillance and studies, and submit the results to FDA annually. FDA will review these results and collect further information about the product's use and health risks. FDA may withdraw the modified risk order at any time if indicated.

10. A risk modification order or exposure modificatior order refers to a single specific product instead of an entire class of tobacco products. As of 31 August 2020, FDA has received 33 MRTP applications since 2011 and issued 12 MRTP orders, including 8 risk modification orders to smokeless tobacco products and 4 exposure modification orders to heated tobacco products ("HTPs") of one brand[8]. No HTP has been granted risk modification order.

Regulatory measures on electronic cigarettes ("e-cigarettes") and HTPs in the European Union ("EU") and the United States

11. The Tobacco Products Directive ("TPD") regulates the manufacture, sale and marketing of tobacco products across the EU. The prevailing TPD, which entered into force on 19 May 2014 as a replacement of the 2001 TPD, was developed in response to the latest scientific evidence on effective tobacco control measures, emerging tobacco products, and ratification of the World Health Organization Framework Convention on Tobacco Control ("WHO FCTC") by EU and its Member States. Member States of EU were required to transpose the TPD into national tobacco control legislation by 20 May 2016.

12. The regulatory measures introduced by the TPD echoes the provisions of WHO FCTC (to which the United State is not a Party) and the recommendations of the FCTC implementation guidelines. It is worth noting that Member States of EU have in place their own legislation for tobacco control, and the TPD seeks to approximate regulatory approaches in certain aspects (e.g. ingredients and emissions of tobacco products and relating reporting obligations, labelling and packaging, ban of tobacco for oral use, notification obligation for novel tobacco products, marketing and labelling of e-cigarettes and refill containers and herbal cigarettes, cross-border distant sale of tobacco products) across EU to ensure smooth functioning of the internal market and to afford a high level of health protection for EU citizens. It does not seek to harmonise all regulatory rules, such as the domestic smoke-free laws, or rules on domestic sales arrangements, advertising, promotion and age limit for sale. Member States are free to regulate such matter within the remit of their jurisdictions and impose requirements beyond measures specified in the TPD to products placed on its domestic market or to prohibit a certain category of tobacco or related products in order to protect public health. Some Member States have introduced complementary or further measures in

[8] https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products#summary

their tobacco control legislation such as plain packaging and advertising or smoking prohibitions.

13. In the United States, the FFDCA is the federal law that regulates tobacco products and product marketing nationwide, whereas states governments retain the authority to implement policies and legislation for tobacco control (e.g. smoke-free laws, local restrictions on sale, distribution and promotion of tobacco products). However, states governments do not have authority regulation of tobacco product structure (except the enactment of fire-safe cigarette laws that regulate the ignition propensity of tobacco products).

Regulation of e-cigarettes

14. Under the TPD, e-cigarettes and/or refill containers of nicotine-containing liquid are subject to, among others, the following regulations:

- a maximum nicotine strength of 20mg/ml;
- maximum volume 10 ml for refill containers or 2ml for single-use cartridges;
- cartridges, tanks and containers containing nicotine liquids are required to be child- and tamper-proof and protected against breakage and leakage;
- prohibition of certain additives (e.g. prohibition to use vitamins, caffeine, additives with colouring properties for emission);
- requirement to display on outside packaging a list of all ingredients, nicotine content, and health warnings about the addictiveness of nicotine;
- requirement to include in unit packets a leaflet on instruction for use and storage, warnings for risk groups, possible adverse effects, addictiveness and toxicity;
- prohibition of any promotional and misleading element in packaging of e-cigarette packs and refillable containers;
- prohibition of direct or indirect promotion in any form;
- requirement for manufacturers and importers to notify and submit product information (e.g. a list of all ingredients and emissions from use and quantities, toxicological data, nicotine doses and uptake) to appropriate authorities before placing new products on the market, and to submit studies on market research relating to the products as well as report on sales volume data on a yearly basis.

Some decisions on e-cigarettes are left to the Member States to regulate as they deem appropriate, such as age limits and regulation of flavours. The TPD requires the Member States to ensure that only those products that comply with the TPD are allowed to be placed on the market.

15. In the United States, nicotine containing e-cigarettes are regulated by FDA in accordance with the FFDCA. FDA has not issued any product standard (e.g. level of nicotine, flavourings, additives) for e-cigarettes. It requires all new tobacco products to obtain pre-market authorisation on a product-by-product basis. In 2019, FDA released

a guidance document on the premarket authorisation requirements for nicotine containing e-cigarettes, which sets out information that FDA considers to be important for its assessment, for example information related to nicotine exposure warning, protective packaging, certain specified chemicals in e-liquids or aerosols, etc. However, the recommendations in the guidance document are non-binding. Sale of nicotine containing e-cigarettes to anyone under 21 is prohibited. Marketed products must bear the ingredient list and nicotine addictiveness warning statement covering at least 30% of the area on the packaging. Promotion of e-cigarettes is not banned.

Regulation of HTPs

16. In EU, HTPs are "novel tobacco products" under the TPD[9]. Manufacturers and importers must submit a notification to Member States' competent authorities of any novel tobacco product they intend to place on the national market concerned. The notification must include a detailed description of the novel tobacco product, instructions for its use, and specific information regarding ingredients and emissions as detailed in the TPD. The notification must also include the available scientific studies on toxicity, addictiveness and attractiveness of the product, market research on the preferences of various consumer groups, and other available and relevant information, including a risk/benefit analysis of the product, its expected effects on initiation and cessation of tobacco consumption, and predicted consumer perception. Member States may require manufacturers or importers to carry out additional tests or submit additional information, and may introduce a system for the authorisation of novel tobacco products and charge manufactures and importers fees for that authorisation.

17. HTPs are by definition tobacco products under the TPD, which prohibits the placing on the market of cigarettes and roll-your-own tobacco with a characterising flavour (other than the flavour of tobacco). Additives that create impression of health benefit or reduced risks (e.g. vitamin), associated with energy and vitality (e.g. caffeine), have colouring properties for emissions, facilitate inhalation of or nicotine uptake from smoking products, or have carcinogenic, mutagenic and reprotoxic properties in unburnt form are prohibited. These prohibitions also apply to any tobacco product with a characterising flavour whose EU-wide sales volumes represent 3% or more in a particular product category. The TPD also prohibits promotional elements, presentation that create erroneous impression about health effects, and any reference to taste, smell and flavourings on tobacco product packets.

18. In the United States, application for marketing authorisation must be made for any HTPs before they could be legally marketed and FDA grants authorisation on a product-by-product basis. While FDA has not issued specific product standard for HTPs, the FFDCA specifically prohibits cigarettes from containing characterising flavours other than the flavour of tobacco or menthol. HTPs that fulfill the legal definition of cigarettes under the FFDCA are regulated as such. Requirements imposed

[9] https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/ENVI/DV/2020/02-17/Rys_e-cigarettes_EN.pdf

by the FFDCA on cigarettes, such as health warning occupying 50% of product package, prohibition of sale to anyone under 21, apply to these HTPs.

Estimated selling price of the most sold brands of illicit cigarettes in Hong Kong

19. The estimated selling price of the most sold brands of illicit cigarettes in Hong Kong ranges from around $20 to $30 per pack.

Food and Health Bureau
Department of Health
Customs and Excise Department
February 2021