3|2014 June-July

tobaccojournal INTERNATIONAL TJI

in association with World Tobacco

EUROMONITOR TOBACCO REPORT
SEE PAGE 44

Queue here for approval

Photo: Joe Mapother

Queue here for approval

The US Food and Drug Administration wants to expand its list of regulated tobacco products. Industry experts say the agency's proposal will close the market to innovation and saddle smaller companies with ruinous costs.

With the new proposed FDA rule on deeming, we're taking another very important step toward the goal of a tobacco-free generation", said Health and Human Services Secretary Kathleen Sebelius when the initiative was unveiled in April.

Electronic cigarettes, shisha, cigars, pipe tobacco, nicotine gels and dissolvable products not already falling into the regulated smokeless category will be treated as tobacco products under the FDA proposal. The agency already has authority over cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco under the Family Smoking Prevention and Control Act of 2009. That act provides for future expansion of regulatory powers, which is what the FDA has embarked upon. The request for broader powers is called a deeming rule.

Sebelius directs the ministry that oversees FDA and Mitch Zeller heads the Center for Tobacco Products within FDA. Speaking at the same 24 April press conference as Secretary Sebelius, Zeller had this to say about deeming: "The deeming rule differs from most public health regulations in that it is an enabling regulation. It will allow us to propose regulatory action on these and yet to be conceived tobacco products in the future under the standard appropriate for the protection of the public health."

Photos: Joe Mapother

Deeming is just the beginning, Zeller appears to be saying. The main course is yet to come. Once achieved, the enabling powers will allow FDA, for example, to seek authorisation to restrict advertising venues for e-cig products or use of flavours in e-cigs and cigars that are judged to be overtly appealing to youth.

The tobacco-free goal Sebelius referred to was set by the government early this year and applies to the next generation. This timeline itself is enough to conclude the deeming rule is not tobacco industry friendly.

Manufacturers of newly deemed tobacco products will be required to undergo FDA review to stay on the market or to be introduced as new products. These applications must be filed within 24 months of a final deeming rule. That application deadline is expected in 2017. Products may stay on the market pending a ruling, but to request a ruling will cost time and money.

In cases where a product can be cited that was in the market as of 15 Feb, 2007, and where that product is similar in design and health impact to a newly deemed product, the manufacturer may file what FDA calls a substantial equivalence application.

For products like e-cigarettes, where a predicate product prior to 2007 is not readily available, the FDA suggests filing for pre-market review. Total time for a pre-market application is estimated at 5,016 hours. At USD 10, the minimum hourly wage in California, those hours would cost USD 51,060. At USD 100 an hour, an application would cost a cool half-million – per product.

Cost and complexity have prompted protests that the deeming rule will drive out startups and smaller companies. Critics say control of the newly regulated products will land in the hands of – drum roll please – Big Tobacco.

If the government is serious about smoke-free, which generally is defined as less than 5 per cent of the population, it would make perfect sense to limit ownership of newly regulated products to existing tobacco companies. Why encourage the spread of something you intend to all but eliminate?

Since April government officials have been silent on the deeming rule because it has entered the public comment period. However a four-day annual conference of the Tobacco Merchants Association (TMA) in the state of Virginia offered a chance to hear what the industry and outside experts have to say, and presumably also send to the FDA. Their comments appear in this article and succeeding ones on e-cigarettes (p. 30), the FDA approval process (p. 32) and cigars (p. 33).

There was general agreement it will be another year before a final deeming rule can be expected (legal challenges excepted). The statute as proposed would take effect 24 months later, in 2017. This could entail seeking FDA approval for a decade of new products; from 2007 until 2017. And 10 years worth of innovation means a lot of time and money spent on just the first round of product applications, said several industry representatives.

Pending implementation of federal regulation of previously unregulated or partially regulated products, more state governments can be expected to jump into the gap. Their target has been e-cigarettes, the newest of the newly to be deemed. "We're going to have more states regulating", said Goldman Sachs analyst Judy Hong.

Only two states have simply expanded their smoking prohibitions to include e-cigarettes , with another to follow in 2017, according to data compiled by the American Nonsmokers' Rights Foundation. Most states to date (10) restrict e-cig use only in specified locations such as schools, state buildings, public transport or prisons. More than 270 local governments have placed some sort of restriction on e-cigarette use.

Public comment extension?

FDA says it will close 75 days of public comment on its deeming rule on 9 July, but the agency will likely extend that deadline due to demand, said Marc Scheineson, an attorney with Alston & Bird. Extension requests have been filed, the FDA confirmed.

"Reasonably, they will have to grant an extension," Scheineson said. In the case of last year's menthol comment period, an additional 60 days were allowed.

Scheineson characterised the FDA proposal as "a skeleton of five or six ideas and requests for comments in 53 areas". He didn't hazard a guess on how many comments could be expected, but said the menthol public-comment period drew more than 200,000.

Among FDA's 'half-dozen specific ideas' are: newly deemed tobacco products must not only seek approval for new products, but also submit product/ingredient lists for all their products. Sales to minors would be prohibited. Distribution of free samples would be banned. Health warnings would be required on packaging, including on component packaging of e-liquids, e-cartridges, shisha, and flavoured charcoal. Vending machine sales would be prohibited.

Manufacturers may ask the government for certification as a modified risk product (MRTP) only if FDA confirms scientific evidence backs the claim, and that marketing the product would benefit public health.

Although the voices demanding government acceptance of e-cigarettes as an MRTP are loud, experts say the scientific evidence available is too scanty on a product that has been in existence for roughly one decade.

"We have to change the mentality of the e-cigarette industry", to develop the needed science and laboratory support, said Konstantinos Farsalinos, a researcher at the Onassis Cardiac Surgery Center. "They don't have the research mentality."

Swedish Match, the snus maker whose product is banned in most of the European Union, announced in June that it would ask FDA for MRTP certification.

"(Deeming) is a skeleton of five or six ideas and requests for comments in 53 areas"

Marc Scheineson

Unlike e-cigarettes, snus have been on the market in Sweden since the 17th Century.

Rebuffed in Europe again when the EU approved a successor to its Tobacco Products Directive this year, Swedish Match apparently intends to prove its case in the US.

Obtaining MRTP approval will not be easy. The snus maker will have to convince US officials that their product is not only is less dangerous, but that it will also benefit public health. Swedish Match said its FDA application consists of more than 100,000 pages.

Existing curbs will apply

As tobacco products, the newly deemed products in the US would also be subjected to existing regulations. Cigar makers, for example, no longer would be allowed to describe their products as 'mild', 'light', or 'low'.

FDA is soliciting input on whether to regulate all cigars equally or whether premium cigars should be treated differently. The agency asks which provisions of its proposal are appropriate and which not appropriate, for different types of cigars.

FDA notes sales of small cigars quadrupled in the early 1970s when they were taxed at a much lower rate than cigarettes, and advertising for those products was allowed to continue after the ban on cigarette ads. The agency says some of these small cigar makers may be masking what federal statute defines as a cigarette to escape the existing ban on characterising flavours (menthol excepted). They ask what the public thinks FDA ought to do.

Use of flavours also can be expected to receive more scrutiny, based on what FDA is requesting the public to submit comments on.

"FDA is aware that some tobacco products, such as e-cigarettes and certain cigars, are being marketed with characterising flavours, and that these flavours can be especially attractive to youth", states the proposed rule. The agency asks for research findings on the long-term effects of using flavoured tobacco products. Whether using flavoured tobacco products is an inducement to cigarette use is another question FDA said it would like answered.

"Many of the products proposed to be covered by this rule are offered in fruit or candy flavours", FDA writes. "The statutory prohibition against characterising flavours will not apply automatically to those products. However, once they are deemed, FDA may establish a product standard prohibiting flavours in those products. FDA requests information and data that would support establishing such a standard."

E-cigarette representatives attending the Virginia TMA meeting lashed out at the arbitrary 2007 cut-off for predicate products. The date signifies nothing other than when the original bill granting tobacco regulatory powers to FDA was introduced in Congress. FDA also notes the arbitrary nature of 15 Feb, but says its hands are tied without help from Congress.

However Congress may not be inclined to help establish a reference date for predicate products that is more accommodating to, in particular, e-cigarettes.

"In spite of the growing popularity of nicotine delivery products, decades of research shows that exposure to nicotine increases risk of addiction and has adverse health consequences," wrote US Sen Richard Durbin, who has called for banning use of e-cigarettes on Capitol Hill. In the absence of federal oversight, these products are taking advantage of the regulatory vacuum to market nicotine products to youth and risk addicting a new generation to nicotine."

Search for a scientific base

With or without help from Congress, establishing a technology link to early e-products and what is coming onto the market today will be difficult.

"Even if there was a predicate product, I don't think this would be a viable option for an advanced (e-cig) product", comments Azim Chowdhury, an attorney with Keller & Heckman.

"That's a big problem," admits Jan Andries Verleur, chief executive and co-founder of VMR Products, a vertically integrated e-cigarette company founded five years ago.

"We could have a reference product established that will have no relationship to what users want, or will buy", says Bill Bartkowski, president of VapAria, a US research company.

FDA is charged ultimately with protecting public health, and here the deeming rule impales itself on the horns of a moral dilemma. Because e-cigarette makers in 2010 successfully challenged FDA on its attempts to regulate the sector as part of the pharmaceutical industry, e-cigs are on the road to becoming a regulated tobacco product.

And that means e-cig makers generally will be prohibited from saying their products are safer than cigarettes.

Joe Mapother