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DRAFT AMENDMENTS TO THE TOBACCO CONTROL ACT

(Act no. 14 of 9 March 1973 relating to prevention of the harmful effects of tobacco)

Additions and amendments are italicised.

*§ 6A-1 Registration, quality and safety related to electronic cigarettes*

*It is prohibited to sell or to hand over electronic cigarettes or refill containers which are not registered with the Norwegian Medicines Agency.*

*Manufacturers and importers of electronic cigarettes and refill containers shall apply to register their products at least six months the intended placing on the Norwegian market. A new registration shall be submitted for each substantial modification of the product.*

*The Ministry may make supplementary regulations concerning the registration of electronic cigarettes, making the information received publically available and charging fees to cover expenses relating to the registration and control of electronic cigarettes.*

*The Ministry may make supplementary regulations concerning requirements to the quality, safety, design and instructions for use.*

*§ 6A-2 Adverse effects*

*Manufacturers, importers and distributers of electronic cigarettes and refill containers shall establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products.*

*Should any of these economic operators consider or have reason to believe that electronic cigarettes or refill containers, which are in their possession and are intended to be placed on the market or are placed on the market, are not safe or are not of good quality or are otherwise not in conformity with this Act, that economic operator shall immediately take the corrective action necessary to bring the product concerned into conformity with this Act, to withdraw or to recall it, as appropriate. In such cases the economic operator shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available or is intended to be made available, giving details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results of such corrective action.*

*The Ministry may make supplementary regulations concerning corrective actions and information duties.*

*§ 6A-3 Market surveillance*

*Manufacturers and importers of electronic cigarettes and refill containers shall annually submit to the Directorate of Health data on sales volume, preferences of various consumer groups, mode of sale and summaries of market surveys.*

*§ 32 second section Ingredients and emissions*

The Ministry may make supplementary regulations regarding the ingredients in tobacco products *and tobacco surrogates,* including *the prohibition of certain additives,* maximum levels of ingredients *and emissions and the measurement methods and control of emissions.*