
Order on studies of specific additives in tobacco products and more detailed requirements for labelling and packaging of cigarettes and rolling tobacco etc.¹⁾

Pursuant to § 4, clause 2, § 5 clause 4, § 20, clause 3 and 21 of Act no. 608 of the 7th of June 2016 on tobacco products etc. it is hereby decreed that:

Chapter 1

Studies of cigarettes and rolling tobacco containing additives on the priority list

§ 1. In relation to studies of cigarettes and rolling tobacco pursuant to the Act's § 4 it shall be established whether the specific additive on the priority list:

- 1) Contributes to the relevant products' toxicity or addictive properties and whether this means that some of the affected products' toxicity or addictive properties are increased substantially or measurably.
- 2) Emits a distinctive aroma.
- 3) Makes inhaling and nicotine uptake far easier
- 4) If the formation of substances with carcinogenic, mutagenic or reprotoxic properties (CMR properties,) stems from the amounts involved, and this means some of the said products' CMR properties increase substantially or measurably.

Clause 2. Studies pursuant to clause 1 shall consider the intended use of the tobacco product in question.

Clause 3. Studies pursuant to clause 1 shall especially examine tests of the emissions caused by the burning process involving the relevant additive and also an examination of the interaction of the relevant additives with other ingredients contained in said tobacco product.

§ 2. Manufacturers or importers that are using the same additives listed on the priority list in their tobacco products can undertake a joint study, as per § 1 and submit a joint report as per the Act's § 5, where they are using the relevant additives in a comparable product composition.

Clause 2. Should the manufacturers or importers decide to undertake a joint study, all parties have a responsibility to deliver any relevant documentation on request from the Danish Safety Technology Authority, as per the Act's § 5 clause 1-3.

Small and medium sized companies

§ 3. Small and medium sized companies can be exempted from obligations in the Act's § 4 and § 5, where

- 1) another manufacturer or importer is carrying out a study and preparing a report to Danish Safety Technology Authority and the European Commission regarding a specific additive on the priority list, and
- 2) said company satisfies the criteria for micro-companies, small companies or medium sized companies in the Commission's recommendations of 6th of May 2003 on the definition of micro-companies, small and medium sized companies (notified under number K (2003) 1422) (EEA relevant text) (2003/361/EU).

Unofficial Translation

Clause 2. It is the manufacturer's or importer's responsibility to deliver documentation for § 3, stk. 1, nos. 1-2, on request from the Danish Safety Technology Authority.

Chapter 2

Peer review

§ 4. The Danish Safety Technology Authority and the European Commission can demand that reports prepared and submitted pursuant to the Act's § 5, are subjected to peer review by an independent scientific body, cf. the Act's § 5, clause 2.

§ 5. The peer review shall primarily examine the reports' thoroughness, methodology and conclusions having due regard to the requirements for such studies in § 1 and § 2.

Chapter 3

More detailed requirements for labelling

§ 6. Those elements and features that are banned as per the Tobacco Products Act's § 20, clause 1-4, can include, but are not restricted to, text, symbols, names, brands, figures or other signs.

Chapter 4

Functionality, size etc..

§ 7. Single packets of cigarettes shall be box shaped.

Clause 2. A single packet of cigarettes can be made as a carton or a soft material and must not have an opening that can be closed or sealed again after the first opening, apart from flip-top lids and folding cartons with a hinged lid. With regard to flip-top and hinged lids, the lid must only be hinged on the rear of the single pack.

Clause 3. A single packet of cigarettes shall contain a minimum of 20 cigarettes.

§ 8. Single packs of rolling tobacco shall be box shaped, cylindrical or have the form of a pouch. 'Pouch' refers to a single pack that has the form of either a rectangular pocket with a flap that covers the opening (rectangular pouch) or a standing pouch.

Clause 2. Single packs of rolling tobacco shall contain a minimum of 30 grams of tobacco.

Chapter 5

Coming into force

§ 9. This Order come into force on the 8th of July 2016.

The Danish Health Authority, this 4th of July 2016

SØREN BROSTRØM

/ Hanne Vibjerg

Unofficial Translation

The Act implements parts of the European Parliament's and Council's directive 2014/40/EU of 3rd of April 2014 on mutual harmonisation of member state laws and administrative orders on the production, presentation and sale of tobacco and related products and the abrogation of directive 2001/37/EU, Official Journal of the European Union 2014, no. L 127, page 1.