

ANNEX II

Requirements on studies

Tobacco and related products

According to § 8 (4) of the Austrian tobacco and non-smokers protection law, implementing Article 5(3) of the Directive 2014/40/EU on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, manufacturers and importers shall submit a list of all ingredients, which “[...] shall also be accompanied by the relevant toxicological data regarding the ingredients in burnt or unburnt form, as appropriate, referring in particular to their effects on the health of consumers and taking into account, inter alia, any addictive effects. [...]”

All chemical ingredients of tobacco products or related products are also subject to **Regulations (EC) No 1272/2008 (CLP)** and (EC) No 1907/2006 (REACH). Consequently, according requirements as well as requirements of Directive **2010/63/EU (protection of laboratory animals) need to be fulfilled by toxicological studies**. Furthermore, any submitted data should comply with **OECD principles of Good Laboratory Practice (GLP) and any other internationally recognized and validated methods** to ensure high quality and reliability of information.

All available information on the toxicity of chemical ingredients and emitted substances shall be submitted in readable format (preferably pdf in English or German) via EU-CEG. Special attention shall be drawn to local and systemic toxicity of each ingredient and emission, after short and long term exposure, via the specific route according to the product´s consumption (e.g. inhalation for cigarettes). Besides all information on underlying studies, submitted data shall include a hazard assessment conclusion, hence a DNEL (Derived No Effect Level) or equivalent value, with details on its derivation (Point of departure, assessment factors etc.). Furthermore, science based information on any additive effects of ingredients and emissions shall be submitted.

Note: By **Regulation (EC) 1272/2008 (CLP)** and Regulation (EC) 1907/2006 (REACH) toxicological data on chemical ingredients might already be procurable in many cases.

Electronic cigarettes

According to § 10b (3) Z 3 of the Austrian tobacco and non-smokers protection, implementing Article 20(2)(c) of EU Directive 2014/40/EU, manufacturers and importers shall submit “[...] toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect; [...]” (Directive 2014/40/EU Article 20 2.).

All chemical ingredients of Electronic Cigarettes are also subject to Regulations (EC) No 1272/2008 (CLP) and (EC) No 1907/2006 (REACH). Consequently, according requirements as well as requirements of Directive 2010/63/EU (protection of laboratory animals) need to be fulfilled by toxicological studies. Furthermore, any submitted data should comply with OECD principles of

Good Laboratory Practice (GLP) and any other internationally recognized and validated methods **to ensure high quality and reliability of information.**

All available information on the toxicity of chemical ingredients and emitted substances shall be submitted in readable format (preferably pdf in English or German) via EU-CEG. Special attention shall be drawn to local and systemic toxicity of each ingredient and emission after short and long term exposure via inhalation route. Besides all information on underlying studies, submitted data shall include a hazard assessment conclusion, hence a DNEL (Derived No Effect Level) or equivalent value for each toxicological endpoint, with details on the derivation (Point of departure, assessment factors etc.). Furthermore, science based information on any additive effects of ingredients and emissions shall be submitted.

Note: By Regulation (EC) 1272/2008 (CLP) and **Regulation (EC) 1907/2006 (REACH) toxicological data on chemical ingredients might already be procurable in many case.**

Requirements on consumer preferences

The information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users shall include;

- gender
- age
 - younger than 15 years old
 - older than 15 years old periods of 5 years (e.g. 15 - 19, 20 - 24, 25 - 29...)
- reason for consumption
 - to quit smoking
 - to reduce smoking
- costs
- Other:
- frequency of consumption
 - daily/almost daily
 - occasionally/sporadically
- previous consumption of tobacco products
 - yes/no
- highest level of education
- employment status

Note that these requirements are based on the current level of knowledge and can/must be changed where appropriate. According information will be available on the AGES-website.