



BUNDESMINISTERIUM FÜR  
ARBEIT, SOZIALES, GESUNDHEIT  
UND KONSUMENTENSCHUTZ



# Guideline

for approval

## of novel tobacco products

pursuant to § 3(2) of the Ordinance with regard to the  
approval of novel tobacco products (NTZuIV as  
amended)

(September 2018)

## Authorisation of novel tobacco products

in accordance with § 10a Tobacco and Non-Smoking Protection Act (TNRSG) (BGBl. Nr. 431/1995 as amended) and the Ordinance on the Approval of New Tobacco Products (NTZulV) (BGBl. II No. 42/2017 as amended)

In Austria, new tobacco products according to §10a TNRSG may only be placed on the market if they are approved. The application for approval must be submitted electronically to the assessment body of the Austrian Agency for Health and Food Safety Ltd. (AGES).

A novel tobacco product under the TNRSG is a tobacco product that

- does not fall into one of the following categories: cigarettes, rolling tobacco, pipe tobacco, water pipe tobacco, cigars, cigarillos, chewing tobacco, snuff and oral tobacco
- was first placed on the market after 19 May 2014

An applicant for approval may only be who intends to place the product for which approval is sought on the Austrian market.

The assessment body shall assess the product for which approval is sought and prepare an expert opinion on the product. The result of the assessment shall determine whether or not the product, when used as intended (as a smoked tobacco product or a smokeless tobacco product), complies with the applicable requirements of the TNRSG, including the regulations issued on its basis. Since novel tobacco products are products that are not yet known in their respective form and have therefore not been tested, it is always necessary to decide which methods are to be used in each individual case when evaluating them.

The valuation by AGES generally includes, and if applicable

- Analysis of ingredients
- Measurement of emissions
- Product safety testing
- Control of compliance with appearance regulations
- Evaluation of the submitted documents\* (studies, test reports, risk-benefit analysis, etc.)

As the admission assessment is a case-by-case assessment, it may take some time.

An application for authorisation does not replace the notification obligations (EU CEG) generally applicable to tobacco products.

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\* For information intended for consumers:

- The statements must correspond to the results of underlying scientific studies and must not represent generalised conclusions of such studies.
- It must not be suggested that the use of the product in question does not pose a health risk or even give the appearance of a health benefit.
- The statements must not be directed specifically at the target group of young people.

## Watchlist Application for admission

The fee for the admission of new tobacco products according to § 10a TNRSG is 7.953,-- Euro and has to be paid to AGES at the latest four weeks after application.

If an application for admission is withdrawn within four weeks of submission of the application, or if the applicant fails to comply with any improvement order or fails to do so in due time and the application is therefore rejected, 10 % of the admission fee shall be payable. If the application is withdrawn after four weeks have elapsed since the application was submitted or if an application for admission is rejected, the entire admission fee must be paid.

The form (link) must be accompanied by the following documents:

- instruction manual
- Technical data
- List of all ingredients and additives
- List of emissions
- Information on material properties
- information on product safety and quality assurance and the measures envisaged to that end
- References to current expert opinions, test reports or scientific work
- Scientific studies on toxicity, addiction potential and attractiveness
- studies, summaries thereof and market research on the preferences of different consumer groups
- Risk-benefit analysis, expected impact on exit/entry tobacco consumption, expected consumer perception
- Sample with label
- Admission documents for an application for admission in another EU Member State (if available)

AGES may - if it considers that the information is incomplete - request additional documents.