

## **ANNEX I**

The guideline and its referring documents should help all submitters to fulfill their submission obligation correctly and completely.

This guideline gives information on national requirements and supplementary information on certain data fields of the European submission system Common Entry Gate (EU-CEG) and is structured according to the Data Dictionary of the European Commission (available under [https://ec.europa.eu/health/euceg/download\\_en](https://ec.europa.eu/health/euceg/download_en)).

Under this URL you can also find translations of the data fields into all EU-languages.

### Note:

- With regard to below stated attachments (marked yellow):  
Either the required data or a declaration that this data is not available (if true) has to be submitted.
  
- The required studies as well as the information on various consumer groups (§ 10d (1) Z 2 TNRSG) must fulfill the requirements of ANNEX II
  
- All files must be made available as PDF or PDF/A

<b>Attachments according to Austrian national law (TNRSG)</b>	<b>Regulated by</b>
<b>Applying to Tobacco Products and E-Cigarettes</b>	
1. take-over declaration of the submitter on behalf of the manufacturer (if true)	§ 8(2)(3) TNRSG <sup>1</sup>
2. methods of measurement of emissions other than for TNCO	§ 8(4b) TNRSG
3. internal/external studies <u>available</u> on market research and preferences	§ 8(8) TNRSG
4. summaries of market surveys <u>carried out</u> launching a new product	§ 8(8) TNRSG
<b>Applying to Cigarettes and RYO-Tobacco</b>	
5. technical document setting out a general description of additives used and their properties	§ 8(4a) TNRSG
6. comprehensive studies on additives of priority list (if true)	§ 8a(2) TNRSG
<b>Applying to E-Cigarettes</b>	
7. information on nicotine dose and uptake	§ 10b(3) Z 4 TNRSG
8. description of the components of the product (incl. opening and refill mechanism)	§ 10b(3) Z 5 TNRSG
9. description of the production process, including whether it involves series production and	§ 10b(3) Z 6 TNRSG
10. information on the preferences of various consumer groups	§ 10d(1) Z 2 TNRSG
11. executive summaries of any market surveys <u>carried out</u> , including an English translation thereof	§ 10d(1) Z 4 TNRSG
<b>Applying to Novel Tobacco Products</b>	
12. detailed description of the novel tobacco product and instruction for use	§ 10a(2) Z 1 TNRSG

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<sup>1</sup> [Austrian national tobacco law \(Tabak- und NichtraucherInnen- bzw. Nichtraucherschutzgesetz \(TNRSG\), BGBl. Nr. 431/1995, in der Fassung des Bundesgesetzes BGBl. I Nr. 22/2016\)](#)

13.	<u>available</u> scientific studies on toxicity, addictiveness and attractiveness	§ 10a(2) Z 3 TNRS
14.	<u>available</u> studies, executive summaries thereof and market research on preferences	§ 10a(2) Z 4 TNRS
15.	other <u>available</u> and relevant information (risk/benefit analysis...)	§ 10a(2) Z 5 TNRS
16.	Evidence of business license	§ 5(3) Z 2 NTZuV <sup>2</sup>
17.	Product information	§ 5(3) Z 5 lit. a, b, c, e, NTZuV
18.	Current referring reports, academic works etc	§ 5(3) Z 6 NTZuV
19.	Information on product safety, quality assurance and description of measures taken	§ 5(3) Z 7 NTZuV

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<sup>2</sup> [Registration regulation \(Verordnung der Bundesministerin für Gesundheit und Frauen hinsichtlich der Zulassung neuartiger Tabakerzeugnisse \(NTZuV\), BGBl. II Nr. 42/2017\)](#)