Regulation of e-cigarettes in Germany and other EU countries: Differences, obstacles, solutions

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Introduction to TPD2 regulation

Article 20 of the EU directive concerning the manufacture, presentation and sale of tobacco and related products (April 2014)

- Product limitation
- Product notification
- Product presentation
Introduction to TPD2 regulation

**Product limitation**
- max. 20mg/ml Nicotine
- max. 10ml bottles (2ml for tanks)
- forbidden additives / ingredients
- consistent nicotine delivery
- child- & tamperproof, non-leaking, non-breaking

**Product notification**
- 6 months before market entry; fees possible
- annual submission of data on sales, consumers, ...

**Product presentation**
- leaflet and warnings on outer packaging required
- restrictions on commercial communication
Introduction to TPD2 regulation

Article 20 of the EU directive concerning the manufacture, presentation and sale of tobacco and related products (April 2014)

01.1 Product limitation

01.2 Product notification

01.3 Product presentation
Agenda

01. Introduction to TPD2 regulation

02. Transposition examples

03. Effectiveness and problems

04. Solutions and outlook
Differences in interpretation and implementation of the EU directive regulation on national levels

- **United Kingdom**
- **France**
- **Germany**
Transposition examples

United Kingdom
• 2ml max applies to all tanks
• no additional “forbidden ingredients”
• Notification fees: 150 GBP (+60 GBP p.a.)
• no real 6 months waiting period (40k entries); extensive guidance by MHRA available
• annual submission of data is enforced
• restrictions on ads, guidance by ASA available
• no restrictions on public usage

France

Germany
Transposition examples

France
- 2ml max applies to disposable cartridges w/ nicotine only
- presentation as smoking cessation = medicinal product
- no additional “forbidden ingredients”
- Notification fees: 295€ (no annual fees)
- only nic-containing products are notified (37k entries)
- additional “national notification” required for nic-products
- annual submission of data is enforced
- restrictions on ads, public usage

Germany
Transposition examples

United Kingdom     A152
France             A152

Germany
• 2ml max applies to disposable cartridges w/ nicotine only
• extensive list of additional “forbidden ingredients”
• Notification fees: none
• strict 6 months waiting period; multiple notifications for same product from every importer, (132k entries)
• annual submission of data not enforced
• restrictions on ads, not on public usage
• Discussion on expanding regulation to nic-free liquids
Transposition examples

**Differences** in interpretation and implementation of the EU directive regulation on national levels

- **02.12** United Kingdom
- **02.12** France
- **02.13** Germany
Agenda

01 Introduction to TPD2 regulation
02 Transposition examples
03 Effectiveness and problems
04 Solutions and outlook
### Effectiveness and problems

<table>
<thead>
<tr>
<th></th>
<th>UK</th>
<th>FR</th>
<th>GE</th>
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<tbody>
<tr>
<td>Number of notifications</td>
<td>40k</td>
<td>37k</td>
<td>132k</td>
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<tr>
<td>Number of authorities</td>
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<td>16+</td>
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<td>Release of new device</td>
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<td>0 d</td>
<td>6 mon</td>
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<tr>
<td>Refillable tanks size</td>
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<td>∞</td>
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<tr>
<td>Forbidden ingredients</td>
<td>few</td>
<td>few</td>
<td>many</td>
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</table>

- Lack of enforcement; lack of proficiency
- Cross-border-sales, direct imports (gearbest/ebay/amazon)
- Distortion of trading conditions, lack of harmonization
Agenda

01. Introduction to TPD2 regulation

02. Transposition examples

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Solutions and outlook

- Evaluation, Harmonization
- National pressure & education
- ECI “Vaping is NOT tobacco”
Agenda

- **A01** Introduction to TPD2 regulation
- **A02** Transposition examples
- **A03** Effectiveness and problems
- **A04** Solutions and outlook
Thank you for Your attention

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