

6th Global Forum on Nicotine

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

Michal Dobrajc

Verband des eZigarettenhandels (VdeH)

German Electronic Cigarette Trade Association

Friday, June 14th 2019



Agenda

01

Introduction to TPD2 regulation

02

Transposition examples

03

Effectiveness and problems

04

Solutions and outlook



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**

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

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 GDPR 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

0211

United Kingdom

0212

France

A152

0213

Germany

A152



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

A152

Germany

A152

United Kingdom

A152

France

- 2ml max applies to disposable cartridges w/ nicotine only
- presentation as smoking cessation = medicinal product
- no additional “forbidden ingredients”
- Notification fees: 295€ (A152 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

A152

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

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

0211

United Kingdom

0212

France

A152

0213

Germany

A152





Agenda

01

Introduction to PSD2 regulation

02

Transposition examples

03

Effectiveness and problems

04

Solutions and outlook



	UK	FR	GE
Number of notifications	40k	37k	132k
Number of authorities	1	1	16+
Release of new device	2-4 wk	0 d	6 mon
Refillable tanks size	2 ml	∞	∞
Forbidden ingredients	few	few	many

- **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

03

Effectiveness and problems

04

Solutions and outlook



04.12

Evaluation, Harmonization

04.12

National pressure & education

04.13

ECI “Vaping is NOT tobacco”





Agenda

01

Introduction to TPD2 regulation

02

Transposition examples

03

Effectiveness and problems

04

Solutions and outlook



**Thank you for
Your attention**

Michal Dobrajc

Verband des eZigarettenhandels (VdeH)

German Electronic Cigarette Trade Association

michal.dobrajc@vd-eh.de

www.vd-eh.de