

Vejledning til registrering af genopfyldningsbeholdere og elektroniske cigaretter uden nikotin i EU-CEG til markedsføring i Danmark

Scope

Denne vejledning beskriver, hvordan man **udfylder** obligatorisk information i EU-CEG XML creator tool til anmeldelse af genopfyldningsbeholdere og elektroniske cigaretter uden nikotin til markedsføring i Danmark.

Denne vejledning dækker ikke de tekniske beskrivelser af de anvendte it-værktøjer.

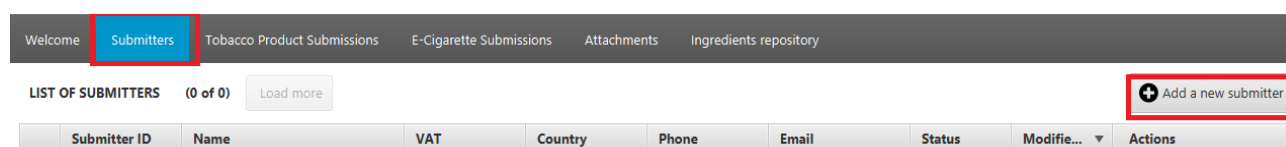
Hvis du har brug for almindelig brugervejledning, kan du bruge [EU-CEG Step-by-step guide](#)

Det anbefales at benytte step by step guiden for at få en mere detaljeret teknisk assistance til EU-CEG XML anmeldesystem. Den beskriver, hvordan du opretter en ny EU-login-konto, hvor du finder XML creator tool og XML upload tool og hvordan man arbejder inden for disse miljøer; hvordan man opretter XML anmeldelser, og hvordan man afsender nøgleoplysninger til de kompetente myndigheder i de respektive EU-lande.

Hvis du ikke har et indberetter-ID, skal du ansøge om et indberetter-ID inden XML creator tool og XML upload tool kan anvendes. XML creator tool opdateres løbende på [CIRCABC](#). Her findes der også en vejledning til at hente XML creator tool til sin PC. Der findes en [data dictionary](#) for felterne og felterne er beskrevet i bilaget til [Kommissionens gennemførelsesafgørelse \(EU\) 2015/2183](#) af 24. november 2015.

Submitters

På forsiden af EU-CEG XML creator tool, klik på 'Submitters' og herefter på '+ Add a new submitter'.



The screenshot shows the top navigation bar of the EU-CEG XML creator tool. The 'Submitters' menu item is highlighted with a red box. Below the navigation bar, there is a section titled 'LIST OF SUBMITTERS (0 of 0)' with a 'Load more' button. To the right of this section, there is a button labeled '+ Add a new submitter', which is also highlighted with a red box. Below the button, there is a table with the following columns: Submitter ID, Name, VAT, Country, Phone, Email, Status, Modifie..., and Actions.

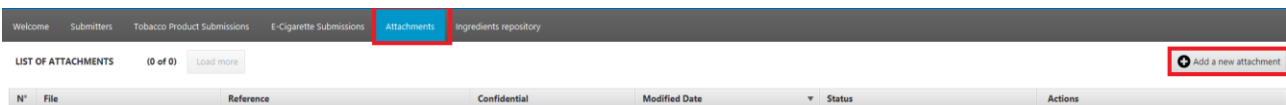
Submitter ID	Name	VAT	Country	Phone	Email	Status	Modifie...	Actions
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Udfyld oplysning om indberetter.

Vedhæftede filer

Før du starter registreringen, skal vedhæftningsfiler først tilføjes, for at kunne vælge dem senere i processen. Du har som minimum brug for en 'E-cigaretteproduktionsfil' i registreringsprocessen for e-væsker uden nikotin.

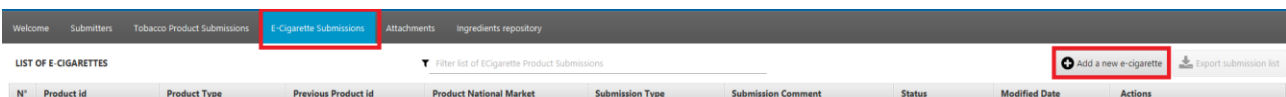
På forsiden af EU-CEG XML creator tool, klik 'Attachments' og 'Add a new attachment'.



Nu kan vedhæftningsfilerne vælges fra siden med e-cigarette anmeldelse.

E-cigarette Submissions – Genopfyldningsbeholdere og engangs e-cigaretter uden nikotin

På forsiden af EU-CEG XML creator tool, klik 'E-cigarette Submissions' og 'Add a new e-cigarette'.



I de følgende afsnit er krav til de obligatoriske oplysninger angivet for hvert faneblad. Hvis du har yderligere information, er du velkommen til at angive oplysningerne i de relevante felter.

Submission info

Submission info | Submitter | Product details | Product presentation | Ingredients | Emissions | Product design

Submission type * 1 - New product Confidential

Previous product ID Confidential

Product type * Other Confidential

General comment E-væske uden nikotin Confidential

*: mandatory to validate the xml

- Vælg 'Submission type'
- Vælg 'Production type' 'Other'
- For genopfyldningsbeholdere uden nikotin: Skriv "E-væske uden nikotin" i 'General comment'
- For engangs e-cigaretter uden nikotin: Skriv "Engangs e-cigaretet uden nikotin" i 'General comment'

Submitter

Submission info | Submitter | Product details | Product presentation | Ingredients | Emissions | Product design

Submitter Type * Select Is Submitter info confidential Select submitter

Submitter Details

Submitter ID * Name *

SME Address *

VAT * Country *

VAT is not avail. Phone *

Email *

Submitter Hierarchy

Has parent company Has affiliate company(ies) Has enterer company Has natural or legal representative company (Art.20(2))

▶ Parent Company

▶ Affiliate(s) company

▶ Enterer company

▶ Natural or legal representative

- Vælg 'Submitter Type'
- Vælg 'Select Submitter'

Product details

Submission info | Submitter | Product details | Product presentation | Ingredients | Emissions | Product design

Product ID * Confidential

Existing other products Confidential Other product Id(s) Confidential List all products you are aware of

Existing other same composition products Confidential Other product(s) with same composition Confidential

Weight of e-liquid (mg) Confidential Volume of e-liquid (ml) Confidential
Per one product unit

CLP Classification (as a mixture) Confidential

Market research files Select a file + - Market studies summary files Select a file + -

Manufacturer identification Confidential

Has Submitter ID	Submitter ID *	Name *	Address *	Country *	Phone *	Email *
<input type="checkbox"/>	<input type="text" value="00000"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="+0000000000"/>	<input type="text" value="email@xxxx.ZZZ"/>

Production site address(es) Confidential Address * Country * Phone Email

* : mandatory to validate the xml

Skriv, som minimum:

- Product ID
- Existing other products
- Existing other same composition products
- Weight of e-liquid (mg) per produktenhed i mg
- Volume of e-liquid (ml) per produktenhed i ml

Product presentation

Start med at klikke på 'Add new presentation' for at aktivere felterne

Submission info | Submitter | Product details | Product presentation | Ingredients | Emissions | Product design

N°	Brand name	Launch date	National Market	Product number type	Product number value
No content in table					

[Add new presentation](#) [delete presentation](#)

N°	Brand name	Launch date	National Market	Product number type	Product number value
1					

National market * *Confidential*

National comment *Confidential*

Brand name * *Confidential*

Brand subtype name exists *Confidential*

Brand subtype name *Confidential*

Launch date * *Confidential*

Withdrawal indication *Confidential*

Withdrawal date *Confidential*

Product number type * *Confidential*

Product number * *Confidential*

Units per packet * *Confidential*

Unit packet picture file

Annual sales data (use "+" button to add additional year)

Sales volume (units) *Confidential*

Sales year *Confidential*

Sales mode

* : mandatory to validate the xml

Vælg eller udfyld, som minimum felterne:

- National market
- Brand name
- Launch date
- Product type number
- Product number
- Units per package

Ingredients

ALLE ingredienser skal være anført her, inklusive alle stoffer fra aromaer ned til CAS-niveauer. Klik på 'Add new ingredient' for at aktivere felterne.

N°	Name	Category	Function	CAS number	FEMA number	Additive number	FL number	EC number	From repository
No content in table									

N°	Name	Category	Function	CAS number	FEMA number	Additive number	FL number	EC number	From repository
1	Glycerol			56-81-5					N

Name * *Confidential*

CAS number exists *Confidential* **CAS number *** *Confidential*

Additional CAS number(s) *Confidential*

Food additive number *Confidential* **FEMA number** *Confidential*

FL number *Confidential* **EC number** *Confidential*

Other number *Confidential*

Toxicity status *Confidential*

REACH registration status *Confidential* **REACH registration number *** *Confidential*

Specific information

Recipe quantity (mg) * *Confidential*

Ingredient function *Confidential* **Other function** *Confidential*

- Name
- CAS number
- Recipe quantity (mg) (per production unit)
- Toxicity status
- REACH registration status

Specific information

Recipe quantity (mg) * *Confidential*

Ingredient function *Confidential* **Other function** *Confidential*

Kit - Identify container/cartridge *Confidential*

Should the kit contain multiple e-liquids, please clarify for which container/cartridge the indicated quantity applies (ID or name)

CLP

CLP whether classification *Confidential*

CLP acute tox oral *Confidential* **CLP acute tox dermal** *Confidential*

CLP acute tox inhalation *Confidential* **CLP skin corrosive/irritant** *Confidential*

CLP eye damage/irritation *Confidential* **CLP respiratory sensitisation** *Confidential*

CLP skin sensitisation *Confidential* **CLP mutagen/genotox** *Confidential*

CLP carcinogenity *Confidential* **CLP reproductive tox** *Confidential*

CLP aspiration tox *Confidential*

CLP STOT *Confidential*

CLP STOT description
Reference to relevant exposure type(s) and specific organ(s) affected
 Confidential

- CLP whether classification

Toxicity data

Tox data availability *	<input type="checkbox"/>	<input type="checkbox"/>	Confidential	<input type="checkbox"/>
Tox CMR	<input type="checkbox"/>	<input type="checkbox"/>	Confidential	<input type="checkbox"/>
Tox additive	<input type="checkbox"/>	<input type="checkbox"/>	Confidential	<input type="checkbox"/>
Tox emission	<input type="checkbox"/>	<input type="checkbox"/>	Confidential	<input type="checkbox"/>
Tox cardio pulmonary	<input type="checkbox"/>	<input type="checkbox"/>	Confidential	<input type="checkbox"/>
Other tox	<input type="checkbox"/>	<input type="checkbox"/>	Confidential	<input type="checkbox"/>

Tox CMR files	<input type="text"/>	Select a file	+ -
Tox Additive files	<input type="text"/>	Select a file	+ -
Tox Emission files	<input type="text"/>	Select a file	+ -
Tox CardioPulmonary files	<input type="text"/>	Select a file	+ -
Tox other files	<input type="text"/>	Select a file	+ -

* : mandatory to validate the xml

- Tox data availability

Emissions

Emissionsoplysninger er ikke et krav

Submission info | Submitter | Product details | Product presentation | Ingredients | Emissions | Product design

N°	Name	CAS number	IUPAC number	Quantity (without unit)	Unit of measurement
No content in table					

Add new emission | Delete emission

Product(s) used for testing
If additional product(s) required for use/testing

Product(s) used for testing
If additional product(s) required for use/testing

Emission Name * Confidential

Emission IUPAC name Confidential

Emission CAS number Confidential

Emission name if other Confidential

Emission CAS number Confidential

Unit of measurement * Confidential

The unit in which this emission is measured

Product combination measured
If more than one combination of e-cigarette and refill container included

Method description file * Select a file

* : mandatory to validate the xml

Product design

Submission info | Submitter | Product details | Product presentation | Ingredients | Emissions | Product design

Description to facilitate product identification * Confidential

Including description of all items and individual parts

Volume / capacity (ml) Confidential

Tank size for device; actual volume for cartridge/container

Battery type Confidential

Battery type capacity (mAh) Confidential

Volt/Watt adjustable * Confidential

Voltage (V) Confidential

Voltage lower range (V) Confidential

Voltage upper range (V) Confidential

Wattage (W) Confidential

Wattage upper range (W) Confidential

Wick changeable Confidential

Airflow adjustable Confidential

Coil composition Confidential

Coil resistance Confidential

If kit has more than one coil, provide the value of the lowest resistance

Production conformity decl. Confidential

Quality and safety responsibility declaration Confidential

High purity declaration Confidential

Non risk human health declaration Confidential

Consistent dosing declaration Confidential

Kit - identification of e-cig device/container/cartridge Confidential

Child resistant and tamper proof declaration Confidential

Nicotine dose/uptake file * Select a file

Production file * Select a file

Opening/refill description file Select a file

Leaflet / Information for consumers file Select a file

Consistent dosing methods file Select a file

Vælg eller udfyld, som minimum:

- Description to facilitate product identification
- Volume / capacity (ml)
- Production conformity decl.
- Child resistant and tamper proof declaration

- Quality and safety responsibility declaration
- Non risk human health declaration
- Production file

Færdiggørelse

Når alt er udfyldt skal XML filen gemmes ved at klikke på 'Save'. Det kan anbefales at klikke på 'Validate' som kontrol for at alt er udfyldt.



Hvis alt ikke er udfyldt, vil der komme en pop up besked om, hvad der mangler at bliver udfyldt. Ellers kommer der en besked om at den pågældende XML fil er 'valid'

E-Cigarette Product Submission is valid.

Close

Herefter skal XML filen uploades til EU-CEG systemet.

Det er til enhver tid en submitters ansvar, at det oplyste er korrekt.