Tubakatoodete ja e-sigarettide KKK

Q1: Which are the notification fees/product for your country? IsThere are annual fees/product? If yes which is the amount of the annual fees/product?

A1: There are no fees for notification or annual fees in Estonia.

Q2: Are the cross border sales of electronic cigarettes and e-liquids to customers permitted to your country?

A2: Cross border sales of electronic cigarettes and e-liquids is prohibited.

Q3: Can you give me guidance as to what is required, in order that we can supply the Estonian company, and that they can in turn sell our products within the Estonian market?

A3: You have to make notifications for Your products in EU-CEG database for Estonia or if You have already notified for other countries, then just mark Estonia and Estonian company in Your already existing notification.

Q4: Kas Prantsusmaalt tohib saata prantsuskeelse märgistusega pudeleid, kui me ise sildid külge paneme?

A4: Prantsuskeelse märgistusega pudeleid tohib saata tingimusel, et enne müüki jõudmist Te lisate neile nõuetekohase eestikeelse märgistuse.

Q5: We would like to ask whether both importer and manufacturer(outside EU) need to submit notification for the same product?

A5: If manufacturer has already made the notification then he should mark there importer as well and countries where this product will be sold and then importer has no need to make the new notification for the same product.

Q6: We want to know for what compunds do you require emission testings.

A6: As we have seen, components of each e-liquid are slightly different, so we cannot give You the full list of compounds that should be tested. So let me put it this way: we would like to see emission tests for all emitting substances, especially for substances that are classified as dangerous according to CLP regulation (like nicotine).

Q7: Is there any methodology or condition that needs to be observed when testing e-cig products according to the requirements of the common notification?

A7: We haven’t developed any certain guidlines for testing e-cig products according to the requirements of the common notification, we just follow the requirements of directive 2014/40 and Estonian Tobacco Act.

Q8: Is there any guidance page for notifications? Where it can be found?

A8: In Estonia this guidance page (in Estonian) can be found here: http://www.terviseamet.ee/kemikaaliohutus/toodete-ohutus/tubakatooted.html and the main page is European Commission page of course: http://ec.europa.eu/health/euceg/step_by_step_en

Q9: Whether it would be acceptable for placing on the unit packet only information about the names of used aromas/flavours without giving details of what substances they are composed of. Or do you require a detailed list of all chemicals regardless of the confidential concentration 0,1%.

A9: On the package should be given the details of ingredients of aromas/flavours (name of the chemical compounds). We take into account the Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 Article 6 point 2a, according to which Commission considers components less than 0,1% as confidential. According to this You do not have to indicate on the labelling of the product ingredients which content in the final mixture is less than 0,1%, unless it is not in conflict with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 (CLP-regulation). It means, that according to CLP regulation Art 18 (1) and (3) b:

1. The label shall include details permitting the identification of the substance or mixture (hereinafter referred to as 'product identifiers').

3. The product identifier for a mixture shall consist of both of the following:

b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard.

As e-liquids are chemical mixtures, they have to meet the requirements of TPD (Tobacco Act in Estonia) and CLP-regulation as well. So if there is an ingredient in the mixture, which content is less than 0,1%, but which changes mixture classification to above mentioned way, then it is not considered as a confidential component and it should be indicated on the labelling of the product.

Q10: We are going to placed e-liquids on Estonian market. Where we can find some information about what we should prepare in this subject? Please, can You give us some information about Your local legal basis in TPD Directive.

A10: In Estonia e-liquids are regulated by Tobacco Act, which English version You can find here: https://www.riigiteataja.ee/en/eli/511072016005/consolide

Q11: My question this time is about the leaflet. What do you think about such solution, that there is no leaflet attached and all information from the leaflet are placed on the unit packet (cardboard box)? Is this kind of idea acceptable in your country?

A11: According to Estonian Tobacco Act §16^2 (4):

The sales packaging of pre-filled electronic cigarettes and refill containers shall include a leaflet with information on:
1) instructions for use and storage of the product, including a reference that the product is not recommended for use by non-smokers;
2) contra-indications;
3) warnings for specific risk groups;
4) possible adverse effects;
5) addictiveness and toxicity;
6) contact details of the undertaking importing these products into Estonia for transfer or the undertaking manufacturing tobacco products in Estonia.

This means that leaflet is required by the law and should be included to sales package.

Q12: I would like to ask about non-nicotine products, are there any requirements coming from TPD regulation in your country or your national law.

A12: According to Estonian Tobacco Act § 31. Products related to tobacco products
(1) “Products related to tobacco products” are:
1) products used similarly to tobacco products which imitate consumption of tobacco products and products used to replace tobacco products, including electronic cigarette, herbal products for smoking, different materials to replace waterpipe tobacco and tobacco-free snus, regardless of the nicotine yield of such products.

So the requirements are the same like to other products realted to tobacco products.

Q13: Question about adding new brand names to already notified products, is this kind of modification is free of charge, and if we add a new brand name will it have to wait 6 months to be placed on the market, and is it correct to do this by adding new "product presentation" in the xml-tool?

A13: Regarding cost of adding new brand names please be informed, that notification in Estonia has no state fees, so it is free. And yes, reporting of new products means, that notification should be made 6 months before placing on the market. And it is correct to add new „product presentation“.

Q14: Regarding e-cigarettes the time gap from notification to putting on the market is in 99.9% of EU until 6 month and not 6 month, is it the same in Estonia or Estonia have different way ? If it is 6 months can You or somebody in Estonia make it faster and to save us a lot of money and to let us to make it good and as need in Estonia and to help our customer ?

A14: TPD was taken over by each Memberstate a little differently. Estonian Tobacco Act clearly states: „Undertakings importing electronic cigarettes or refill containers or electronic cigarettes and refill containers into Estonia for transfer or undertakings manufacturing these in Estonia shall submit to the Health Board a report in electronic form six months before the intended placing on the market of a product or for each substantial modification of the product.“

So we can’t make process any quicker.

Q15: We use box of ten pcs as transport box without any printing and we are giving one sticker on top to close the box and make note on flavor and nicotine. After TPD does box of ten (transportation box) need to have frame with warning? If so what is the size of frame and how much of area it need to cover? How many languages does it need to contain? Does the box of ten need to have printed ingredient list or label is acceptable? Also frame with warning can be sticker or need to be printed?

A15: Regarding demands for labelling Estonian Tobacco Act states:
(1) Pre-filled electronic cigarettes and refill containers shall comply with the conditions provided for in subsections 11 (1) and (2), except for clauses (2) 1) and 2), of this Act, and the following information shall appear on each sales packaging and the grouped packaging directly covering the sales packaging:
1) a list of the ingredients contained in the product in descending order of the weight;
2) an indication of the nicotine content of the product and the delivery per dose;
3) the batch number;
4) a recommendation to keep the product out of reach of children.

Q16: SubmitterA (ID: 00001) submits products 00001-16-00001 with brand "Alpha" on December 28th 2016, products can be sold on May 28th 2017 under brand "Alpha". Submitter (ID: 00002) buy same products from submitterA (ID00001)sold under brand "Beta" and registers under number 00002-17-00001 on February 15th 2017 referring to products 00001-16-00001 in its own submission (00002-17-00001). Can Submitter B start to sell on May 28th 2017 or should it wait until August 15th 2017 to start selling?

A16: If the brand name changes and package too, then we consider it as a new product. So in the case You presented in Your letter product „Alpha" can be sold on June 28th 2017 (delay from notification is 6 months) and product „Beta" can be sold on August 15th 2017 (delay from notification is 6 months).

Q17: Do you know the date by which manufacturers and importers of tobacco and related products (e.g.: e-cigarettes and refill containers) have to report their sales volumes per brand and type yearly?

A17: We would appreciate if we receive reports of sales volumes per brand and type yearly during the first half of the year (data about 2016 we would like to receive before July 01, 2017 etc.).

Q18: Is there now available tobacco products register list in Estonia?

A18: There is available list of notifiers of tobacco products and e-liquid products (18.01.2017) and tar, CO and nicotine content in cigarettes. Tables with these data You can find on:

1. http://www.terviseamet.ee/fileadmin/dok/Kemikaaliohutus/tooted/tubaka_statistika.pdf
2. http://www.terviseamet.ee/fileadmin/dok/Kemikaaliohutus/tooted/e-sigarettide_statistika.pdf
3. http://www.terviseamet.ee/fileadmin/dok/Kemikaaliohutus/tooted/Tubakatoodete_koostis.pdf

Q19: What e-cigarette products need to be notified?

A19: The non-inclusive list of products, that should be notified is the following:

1. Electronic cigarette – Disposable.
2. Electronic cigarette – Rechargeable, device only Any rechargeable which can also be used as a refillable should be reported under the refillable category.
3. Electronic cigarette – Rechargeable, placed on the market with one type of e-liquid (fixed combination). Any rechargeable which can also be used as a refillable should be reported under the refillable category
4. Electronic cigarette – Refillable, device only.
5. Electronic cigarette – Refillable, placed on the market with one type of e-liquid (fixed combination).
6. Individual part of electronic cigarette capable of containing e-liquid.
7. Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge.
8. Refill container/cartridge containing e-liquid.

Q20: A refillable tank sold without eliquid, is this limited to the 2ml limit like the pre filled tanks and disposable cartridges?

A20: Nicotine-containing disposable electronic cigarettes and single use cartridges or tanks shall not exceed a volume of 2 ml. Nicotine-containing refill containers of electronic cigarettes shall not exceed a volume of 10 ml.

Q21: The child proof requirements, in the UK they have said this can be achieved by:
a) making the product child proof
b) making the products packaging child proof
what is your position on this?

A21: We think the same way as UK.

Q22: Can we just send one comprehensive annual report for all the registered product by email ? Some of the MS have already acceptable this way.

A22: We would prefer to receive this information through EUCEG portal. This is more secure system than e-mail.

Q23: Kas Eestis on peale TPD jõustumist (20. Mai 2017) lubatud müüa elektroonilise sigareti vedelikku ka multipakis? Täpsustaks, et TPD järgi ei tohi ÜHE pudeli mahutavus olla suurem kui 10 ml.

A23: Pakendiseaduse mõistes on antud juhul tegemist rühmapakendiga. Tubakaseaduse § 162 „Elektroonilise sigareti märgistamine“ on toodud ära nõuded rühmapakendile. Kui rühmapakend vastab neile nõuetele ning samuti on ka pudelikesed nõutud ruumalaga ja nõuetekohaselt märgistatud, siis on toodete müük rühmapakendis lubatud.

Q24: Can you please kindly give us advices on the nicotine base liquid? If we sell nicotine base liquid in bulk (kg) to importers in your country , and they remix/modify and repack to individual bottles, should we submit TPD notifications for the nicotine base liquid in bulk or it is the importers'(also the manufacturer of the finished e-liquid) responsibility to register the finished products? Should nicotine base liquid in bulk (kg) comply with TPD?

A24: If You sell this nicotine base liquid in bulk, then it has to be labelled according to CLP-regulation (like all chemicals). And when importer will remix/modify and repack, then this end-product has to comply with Estonian Tobacco Act and CLP-regulation as well and then the notification has to be made by the importer, because then the importer is the responsible person.

Q25: Kas ilma nikotiinita vedelikud tuleb või ei tule registreerida EUCEG andmebaasis?

A25: 0-nikotiiniga e-vedelikud peavad samuti olema registreeritud. Nimelt ütleb Tubakaseaduse § 31 järgmist: Tubakatootega seonduvad tooted on tubakatootega sarnaselt kasutatavad tooted, millega imiteeritakse tubakatoodete tarbimist, ja tooted, mida kasutatakse tubakatoodete asendamiseks, sealhulgas elektrooniline sigaret, taimsed suitsetatavad tooted, erinevad materjalid vesipiibutubaka asendamiseks ja tubakavaba huuletubakas, sõltumata nende toodete nikotiinisisaldusest.

Sellest punktist lähtuvalt peavad kõik tubakatootega sarnaselt kasutatavad tooted olema registreeritud, sõltumata sellest, kas nad sisaldavad nikotiini või mitte.

Q26: Kas tootearenduseks mõeldud üksikuid näidiseid oleks võimalik tellida ka ilma teavituseta, kuna pole kindel, kas need tooted meie ettevõttele ikkagi sobivad ja kas me tahaksime neid edaspidi müüa?

A26: Kokkuleppel järelevalveasutustega on selline võimalus olemas. Selleks peab tootel olema markeering NOT FOR SALE (nagu mitmetes teisteski liikmesriikides) ning samuti peaks olema vastav markeering/info ka saatelehel, et oleks teada, et tegemist on tootearenduse näidistega. Samuti tuleks eelnevalt saata Eesti Maksu- ja Tolliametile ning Terviseametile nimekiri oodatavatest toodetest ja nende kogustest

Q27: Kas Terviseamet teostab tubakatoodete ja nendega seonduvate toodete analüüse?

A27: Terviseamet tubakatoodete analüüse ei teosta. Euroopa Komisjoni poolt heakskiidetud laborite nimekiri on avaldatud Euroopa Komisjoni kodulehel:
https://ec.europa.eu/health/sites/health/files/tobacco/docs/approved_laboratories_en.pdf

Q28: We have notified our products via Common Entry Gate, including 0 nicotine liquids. Now our marketing department is going to change Glycerol and Propylene Glycol ratio in some of our 0 nicotine products. My question is, if it will be considered as substantial change or minor change? Will it influence the notification process? Should we wait 6 months after this modification or we can sell our products immediately?

A28: if You have already notified about this 0 nicotine liquids, then You just have to make the correction in EUCEG database and You do not have to wait additional 6 months after the correction.

6 months waiting period is connected with the date of first notification or with the date of major change. This change we consider as a minor change.

Q29: Kuna pakendil on kirjas "toidumaitsestaja" ning pole ühtegi märget ega seotust e-sigaretiga, saan ma õigesti aru, et ma võin usast/euroopast eraisikuna koduseks tarbimiseks toidumaitsestajaid tellida?

A29: Tubakaseaduse mõistes kui Te omale toidumaitsestajaid tahate tellida ja seos e-vedelikega puudub, siis Terviseamet Teile takistusi ei tee. Igaks juhuks soovitaksime aga toidumaitsestajatele kehtestatud nõuete osas küsida nõu ka Veterinaar- ja Toiduametist, kelle pädevusse toiduained ja maitseained kuuluvad.

Q30: Are electronic cigarettes prohibited in your country to people under 18 years old or 16 years old?

A30: Please be informed, that in Estonia electronic cigarettes are prohibited to people under 18 years old.

Q31: Kas ja kuidas oleks võimalik näha kõiki tooteid, mis on Eestisse e-sigareti tootjate poolt registreeritud?

A31: Selle nimekirja võib leida Terviseameti kodulehelt aadressilt:
http://www.terviseamet.ee/kemikaaliohutus/toodete-ohutus/tubakatooted.html
Selle lehe kõige alumine rida sisaldab linki exceli tabelile, kus on toodud andmed Eestis teavitatud e-sigareti toodete kohta. Tabelit uuendatakse kord kuus.

Q32: Can e-cigarettes be displayed at the point-of-sale like supermarkets, or specialized tobacco shops?

A32: Yes, we have here no restrictions.

Q33: Can e-cigarettes be advertised at theaters movies, social media (such as Facebook), supermarkets selling e-cigarettes, inside specialized tobacco shops, in the windows of specialized tobacco shops?

A33: Any kind of promotion of tobacco products and related products (like e-cigarettes) is prohibited.

Q34: Is there also some list where is possible to see all e-juice names (brands, nikotinstrenghts, tastes etc.) ?

A34: This list is published on our website:
http://www.terviseamet.ee/fileadmin/dok/Kemikaaliohutus/tooted/E-sigaretid.xlsx

Q35: Where can we review the progress of the product submission to confirm if our product notification is complete?

A35: We are not publishing results of review process. If Your notifications are submitted to the EU-CEG system, then consider it's done. If we will find any problems with notifications, then we will inform You.

Q36: Öelge palun, kui me müüme baasi 10 ml pudelites nikotiinisisaldusega 30 mg/ml ja 60 mg/ml, mille põhjaks on propüleenglükool. Aga seda baasi ei kasutata vedelikuna e-sigarettide jaoks, see tähendab, et seda ei saa kasutada vedelikuna e-sigareti täitmiseks. Seda kasutatakse komponendina ise segamiseks, et saada nõrgemaid baase segamiseks nikotiini sisaldusega 3 mg ja 6 mg. Küsimus, kas seda saab müüa sel viisil?

A36: Tarbijatele sellise nikotiinisisaldusega vedelikke ei tohi müüa. Sellise sisaldusega vedelikke võib osta ainult tootja ja kasutada e-vedelike tootmiseks.

Q37: Kas maitsestajatest, mis ei sisalda nikotiini, peab teavitama?

A37: Ei pea.

Q38: I would like to ask you which is the pricing policy for TPD compliant products in your country? In detail: is the economic advantage forbidden in your country? (meaning for example that a 3-pack cannot be cheaper than 3 bottles sold individually – or for example a 6-pack cannot be cheaper than the price of two 3-packs when customers buy it in stores).

A38: Economic advantage is not regulated in Estonian Tobacco Act. So it is not forbidden.

Q39: Our company have already registered our product's TPD report on EU-CEG, will you please check whether the attached list have been approved in Estonia's system?

A39: Please be informed, that information about all notifications we have received on e-cigarettes is published in our website: http://www.terviseamet.ee/fileadmin/dok/Kemikaaliohutus/tooted/E-sigaretid-05.17.xlsx or http://www.terviseamet.ee/kemikaaliohutus/toodete-ohutus/tubakatooted.html and on that page it is the last link.
Updates of these tables are launched once in a month. So that is the place where You can check what notifications we have received.

Q40: Minu õigusi tarbijana on räigelt rikutult. Sigarettide pakkide pealt on eemaldatud tõrva ja nikotiini märgised. Palun olukord viivitamatult normaliseerida ning märgistused taastada. Tegu on aktiivse minu tervise kahjustamisega – kuni uute pakendite lettidele saabumiseni teha kaubandusasutustele ettekirjutus antud informatsiooni edastamiseks nähtaval kohal asuva teabelehega. Ettevõte: Kõik tubakat müüvad ettevõtted

A40: Vastavalt kehtiva tubakaseaduse § 11 lg 2 p 2 „Tubakatoote pakendi märgistus ei tohi sisaldada teavet ega kasutada ühtegi teksti või kujutist, mis annab teavet tubakatoote nikotiini-, tõrva- või

vingugaasisisalduse kohta“. See nõue tuli tubakaseadusesse Euroopa Parlamendi ja Nõukogu direktiivist 2014/40/EL, mille artikli 13 p 1 (a) on öeldud, et „tubakatoote märgistus ei tohi sisaldada mingit teavet tubakatoote nikotiini-, tõrva- või süsinikmonooksiidisisalduse kohta“.
Sellise nõude kehtestamise põhjused on toodud eelnimetatud direktiivi preambulas, mille punktis 25 on öeldud:
„Märgistamist käsitlevaid õigusnorme tuleks kohandada ka vastavalt uutele teaduslikele tõenditele. Näiteks tõrva, nikotiini või süsinikmonooksiidi eraldumise koguse märkimine sigarettide tarbijapakkidele on osutunud eksitavaks, sest tarbijatele jääb mulje, et teatavad sigaretid on muudest sigarettidest vähem kahjulikud.“
ja mille punktis 27 on öeldud „Tubakatooted või nende pakendid võivad eksitada tarbijaid, eelkõige noori, kellel jääb mulje, nagu oleks toode vähem kahjulik. Selline mõju on teatavatel väljenditel, nagu „vähese tõrvasisaldusega” (low-tar), „lahja” (light), „eriti lahja” (ultra-light), „mahe” (mild), „looduslik” (natural), „orgaaniline” (organic), „lisaaineteta” (without additives), „maitse- ja lõhnaaineteta” (without flavours), „peenikesed” (slim), ning nimetustel, piltidel, kujutistel või muude märkidel.“
Seega, kuna kehtivad õigusaktid on keelustanud nikotiini, tõrva ja vingugaasi sisalduste avaldamise tubakatoodete pakenditel, siis puudub igasugune alus ettekirjutuse tegemiseks. Kuna aga on tarbijaid, kes on huvitatud sellistest andmetest, siis on Terviseametile pandud tubakaseadusega kohustus avaldada need andmed oma kodulehel, mida Terviseamet on ka teinud. Andmed tubakatoodete nikotiini, tõrva ja vingugaasi sisalduse kohta leiate Terviseameti kodulehelt aadressil: http://www.terviseamet.ee/fileadmin/dok/Kemikaaliohutus/tooted/Tubakatoodete_koostis.pdf

Q41: I was wondering can you please tell me about the annual report in your country. I would like to know till when such report should be submitted and is there an easier way to do it then trough the EUCEG?

A41: We would like to receive report via EU-CEG, because these data are sensitive and we would like to be sure that data are well protected. The deadline for annual report is not stipulated in Estonian Tobacco Act, but we would prefer to receive it before July 1, 2017.

Q42: Meil on küsimus seoses e-vedeliku tootmise ja turustamisega Eestis. Nimel oleks mõte hakata tootma kodumaist e-vedelikku, mis sisaldab ka nikotiini. Kuidas peaksime asjaga alustama? Kas selleks on tarvis litsentsi? Kui jah, siis kuidas litsents saada? Mis tingimustel võib seda turustada?

A42: Esimese asjana peaksite tutvuma e-vedelikele, nende märgistusele ja pakenditele kehtestatud nõuetega, mis on sätestatud tubakaseaduses, mille leiate aadressilt:
https://www.riigiteataja.ee/akt/128062016005
Samuti peavad e-vedelikud vastama CLP-määruses (Euroopa parlamendi ja nõukogu määrus (EÜ) nr 1272/2008) kehtestatud nõuetele ja olema vastavalt sellele määrusele ka klassifitseeritud, märgistatud ja pakendatud. CLP määruse leiate aadressilt: http://eur-lex.europa.eu/legal-content/ET/TXT/PDF/?uri=CELEX:02008R1272-20160101&qid=1459844569226&from=ET. Kui Teil tekib selle määrusega seoses küsimusi, näiteks kuidas nimetatud määruse alusel midagi klassifitseeritakse vms, siis saate pöörduda CLP-kasutajatoe poole (http://kemikaaliohutus.sm.ee/index.php?id=153).
Samuti on tubakaseaduses sätestatud järgmine kohustus:
Tubakatootest või sellega seonduvast tootest tuleb teavitada EU-CEG portaali kaudu vähemalt kuus kuud enne kavandatavat turuleviimist. Teavituses nõutavad andmed on sätestatud tubakaseaduse §

102. Juhime Teie tähelepanu asjaolule, et mitmete teavituses nõutavate andmete esitamiseks tuleb toodetele teostada ka laboratoorsed uuringud. Eestis hetkel akrediteeritud laborit selleks ei ole, kuid Euroopa Komisjoni poolt heakskiidetud laborite nimekirja leiate aadressilt: https://ec.europa.eu/health/sites/health/files/tobacco/docs/approved_laboratories_en.pdf. Teavituse tegemise juhendi leiate Euroopa Komisjoni kodulehelt: http://ec.europa.eu/health/euceg/step_by_step_en. Selle juhendi kohaselt tuleb Teil esmalt taotleda Euroopa Komisjonilt Submitter ID. Selle taotlemine võib võtta aega kuni 2 nädalat. Pärast selle kättesaamist toimige teavituse tegemiseks selliselt, nagu on kirjeldatud juhendmaterjalis. Eesti jaoks on teavituse tegemine tasuta, kuid kui soovite tooteid ka väljaspool Eestit turustada, siis soovitame pöörduda vastavate riikide pädevate asutuste poole (https://ec.europa.eu/health/sites/health/files/euceg/docs/contact_point_en.pdf), kuna paljudes riikides on teavituse tegemine ja selle jõus hoidmine tasuline.

Q43: I would like to kindly ask you on provision of information whether or not it is possible to sell multipacks of e-liquids (for example bundle packs of 4 refill containers in one packet) on Estonian market?

A43: Group packages are allowed in Estonia.

Q44: Meie ettevõtte kavatseb tegeleda e-sigarettide ja e-vedelikute jaotusega ja tulevikus müügiga Eestis. Nii palju, kui ma tean, seaduse järgi firma ja tooted peavad olema registreeritud Eestis. Firma, kellega me alustame koostööd saatis meile sertifikaatid ja litsentsid. Kuna see on uus valdkond meie ettevõtte jaoks, me ei ole kindel, kas need dokumendid on õiged või mitte. Kas oleks võimalik küsida Teie abi selles küsimuses?

A44: tooted peavad vastama tubakaseadusega kehtestatud nõuetele. Tubakaseaduse leiate aadressilt: https://www.riigiteataja.ee/akt/128062016006 ja selle põhjal saate hinnata ise toodete nõuetele vastavust väliste tunnuste alusel.

Seaduse järgi peavad tooted olema tõepoolest registreeritud. Registreerimine toimub Euroopa Komisjoni poolt hallatava infoportaali EUCEG kaudu. Nimekiri registreeritud toodetest on avaldatud Terviseameti kodulehel, aadressil: http://www.terviseamet.ee/kemikaaliohutus/toodete-ohutus/tubakatooted.html, kust tuleb valida lehekülje alumises osas olev link „seisuga 13. mai“. Nimekirja uuendatakse sagedusega kord kuus. Järgmine uuendus toimub tõenäoliselt järgmisel nädalal. Sealt nimekirjast saate vaadata, kas Teie tootja on juba Eesti kohta teavituse teinud. Kui jah, siis paluge, et ta oma teavituses lisaks sektsiooni „affiliate company“ Teie ettevõtte nime. Kui teavitust ei ole tehtud, siis tuleb see vastavalt tubakaseadusele teha vähemalt 6 kuud enne kavandatavat turuleviimist. See tähendab, et kui teavitus tehakse näiteks 15. juunil, siis müüa tohib tooteid alles alates 15. detsembrist. Teavituse võite teha ka Teie või võib teha tootja. Tubakaseaduse § 10^2 on toodud loetelu andmetest, mis tuleb teavituses esitada. Täpsemat infot teavituse tegemise protseduuri kohta leiab Euroopa Komisjoni kodulehelt: http://ec.europa.eu/health/euceg/step_by_step_en

Dokumentide (sertifikaatide, litsentside jne) õigsuse tuvastamisega Terviseamet ei tegele.

Q45: Do you require all labelling, e.g Nicotine health warning, to be in English or your official language(s). If yes, can you tell me what languages are required?

A45: According to the Estonian Tobacco Act if refill container/electronic cigarette contains nicotine, the health warning should be in Estonian and this has to be the sentence: „See toode sisaldab nikotiini, mis on kergesti sõltuvust tekitav aine." [This product contains nicotine which is a highly addictive substance.].

Q46: Can the ingredients list be in English?

A46: According to the CLP-Regulation (Regulation (EC) No 1272/2008 of the European Parliament and of the Council) Article 17 (2) „The label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise." So the ingredients list should also be in Estonian.

Q47: Can the ingredients list follow the same structure as the UK regulations e.g "Strawberry Flavouring" ?

A47: Yes, but we prefer to have the chemical name (according to IUPAC nomenclature) or CAS No instead of „Strawberry Flavouring".

Q48: Can we still submit notifications for old products at this moment? if yes, how soon can they be sold after submission?

A48: You can submit notifications for old products too, but the waiting time is six months before You can sell the product on the market (Estonian Tobacco Act §10^2 (1)).

Q49: Now, how does it look like in the case, that the product does only consist of propylene glycol (PG) and vegetable glycerin (VG), which are both substances that per se don't underlie the TPD and can be purchased freely? Is it possible, to sell these substances freely, also in bigger packaging sizes, e.g. 100ml?

A49: if this chemical mixture is in the ready-to-use form for electronic cigarettes, then it belongs under Estonian Tobacco Act, according to which:
(1) "Products related to tobacco products" are:
1) products used similarly to tobacco products which imitate consumption of tobacco products and products used to replace tobacco products, including electronic cigarette, herbal products for smoking, different materials to replace waterpipe tobacco and tobacco-free snus, regardless of the nicotine yield of such products;
This means that if these compounds or this mixture reagardless of its nicotine content or flavourings presence is ready to put into electronic cigarette device for consumption, then it is considered as an e-liquid. But if this mixture is not ready to use and by that we mean, that it should be diluted ot there should be added any additional components except flavourings and nicotine that are necessary for giving him the quality of the e-liquid, then it belongs under chemicals regulations.
According to Estonian Tobacco Act only nicotine-containing refill containers of electronic cigarettes shall not exceed a volume of 10 ml (§ 17). So if these mixtures You were asking about are not

containing any nicotine, then even according to the law in force You can sell them in bigger containers.

Q50: Is for your country possible to proceed to have unit packets without leaflet if all required information will be on package in legible format?

A50: According to Estonian Tobacco Act §16^2 (4) The sales packaging of pre-filled electronic cigarettes and refill containers shall include a leaflet with information on:
1) instructions for use and storage of the product, including a reference that the product is not recommended for use by non-smokers;
2) contra-indications;
3) warnings for specific risk groups;
QQ4) possible adverse effects;
5) addictiveness and toxicity;
6) contact details of the undertaking importing these products into Estonia for transfer or the undertaking manufacturing tobacco products in Estonia.
So according to the Estonian national legislation package has to contain a leaflet.

Q51: There is some news saying that in Estonia, e-liquid which doesn't contain nicotine should also be registered and submit TPD notification, is that true?

A51: E-liquids without nicotine should also be notified. This is based on Estonian Tobacco Act § 3^1 (1) according to which "Products related to tobacco products" are products used similarly to tobacco products which imitate consumption of tobacco products and products used to replace tobacco products, including electronic cigarette, herbal products for smoking, different materials to replace waterpipe tobacco and tobacco-free snus, **regardless of the nicotine yield of such products**;

So according to this e-liquids without nicotine also belong under the regulation of Tobacco Act and according to this Act all e-liquids should be notified.

Q52: I would like to ask you if you confirm that also for zero nicotine e-liquids the transition period before placing on the market is 6 months?

A52: Transition period before placing on the market is 6 months for all e-liquids regardless of their nicotine content.

Q53: Is the filter(for cigarette) containing menthol or tobacco flavor allowed in your country?

A53: according to Estonian Tobacco Act: „Cigarettes and roll-your-own tobacco shall not have a characterising flavour. "Characterising flavour" means a clearly noticeable taste or smell other than one of tobacco, resulting from an additive or a combination of additives which is noticeable before or during the consumption of the tobacco product.

The components of cigarettes and roll-your-own tobacco such as filters, papers, packagings and capsules shall not contain flavourings. It is prohibited to use any technical features allowing modification of the taste or smell of tobacco products or their smoke intensity."

Q54: How are nicotine salts regulated in your country? If an e-liquid contains as one of its ingredients some nicotine salt, rather than free-base nicotine, how is it treated and considered in your country? Does this product go under TPD requirements?

A54: Nicotine salts are regulated under the TPD in the same way as nicotine.

Q55: I would like to ask you if, within TPD, your local transposition mentions the limit of 2ml that cartridge and tank must have?

A55: For us 2 ml limit comes from the Estonian Tobacco Act § 17 (3), according to which „Nicotine-containing disposable electronic cigarettes and single use cartridges or tanks shall not exceed a volume of 2 ml."

Q56: Kas e-vedeliku pakendile ja selle märgistusele kehtivad kemikaalide pakenditele ja märgistusele ette nähtud nõuded?

A56: Jah. Tubakadirektiiv art 20(4) /tubakaseadus näeb ette, et e-vedelikud peavad lisaks olema vastavuses ka teiste Euroopa Liidu seadustega, s.h CLP-määrusega, kui need on klassifitseeritud ohtlikuks.

Q57: Kas e-vedeliku pakendi etiketil võib kasutada näiteks marjade pilti?

A57: Ei. CLP-määruse artiklis 35 lg 2 sätestatakse, et elanikkonnale tarnitava aine või segu pakendi puhul ei tohi kasutada sellist kuju ega kujundust, mis võiks tõmmata endale laste tähelepanu või äratada neis aktiivset uudishimu või eksitada tarbijat või mis sarnaneb toiduainete, sööda, ravimite ja kosmeetika puhul kasutatava esitusviisi või kujundusega, mis eksitaks tarbijat.

Q58: Kui suur peab olema CLP piktogramm e-vedeliku märgistusel?

A58: CLP-määruse II lisa punktis 1.2 nähakse, ette, et piktogramm peab katma vähemalt 1/15 märgistuse pinnast, kusjuures selle pind ei tohi olla väiksem kui 1 cm^2.

Q59: Milline teave peab olema CLP-määruse järgi e-vedeliku märgistusel?

A59: CLP-määruse artiklis 17 on toodud, milline teave peab olema ohtlikuks klassifitseeritud kemikaali märgistusel. Kui tubakaseadus nõuab teavet, millega CLP-määruse nõuded kattuvad, esitatakse see teave märgistusel ainult üks kord.

Q60: Kas e-vedelikule peab olema koostatud ohutuskaart?

A60: Jah, REACH-määruse artikkel 31 kohaselt tuleb saajale esitada ohutuskaart, kui segu on CLP-määruse kohaselt klassifitseeritud ohtlikuks.