

***Welcome to the June newsletter of the MHRA E-cigarette Team, our update providing news and advice about the UK notification scheme for e-cigarette products and compliance with part 6 of the Tobacco and Related Products Regulations 2016. This month we will cover Electrical Waste Guidance, Vigilance Requirements and Standards, Adverse Reaction Reporting and Identifying your Products.***

## **Waste Electrical and Electronic Equipment (WEEE) Regulations**

Vapes, or e-cigarettes, are electrical and electronic equipment (EEE). The WEEE Regulations 2013 require producers of EEE to undertake a range of responsibilities to play their part in protecting natural resources and managing EEE appropriately when it becomes waste. This includes registering as an EEE producer and financing the collection and treatment of WEEE. Vape producers therefore need to ensure they are registered to comply with the WEEE Regulations. The definition of an EEE producer can be found [here](#).

You must register as an EEE producer annually. If you place more than 5 tonnes of EEE on the UK market in a year, you must join a producer compliance scheme (PCS). The PCS takes on your obligations to finance the collection, treatment, recovery, and environmentally sound disposal of household WEEE collected in the UK. If you place less than 5 tonnes of EEE on the UK market in a year, you can register directly with your environmental regulator as a small producer. For England, this is the Environment Agency (EA); for Scotland, this is the Scottish Environmental Protection Agency (SEPA); for Wales, this is Natural Resources Wales (NRW); and for Northern Ireland, this is Northern Ireland Environment Agency (NIEA).

You can find more information about your potential WEEE producer responsibility obligations and how you can register [here](#).

OPSS carry out enforcement on behalf of DEFRA for WEEE regulations. Businesses selling electrical and electronic equipment must offer a process of takeback, either in-store or join Valpak compliance to ensure they have a process of taking back waste single use vapes. As a vape distributor you will also need to ensure you have a process in which you are taking back waste single use vapes. Your Distributor obligations can be found [here](#)

## **Batteries Regulations**

Vapes contain portable batteries. The Waste Batteries and Accumulators Regulations 2009 require producers of batteries to take on responsibilities to minimise harmful effects of waste batteries on the environment. This includes registering as a portable battery producer and financing collection and treatment of waste portable batteries. Vape producers therefore need to ensure they are registered to comply with the Batteries Regulations. The definition of a battery producer can be found [here](#).

You must register as a battery producer annually. If you place more than 1 tonne of portable batteries on the UK market in a year, you must join a battery compliance scheme (BCS). The BCS takes on your duties to finance the collection and treatment of waste portable batteries. If you place less than 1 tonne of portable batteries on the UK market in a year, you must register directly with your environmental regulator.

You can find more information about your potential battery producer responsibility obligations and how you can register [here](#).

## **Packaging Regulations**

The Producer Responsibility Obligations (Packaging Waste) Regulations 2007 require obligated producers of packaging to take on responsibilities to reduce the amount of packaging produced and increase the amount that is recycled. This includes registering as a packaging producer and financing collection and treatment of waste packaging. Vape producers may need to ensure they are registered to comply with the Packaging Regulations. The definition of an obligated packaging producer can be found [here](#). If you are an obligated producer, you must either join a compliance scheme or register directly with your environmental regulator. A compliance scheme will take on your duties to finance the collection and treatment of waste packaging.

You can find more information about your potential packaging producer responsibility obligations and how you can register [here](#). You should be aware that the way UK organisations responsible for packaging must carry out their recycling responsibilities is changing. You can find out if you are affected [here](#).

## **Compliance and Enforcement**

The environmental regulators are responsible for monitoring compliance and carrying out enforcement under the WEEE, Batteries and Packaging Regulations. If you meet the definition of a producer under any of the regulations and do not register, then you are committing an offence and may face enforcement action.

If you would like to speak with the EA, you can contact the National Customer Contact Centre via telephone – 03708506506 – or email – [enquiries@environment-agency.gov.uk](mailto:enquiries@environment-agency.gov.uk).

If you would like to speak with SEPA, you can contact the Customer Service General Enquiries via telephone – 03000996699 – or via the contact form [here](#).

If you would like to speak with NRW, you can contact the General Enquiries via telephone – 03000653000 – or email – [enquiries@naturalresourceswales.gov.uk](mailto:enquiries@naturalresourceswales.gov.uk).

If you would like to speak with NIEA, you can contact via telephone – 03002007856 – or email – [nieainfo@daera-ni.gov.uk](mailto:nieainfo@daera-ni.gov.uk).

## **Vigilance Requirements and Standards**

Manufacturers and Producers are reminded that under the Tobacco and Related Products Regulations 2016 (TRPR) it is their responsibility to ensure the products supplied to the United Kingdom meet the required standards. As a result of a number of recent non-compliance incidents the MHRA will be taking steps, in conjunction with Trading Standards and other UK law enforcement agencies, to support industry in ensuring these standards are met.

This is part of a wider [programme of work](#) across government that the MHRA is supporting

to strengthen the current regulations in the UK surrounding vaping, particularly those relating to young people. These steps are outlined under the headings below.

### **Autumn 2023 Multi Agency Webinar**

The MHRA has worked with a number of UK regulatory and enforcement agencies to provide support for ongoing investigations under various vaping-related UK legislation. As a result of this work the MHRA will be hosting a regulatory webinar which will offer all submitters, importers and distributors the opportunity to take part in guidance presentations and a Q&A with a number of UK bodies.

### **Production File Guidance**

During 2023, the MHRA has been reviewing the standard of Production File documentation and as a result will be consulting with regulatory and industry specialists to produce guidance that will clarify the notification requirements for the submission of these documents. The guidance will be published in late 2023 and will provide submitters with enough time to meet the standards set out in the publication. Prior to requiring this information all submitters should review our guidance publications to ensure that minimum [Due Diligence](#) and [Vigilance](#) standards are being achieved across your production, supply chains and post market monitoring .

### **Adverse Reaction Reports**

Please be aware that we will be writing to all producers and UK nominated responsible persons (affiliates) to request information relating to all suspected adverse reactions reported between **January 1<sup>st</sup> 2021 to June 30<sup>th</sup> 2023**.

The information provided should be anonymised to protect patient and reporter confidentiality but contain as much detail as possible. This includes but is not limited to patient characteristics (age, sex), details of the adverse reaction, onset time (including level of use), outcome and the reporter type (member of the public or healthcare professional).

This information, along with your submitter ID, should be submitted by email to [TPDsafety@mhra.gov.uk](mailto:TPDsafety@mhra.gov.uk) by **July 31<sup>st</sup> 2023**. We will require a response even if to confirm that you have not received any reports.

It remains the legal responsibility of producers to establish and maintain a system for collecting information about all of the suspected adverse effects on human health associated with the products you are responsible for. Failure to establish and maintain a vigilance system for notified products subject to the TRPR, or to provide this information to the regulator is an offence.

### **National Trading Standards Flying Squad (Vaping)**

As announced in Minister O'Brien's [speech](#), new "flying squads" are being funded to enforce the rules on vaping and tackle illicit vapes and underage sales. Led by National Trading Standards and supported by the MHRA, these squads will share intelligence across regional

networks, conduct test purchases and remove banned products from shops and at borders.

## **Product Presentation – Brand and Sub-Brands**

### **Removal of Non-compliant Notifications – Product Names and Branding**

The labelling of unit packets and any outside packaging for electronic cigarettes and refill containers and the product itself shall not include any element or feature that: (a) promotes the product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions; “We interpret this as including a prohibition on misleading safety claims, such as that the product is ‘safe’ or ‘risk-free’. It would also preclude claims for any health benefits of using the product. Submitters are reminded that claims for benefits from using the product or from its ingredients including any suggestion of effects on energy or health (and related terms). Any description of an ingredient as of ‘natural’ origin or organically produced would be similarly prohibited. It would not prohibit an accurate statement of fact relating to the non-inclusion of particular components, ingredients or emissions of tobacco products. We interpret these two provisions as preventing any characterisation of a product as ‘light’, ‘mild’ or similar terms.

In summary, the Chartered Trading Standards Institute and MHRA are of the opinion that the use of terms within product names such as “energy “,” mild” and related or similar terms are clearly in breach of the Regulations. As a result, Submitters are required to review their Notifications and make the appropriate changes to Brand and Sub Brand names (including additional presentations of white label products)

This action is required by the **31<sup>st</sup> July 2023** for all new notifications and notification updates. Notifications submitted from the **1<sup>st</sup> January 2021** must be updated by **1<sup>st</sup> September 2023**. Notifications deemed to be non-compliant after this date will be withdrawn from Publication by the MHRA until compliance is achieved.

### **Identifying your product**

The published list is used by Trading Standards enforcement officers, retailers and consumers alike to check whether a nicotine containing Vaping product is indeed notified and published. For this reason, published products should be clearly identifiable. Producers should amend submissions as soon as possible to avoid any confusion in the retail sector when attempting to identify products.

Please ensure you clearly identify products in your submissions by including the product range, flavour name and nicotine strength of your products under the Brand and Brand Subtype headings (see examples below). We would recommend that all producers consider updating their notified products to include this information as soon as possible.

What it should look like:					
Submitter Name	Product id	Brand Name(s)	Brand Sub Type Name(s)	Product Type	TPD compliance
Star Vape Ltd	00307-16-xxxxx	Star Juice	Star Juice E Liquid Menthol 6mg	Refill container/cartridge containing e-liquid.	Declared
What it should not look like:					
Submitter Name	Product id	Brand Name(s)	Brand Sub Type Name(s)	Product Type	TPD compliance
Star Vape Ltd	00307-16-xxxxx	Star Juice	Star Juice E Liquid	Refill container/cartridge containing e-liquid.	Declared

## Providing Affiliate Company information

If you are a manufacturer based outside of the UK, you must ensure that any relevant information is passed on to your primary UK importers/re-branders. In the majority of cases under UK law this will be the primary importers or re-branders of white label products that will be considered liable parties for the purposes of enforcement. To ensure that the MHRA and UK law enforcers are able to communicate issues of non-compliance, defects and safety to the responsible parties, all submitters are required to review their notifications and identify the appropriate "Affiliate Company" (Under Submitter Info tab)

Please ensure that you have saved all the tabs. If not, the unsaved changes will be lost on submission.

Submitter Info

Submitter Info
SA

**Submitter Type: \***

Manufacturer  Submitter has VAT

Submitter SME

**Country: \***

United Kingdom

**Address: \***

TEST ROAD TEST CITY TT1 1TT

**Phone: \***  **Email: \***

Submitter Has Parent Company  
 Submitter Has Affiliate Company  
 Submitter Appoints Enterer

[SAVE SUBMITTER DETAILS](#)

This action is required by the **31<sup>st</sup> July 2023** for all new Type 1 notifications and notification updates. Notifications submitted from the **1<sup>st</sup> January 2021** must be updated by **1<sup>st</sup> September 2023**.

Non-compliant notifications may be withdrawn from publication after this date until appropriate corrective action is taken.

## How to Contact us

For general enquiries please contact our Customer Services team at [info@mhra.gov.uk](mailto:info@mhra.gov.uk).

If you have any questions about the notification status of your products, please send them directly to our TPD mailbox at [TPDnotifications@mhra.gov.uk](mailto:TPDnotifications@mhra.gov.uk).

To update company contact details email [Reference.Data@mhra.gov.uk](mailto:Reference.Data@mhra.gov.uk).

For any safety concerns contact our Vigilance team at [TPDsafety@mhra.gov.uk](mailto:TPDsafety@mhra.gov.uk).

If you encounter any technical difficulties while using the EU-CEG portal, please contact the EU commission IT helpdesk at [SANTE-EUCEG-ITSUPPORT@ec.europa.eu](mailto:SANTE-EUCEG-ITSUPPORT@ec.europa.eu) (including in your message a 'print screen' of the window where the problem appears).

Thank you for your time in reading and sharing this newsletter with your colleagues.

Regards

### **E-cigarette Team**

Vigilance Risk Management of Medicines

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