SUBMISSION OF NOTIFICATIONS UNDER REGULATION 6 OF THE TOBACCO AND RELATED PRODUCTS REGULATIONS 2016

CHAPTER 9 – GENERAL ADVICE ON DUE DILIGENCE - ELECTRONIC CIGARETTES DEVICES AND REFILL CONTAINERS

INTRODUCTION

Part 6 of the [Tobacco and Related Products Regulations 2016](http://www.legislation.gov.uk/uksi/2016/507/contents/made) (TRPR) places obligations on the manufacturers and importers of electronic cigarettes including the requirement to submit a notification to the MHRA of such products they intend to market.

[Regulation 50](http://www.legislation.gov.uk/uksi/2016/507/regulation/50/made) of the TRPRs sets out the defence of due diligence for suppliers of e-cigarettes and e-liquids (refill containers). This requires that the supplier must exercise all due diligence to avoid the committal of an offence.

MHRA has received a number of enquiries about how companies can meet the legal requirements set out above to manufacture and supply safe products to end consumers. This information below is provided as a starting point for submitters to better understand the ongoing requirements of Part 6 of the TRPR.

Be aware of UK regulations that impact your business and ensure you have reviewed and understood the guidance associated with the relevant legislation. The MHRA does not provide business advice. Submitters that need help to be able to understand the legislation and document their due diligence should contact a relevant trade body, specialist E-Cigarette compliance services and if necessary, seek independent legal advice. Additionally, businesses can contact Trading Standards services to enquire about Primary Authority Partnerships.

PRACTICAL ADVICE ON COMPLIANCE

In order to be able to demonstrate that you have exercised due diligence with regard to the quality of your product, it is not sufficient simply to provide the specific information in the notification of your products to the MHRA under [regulation 31](http://www.legislation.gov.uk/uksi/2016/507/regulation/31/made). Information submitted to the MHRA should be retained as part of your technical dossier and made available to regulatory officers upon request.

To demonstrate due diligence for the safety and quality of your products under [regulation 50](http://www.legislation.gov.uk/uksi/2016/507/regulation/50/made), you will need to demonstrate that you maintain and monitor your product and production standards for every batch. You should be able to provide evidence of systems used to record and monitor production and safety for [regulation 31](http://www.legislation.gov.uk/uksi/2016/507/regulation/31/made), [36](http://www.legislation.gov.uk/uksi/2016/507/regulation/36/made), [37](http://www.legislation.gov.uk/uksi/2016/507/regulation/37/made), [38](http://www.legislation.gov.uk/uksi/2016/507/regulation/38/made) and [39](http://www.legislation.gov.uk/uksi/2016/507/regulation/39/made).

To demonstrate that your product is of acceptable quality and safety throughout the shelf-life of the product, you should have data on the stability of representative batches.

You can achieve these requirements by maintainingtechnical dossiers approved by a competent representative of the company for all products manufactured. Where applicable technical dossiers should contain the following information:

* Product specifications for each product supplied with reports of regular batch testing and product development and stability data
* List of ingredients/components used in the formulation/manufacture of the product with information on all components and ingredients use in the manufacture of the product such as documentation provided by flavour houses /3rd party suppliers in respect of base ingredients /components supplied to you, CAS disclosure where applicable and copies of certificates of conformity and/or analysis and Safety Data Sheets and toxicological risk assessmentsrelating to products as required
* Description and validation of the manufacturing process with certifications for manufacturing facilities and records of safety checks carried out in relation to production facilities

For ongoing monitoring of your product, the following will be useful additions to your records:

* Batch data and batch records, including any corrective action required
* Risk assessments, including any corrective action required
* Records of customer complaints and outcomes, including any corrective action required
* Records of ADR reports, tracking and outcomes, including any corrective action required
* Records of safety reports/ongoing screening, including any corrective action required

Submitters should be satisfied that products and processes meet the required standards of the TRPR 2016 and related production industry legislation. Failure to comply with relevant legislation, guidance and accepted/published business practices associated with any production industry can lead to the commission of criminal offences.

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