

The Tobacco and Related Products Regulations 2016 came into full effect in May 2017; this report provides an overview of the compliance of nicotine inhaling devices with these Regulations across participating Regions in England

Rapid Review of Nicotine Inhaling Product Compliance with the Tobacco Product and Related Products Regulations : 2017

Carried out by Trading Standards Services in England



Chartered Trading Standards Institute

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CONTENTS

| | |
|--|----|
| Summary & Key Points | 2 |
| Phase 3: Nicotine Inhaling Products | 2 |
| 1. Introduction..... | 3 |
| 2. Purpose..... | 3 |
| 3. Scope | 3 |
| 4. Method | 4 |
| 4.1 Method: Notifications | 5 |
| 5. Phase 3: Results | 6 |
| 5.1 Phase 3 – Vists by premise type | 6 |
| 5.2 Phase 3– TRPRs Product Compliance – E cigarettes | 7 |
| 5.2.1 Phase 3 – E cigarettes non- compliance | 7 |
| 5.2.2 Premises with non-compliant E-Cigarettes..... | 8 |
| 5.3 Phase 3- TRPRs Product Compliance – Refill containers..... | 8 |
| 5.3.1 Phase 3 – Refill containers non-compliance | 9 |
| 5.3.2 Premises with non-compliant refill containers..... | 9 |
| 5.4 Actions taken by Trading Standards during compliance monitoring..... | 10 |
| 5.5 Phase 3 – Notifications | 10 |
| 6. Observations & Recommendations for action | 11 |
| Limitations of this review of compliance | 12 |
| Acknowledgements | 12 |
| Annex 1: Process Flow for product referals between TSS and MHRA..... | 13 |
| | |
| Chart 1: Compliance visits by premise type – Phase 3 | 6 |
| Chart 2: TRPs Product Compliance – E-Cigarettes..... | 7 |
| Chart 3: Reasons for E-Cigarette product non-compliance | 7 |
| Chart 4: Premise types and non-compliant E cigarettes | 8 |
| Chart 5: TRPs Product Compliance – Refill container products | 8 |
| Chart 6: Reasons for Refill container product non-compliance | 9 |
| Chart 7: Premise types and non-compliant refill containers | 9 |
| Chart 8: Actions taken by Trading Standards during phase 3 of the review | 10 |
| Chart 9: Products referred by TSS to the MHRA..... | 10 |

SUMMARY & KEY POINTS

- *The Tobacco & Regulated Products Regulations 2016 (TRPRs) came into full effect in May 2017 following a 12month transition period.*
- *This report presents the findings from phase 3 of monitoring carried out by Trading Standards and focuses on the compliance of nicotine inhaling products with these Regulations. Phase 1 and 2 have already been reported by the CTSI and published on the Institute website; more details about the content these prior reviews is given on page 4 of this report.*

PHASE 3: NICOTINE INHALING PRODUCTS

- *A total of 319 Phase 3 compliance visits were conducted in retail premises by Trading Standards Services across 3 regions in England between November 2017 and February 2018. In addition, 34 products that were purchased online were assessed; these are subject of a separate report.*
- *The visits were undertaken as part of a Department of Health and Social Care supported operation designed to assess compliance with the new Regulations. The operation was managed by the Chartered Trading Standards Institute.*
- *Specifically, products were assessed against the Regulations as follows:*

| |
|---|
| E cigarettes & refill containers: See Part 6 of the TRPs |
| Reg 36 product compliant with size requirement |
| Reg 36 product compliant with nicotine strength requirement |
| Reg 36 product child resistant & tamper evident |
| Reg 37 product has information leaflet |
| Reg 37 product carried health warning |
| Notification of sample of products: yes / no for each product identified |

- *Almost a quarter of all products examined were found to be non-compliant with the Regulations – the majority for multiple reasons including labelling issues, lack of health warnings and information leaflets. Where non-compliance was found, appropriate action was taken by the local Trading Standards Service to bring the business into compliance.*

1. INTRODUCTION

The Department of Health and Social Care (DHSC) has requested that a rapid review (RR) of business compliance is undertaken by Trading Standards Services (TSS) in England to establish a base line of compliance and a report of the findings published. The Tobacco and Related Products Regulations 2016 contain several distinct areas of product compliance hence this particular review has been conducted in three phases.

This is the third phase of a DHSC supported project delivered and managed by CTSI; the primary purpose is to **assess the compliance of nicotine inhaling products with the Tobacco and Related Products Regulations 2016¹**.

These Regulations came into force on the 20 May 2016 with a transition period that ended on the 20 May 2017. From 21 May 2017: all relevant products sold or supplied to the UK market must be fully compliant with these Regulations.

2. PURPOSE

The purpose of this review is to assess levels of regulatory compliance by retail businesses with the Tobacco and Related Products Regulations 2016 specifically in relation to the supply of nicotine inhaling products i.e. E cigarettes and refill containers.

3. SCOPE

This was designed to be a rapid review of business compliance carried out by Trading Standards Services (TSS) across a number of authorities in England. A total of 319 compliance visits have been made during phase 3 of the review. A separate review has been undertaken of on line retailers. The data arising from this review will be included in the National Tobacco Control survey for 2017-18.

¹ the Tobacco and Related Products Regulations 2016 available online at: <http://www.legislation.gov.uk/ukxi/2016/507/contents/made> [accessed 3 April 2018]

4. METHOD

The overall review has been carried out by trading standards services in three phases as detailed below:

| Phase | Regulatory and legislation areas | Time frame | Participating Regions | Number of premises to be assessed |
|-------|--|-----------------------------|-----------------------------|-----------------------------------|
| 1 | Product compliance Part 2 TRPs SPoT check Display UAS notice | May to October 2017 | NETSA CEnTSA SWERCOTS | 300 |
| 2 | Product compliance & Notifications (random checks) Part 2 & Part 4 of TRPs | May to October 2017 | Y&H TSEM LTS | 300 |
| 3 | E cigarettes & associated products compliance and notifications (random checks) Part 6 TRPs | November 2017 to April 2018 | TSNW EETSA TSSE | 300 |

The key below provides greater detail of activity in each phase:

| | Compliance area | Specific |
|--|--|---|
| Product Compliance Part 2 TRPs | The Tobacco and Related Products Regulations 2016 | Labelling of tobacco products. |
| SPoT | Standardised Packaging of Tobacco Regulations 2015 | Packaging of cigarettes and Hand Rolling Tobacco. |
| Check display | Tobacco Advertising & Promotion (Display) Regulations 2010 | Display of tobacco products. |
| UAS notices | Underage sales | Age of sale tobacco notices. |
| Product compliance Part 2 TRPs | The Tobacco and Related Products Regulations 2016 | Labelling of tobacco products. |
| Part 4 TRPs Notifications | The Tobacco and Related Products Regulations 2016 | Reporting about tobacco products - checking the system for notifications of products other than cigarettes and HRT. |
| E cigs & associated products compliance and notifications Part 6 TRPs | The Tobacco and Related Products Regulations 2016 | Electronic cigarettes product compliance and checking the system for notifications. |

In advance of the compliance monitoring activity, each participating TSS was provided with guidance and a data collection sheet.

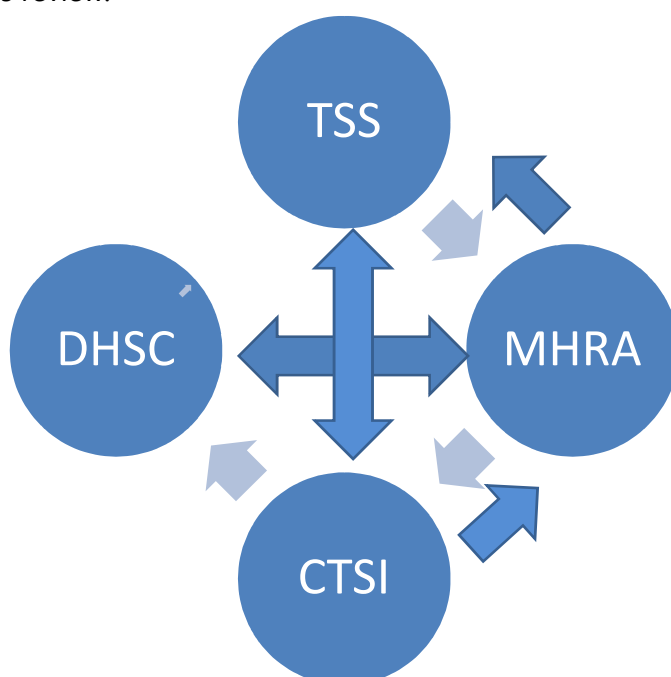
All data was collated by a nominated coordinator in each region and then passed to the CTSI for reporting to the DHSC.

4.1 METHOD: NOTIFICATIONS

All nicotine inhaling products are required to be notified to the Medicines and Healthcare products Regulatory Agency (MHRA); phase 3 of the rapid review seeks to review this by checking a sample of products for inclusion in the published list of E cigarettes and associated products².

In advance of operational activity for phase 3, an agreed process was developed with MHRA to allow for referrals between TSS and MHRA where products appeared to be absent from the published list. This may be found at Annex 1 to this report.

The diagram below represents the flow of information between the relevant parties for the purpose of this review.



² MHRA guidance for E cigarettes – notifications available at: <https://www.gov.uk/guidance/e-cigarettes-regulations-for-consumer-products> [accessed online 17 March 2018]

5. PHASE 3: RESULTS

The following sections present the results of compliance monitoring in Phase 3; this phase was undertaken by TSS in the North West, South East and Eastern Regions. In summary this phase considered:

| |
|---|
| E cigarettes & refill containers: See Part 6 of the TRPs |
| Reg 36 product compliant with size requirement |
| Reg 36 product compliant with nicotine strength requirement |
| Reg 36 product child resistant & tamper evident |
| Reg 37 product has information leaflet |
| Reg 37 product carried health warning |
| Notification of sample of products: yes / no for each product identified |

A total of 319 compliance visits were carried out across these three regions

5.1 PHASE 3 – VISTS BY PREMISE TYPE

The greatest percentage of visits were made to specialist E cigarette businesses with 60%.

17% of the total were made to "other" premises that included: Large retailers, mobile phone shops, pharmacies, market stalls, petrol station kiosks, off licences, photo copying shop and head shops.

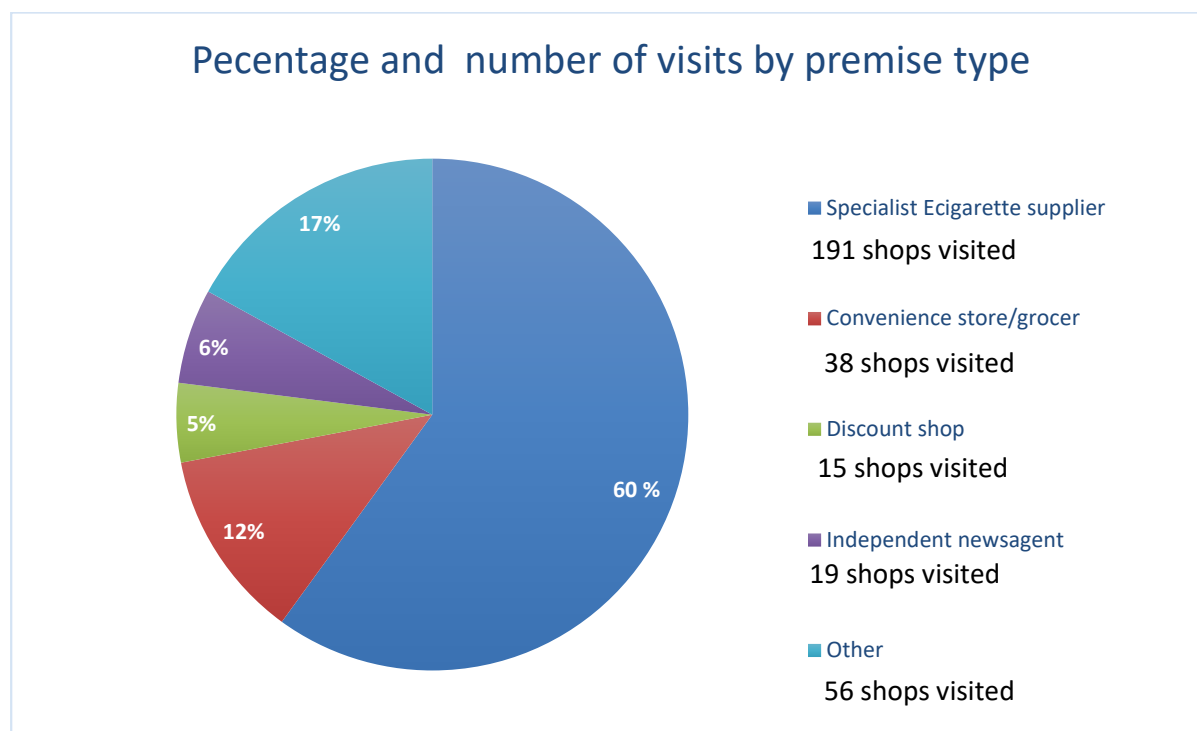


Chart 1: Compliance visits by premise type – Phase 3

5.2 PHASE 3– TRPRS PRODUCT COMPLIANCE – E CIGARETTES

A total of 617 E-cigarette products were assessed during this review. Product compliance with the Tobacco and Related Products Regulations 2016 was found to be 76%.

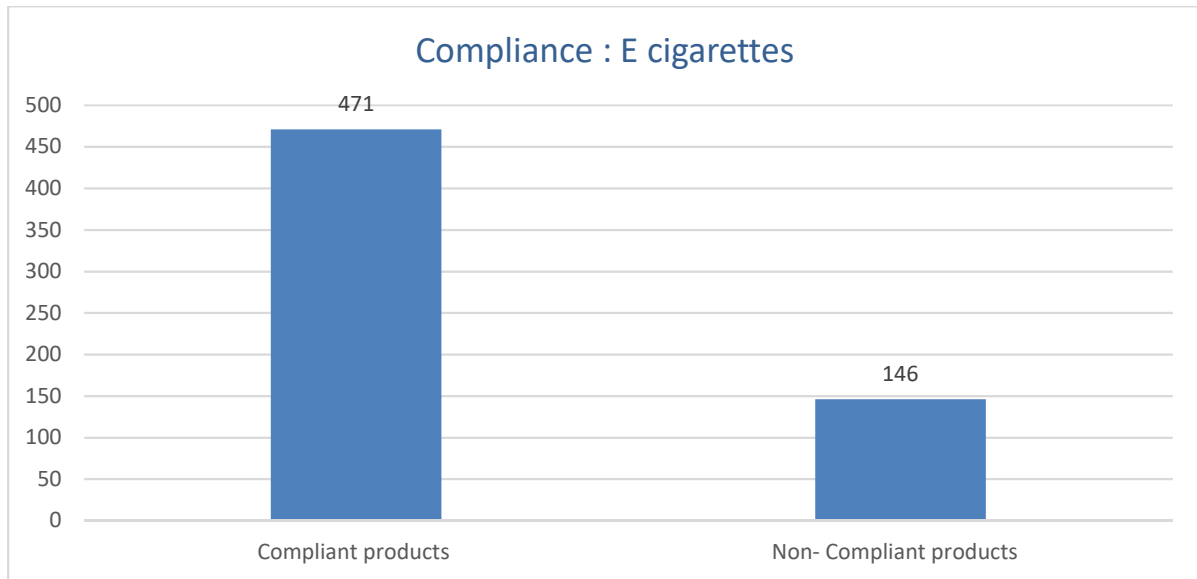


Chart 2: TRPs Product Compliance – E-Cigarettes

5.2.1 PHASE 3 – E CIGARETTES NON- COMPLIANCE

Where non-compliant products were found (76 visits) a variety of reasons were given however the most often recorded reason was "multiple" indicating that the product assessed had several aspects of non-compliance.



Chart 3: Reasons for E-Cigarette product non-compliance

5.2.2 PREMISES WITH NON-COMPLIANT E-CIGARETTES

A total of 146 non-compliant products were found at 76 different premises during this review. The greatest proportion of non-compliant products were found in convenience stores and discount shops [32% and 24% respectively]. 23% of products assessed in specialist suppliers were found to be non-compliant.

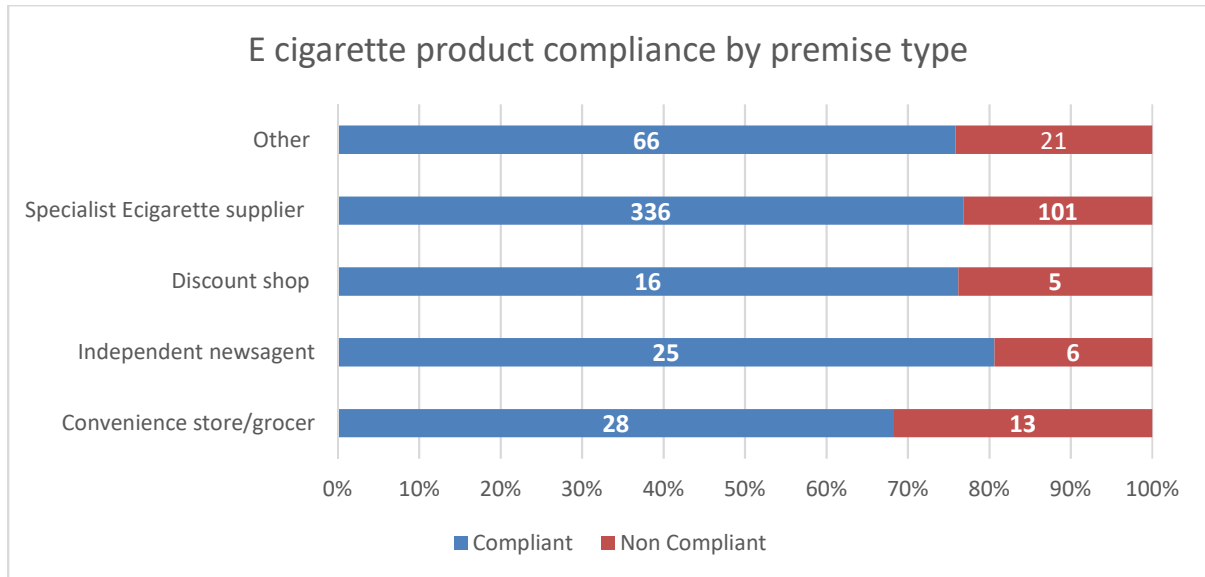


Chart 4: Premise types and non-compliant E cigarettes

5.3 PHASE 3- TRPRS PRODUCT COMPLIANCE – REFILL CONTAINERS

A total of 1953 refill container products (Liquids) were assessed during this review. Product compliance with the Tobacco and Related Products Regulations 2016 was found to be 76%.

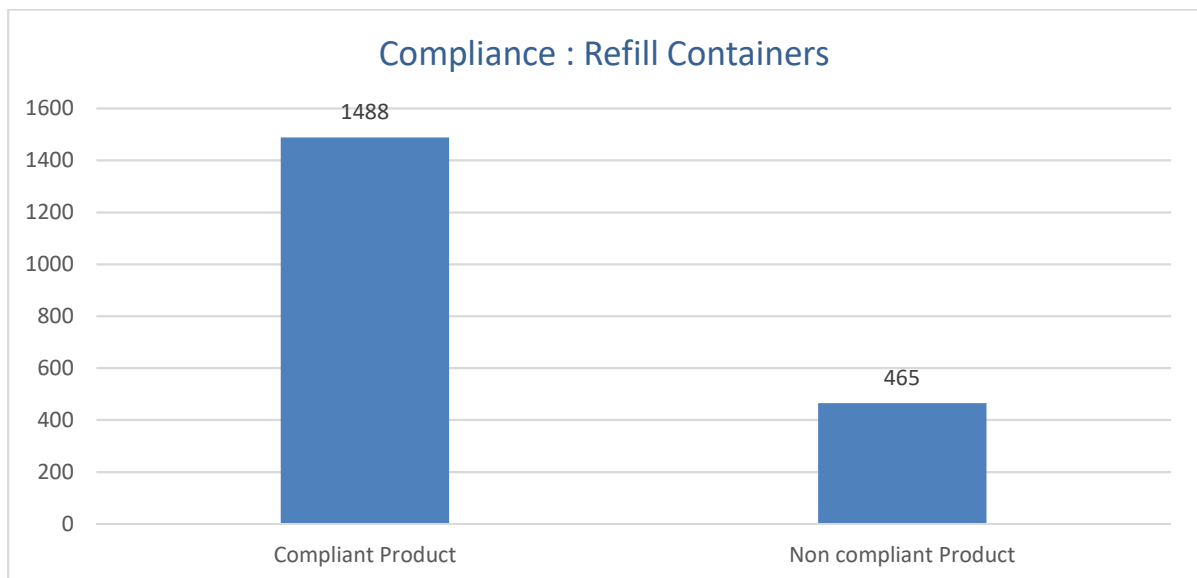


Chart 5: TRPs Product Compliance – Refill container products

5.3.1 PHASE 3 – REFILL CONTAINERS NON-COMPLIANCE

Where non-compliant products were found (124 visits) a variety of reasons were given however the most often recorded reason was “multiple” indicating that the product assessed had several aspects of non-compliance.



Chart 6: Reasons for Refill container product non-compliance

5.3.2 PREMISES WITH NON-COMPLIANT REFILL CONTAINERS

A total of 465 non-compliant products were found at 124 different premises during this review. The greatest proportion of non-compliant products were found in convenience stores and independent newsagents [40% respectively]. 17% of products assessed in specialist suppliers were found to be non-compliant.

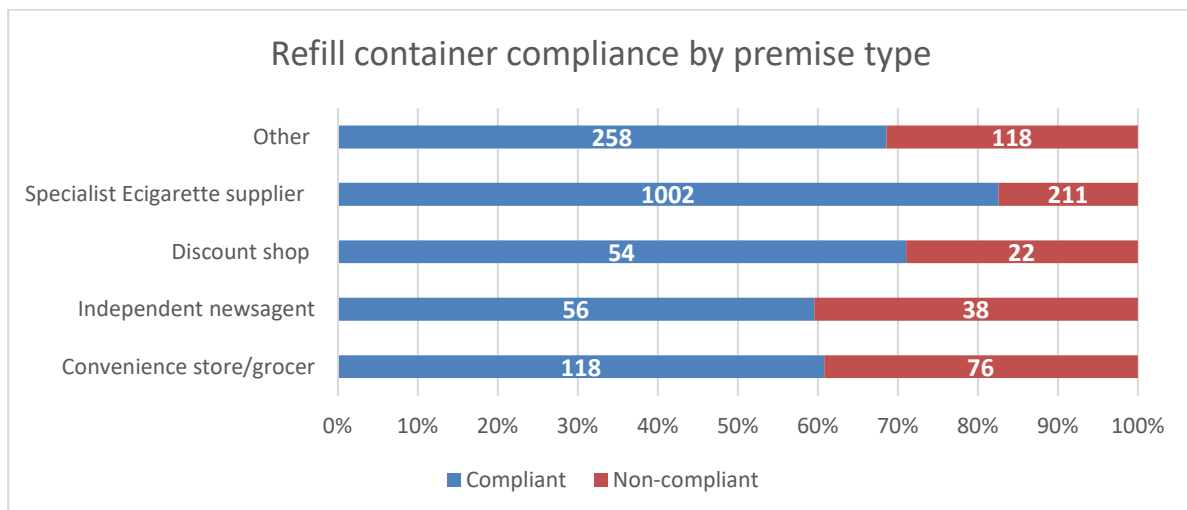


Chart 7: Refill container compliance by premise type

5.4 ACTIONS TAKEN BY TRADING STANDARDS DURING COMPLIANCE MONITORING

A range of actions were taken by Trading Standards during this review; however, the most often cited course of action was “advice given to retailer”. There were no recorded incidents of product suspension by Trading Standards.

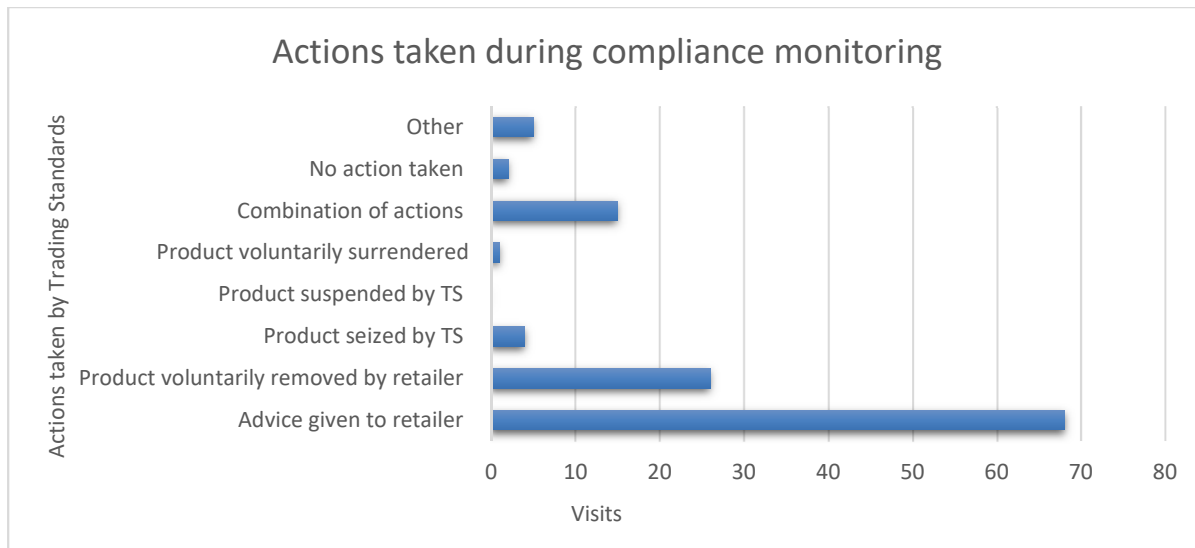


Chart 8: Actions taken by Trading Standards during phase 3 of the review

5.5 PHASE 3 – NOTIFICATIONS

A total of 284* nicotine inhaling products were initially referred to the MHRA by Trading Standards. Of these referrals, 175 products were subsequently located by MHRA and found to be correctly notified leaving 109 products deemed to be not notified.

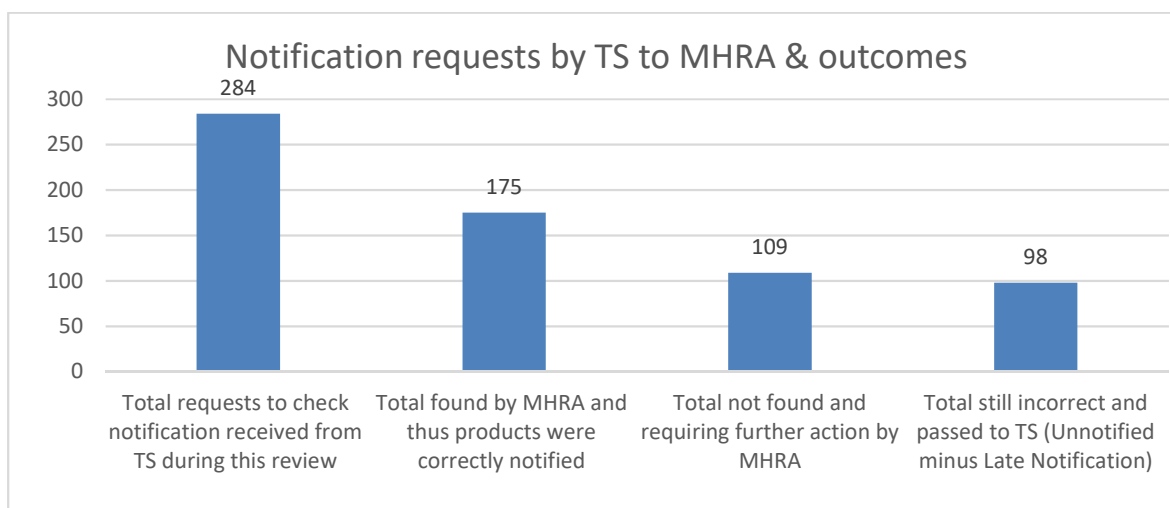


Chart 9: Products referred by TSS to the MHRA

Note: * this includes products submitted by Kent TS as part of the on-line review of product compliance

Of the 109 products that MHRA found to be not notified; there were subsequently 11 products that were the subject of late notification.

A total of **98 products** are now therefore the subject of further action by the MHRA and TSS as appropriate. This will include further attempts by MHRA to contact producers to request notification and, where necessary, follow up action by Trading Standards that may for example involve the removal of non-notified products from the supply chain and liaison with colleagues at the National Trading Standards Ports and Borders Team.

6. OBSERVATIONS & RECOMMENDATIONS FOR ACTION

- The proportion of non-compliant products was found to be the same for both devices and refill containers, with approximately a quarter of all products failing to comply with the Regulations;
- The majority of non-compliance was stated as being for “multiple reasons” suggesting that most failures were not “just a minor labelling issue” but were a combination of several failings;
- The business sector with the highest proportion of non-compliant products was the convenience store / small grocer sector. This may be a factor of a lack of product knowledge in this sector and / or a factor of where the products are sourced from. Further enquiries of these businesses are required to establish the source of the non-compliant products so that appropriate action may be taken to bring both producers and this retail sector of the market into compliance;
- Although the proportion of non-compliant products found in specialist premises was lower at 23% [E cigarettes] and 17% [refill containers] this remains a concern given that these are specialist premises. The average consumer MIGHT reasonably expect a higher degree of product knowledge and expertise from such businesses. This points to a need for ongoing monitoring of this sector and engagement with the relevant industry bodies as appropriate;
- It proved quite difficult for TSS to locate products on the notification list as revealed by the 62% of product referrals made by TSS that were in fact notified products;
- Products that are not correctly notified to MHRA may not be legally supplied. This review has located 98 such products available for supply across the three participating regions in England; MHRA are in the process of making further enquiries. Ongoing liaison between MHRA, CTSI, Regional and local TSS is essential;
- The Regulations provide for both consumer safety and for a level playing field for businesses. Failure to comply with the Regulations is a criminal offence;
- The Regulations cannot now [in 2018] be considered as “new” with a lead in period to assist businesses to get their houses in order; guidance has been produced by MHRA, DHSC and via business companion to assist businesses in compliance;

- Where advice and guidance has been provided to a business but this has failed to bring about compliance, it is recommended that TSS follow their own enforcement policies and escalate their enforcement actions accordingly.

LIMITATIONS OF THIS REVIEW OF COMPLIANCE

It is acknowledged that this is a limited review of compliance. The premises that have been visited have been chosen by local TSS across a total of 31 different council areas in England however the sample size is restricted to 319 premises.

In some cases, the total number of visits made to a particular premise type is correspondingly small and thus the findings of this review are suggestive rather than indicative. See Chart 1 for the total number of visits made by TSS by premise type.

ACKNOWLEDGEMENTS

The author is grateful to colleagues at the DHSC, MHRA, CTSI, and to TS regional coordinators, members of the Tobacco Focus Group and the numerous trading standards professionals who undertook compliance visits as part of the rapid review of regulatory compliance.

ANNEX 1: PROCESS FLOW FOR PRODUCT REFERRALS BETWEEN TSS AND MHRA

