



Department
of Health



The Scottish
Government
Riaghaltas na h-Alba



Department of
Health, Social Services
and Public Safety
www.dhsspsni.gov.uk

Government response to the consultation on implementation of the revised Tobacco Products Directive (2014/40/EU)

January 2016

Title: Government response to the consultation on implementation of the revised Tobacco Products Directive (2014/40/EU).

Author:

Public & International Health Directorate/Health and Wellbeing Division/10800

Document Purpose: Consultation response

Publication date: January 2016

Target audience: General public and businesses and organisations with an interest in the regulation of tobacco and related products (including e-cigarettes)

Contact details:

Department of Health
Tobacco Programme
6th Floor Wellington House
133 – 155 Waterloo Road
London
SE1 8UG

You may re-use the text of this document (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/

© Crown copyright

Published to gov.uk, in PDF format only.

www.gov.uk/dh

Government response to the consultation on the revised Tobacco Products Directive (2014/40/EU)

Prepared by

Department of Health Tobacco Programme

Contents

Executive summary	8
1. Overview of the consultation	10
Purpose of consultation	10
Consultation exercise	11
Purpose of report	11
2. Overview of responses.....	12
Collation, analysis and interpretation of consultation responses.....	12
Number of responses received	12
Comments on the policy.....	14
<i>The Tobacco Industry</i>	14
<i>E-cigarette stakeholders</i>	14
<i>Health Organisations/professionals</i>	15
<i>Enforcement</i>	15
<i>Members of the Public</i>	16
Limitations to elicit representative samples of public opinion	16
3. Responses to the consultation	17
Question 1	17
Should the Government request peer review of any reports submitted by the industry in relation to certain additives contained in a priority list of additives?	
Question 2	20
The Government intends to implement this provision of the Directive [TPD2 Article 8(8)] to mean images, targeted at consumers that are used to promote the sale of products, such as retailer websites offering products for sale. Do you agree with this approach?	
Question 3	22
The TPD2 stipulates where health warnings should appear on packs including that the general warning should appear on the lateral surface. The Government propose to transpose 'lateral' (Article 9) as 'secondary' (defined as the next two largest surfaces of the pack, after the front and the back surfaces) in our domestic legislation. Can you tell us of any packaging shapes where this interpretation would not be the most effective approach / would not work as intended?	
Question 4	24
The TPD2 requires Member States to choose between the warnings 'Smoking kills' or 'Smoking kills – quit now'. The Government is minded to require that tobacco products be labelled with the warning 'Smoking kills – quit now' to align with UK smoking cessation messaging. Do you have any information/evidence that would inform this choice?	

Question 5	27
Are there any other pack shapes for cigarettes, Roll Your Own (RYO/hand- rolling tobacco) and waterpipe tobacco on the market, other than pouches and squat cylindrical tins/tubs, where there may be technical difficulties in applying any of the new health warnings under Articles 9 and 10?	
Question 6	30
To ensure the combined health warnings are applied evenly across each brand of tobacco product, it is proposed that images should appear on between 1/24 (4.15%) and 1/12 (8.33%) of products and each set of images in the TPD2 picture library should be rotated on an annual basis. Are there any additional costs, above and beyond the current regime, imposed by this proposal?	
Question 7	33
The draft regulations require producers to ensure the correct health warning is applied to tobacco products. We are minded to treat retailers who repackage tobacco products at the point of sale the same as producers. For example, individual cigars or loose tobacco packaged at point of sale, should comply with the full labelling provisions, including the rotation of the combined health warning. Do you agree with this approach?	
We also seek further details on the costs and practicalities of such businesses meeting these requirements.	
Question 8	35
The Government is minded to derogate individually wrapped cigars and cigarillos from the full labelling regime, requiring only the general warning 'Smoking kills' or 'Smoking kills – quit now'; one of the text warnings from the combined warning list but no picture; and a reference to the smoking cessation information. Do you agree with this approach?	
Question 9	38
The Government is seeking evidence and information on the supply chains currently used to distribute tobacco products in the UK, such as the number of links in the chain and the number of businesses affected.	
Question 10	38
The Government would welcome initial views on how track and trace and security markings may impact on business, and what the key issues for business will be.	
Question 11	40
If a registration scheme were introduced for cross border distance sales, the Government is minded to require the nomination of an individual to be responsible for verifying that the product complies with the provisions in the UK regulations, before the product is supplied to the consumer. Do you agree with this approach?	
Question 12	43
Should cross-border distance sales of tobacco products to consumers be prohibited?	
Question 13	46

Should cross-border distance sales of e-cigarettes and refills to consumers be prohibited? 49

Question 14 49

What systems to verify the age of customers are available to, or currently used by, businesses involved in distance sales to other EU Member States?..... 51

Question 15 51

Should novel tobacco products be subject to a notification scheme? If "No", please explain why you think an authorisation scheme would be preferable? 54

Question 16 54

Under a notification scheme the Government is minded to include provision to require manufacturers or importers of novel tobacco products to provide, with any notification, information on:.....

- a. the toxicity of the product, its ingredients and emissions;.....
- b. the addictiveness of the product, its ingredients and emissions;.....
- c. the expected effects of the product on the cessation of tobacco consumption by existing users of tobacco products; and.....
- d. the perception of the product by consumers or potential consumers (or predictions as to how the product will be perceived), including the attractiveness of the product.

The Government believes that this information should and will be available to manufacturers and importers prior to launching all new products. Do you agree with this approach? 58

Question 17 58

The Government is minded to use the TPD2 definitions of an 'electronic cigarette' and 'refill container'. Do you foresee any problems with inconsistency with the definitions in The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations? 61

Question 18 61

The Government intends to handle notifications of e-cigarettes and refill containers electronically and make all information contained in notifications automatically available to the public unless this information can be considered truly commercially confidential. What information contained in the notifications should be considered commercially confidential?..... 64

Question 19 64

The Government is minded to put the obligation on 'producers' (which includes manufacturers, importers into the UK and those that rename a product) in the transposing regulations which will ensure that there will always be a person in the UK who collects information about suspected adverse effects in relation to e-cigarettes and refill containers. Do you agree?..... 67

Question 20 67

The Government is minded to give the Secretary of State for Health (SoS) the power to prohibit the supply of an e-cigarette or refill container or to require producers and

suppliers to recall a product if he/she considers them a serious risk to public health. Do you think there are other options that should be provided to the SoS, for example the power to require modification of a product or to require enhanced monitoring and/or reporting of company data?

Question 21 70

The TPD2 provides Member States with two options on the wording prescribed in the health warnings to appear on packs of e-cigarettes and refill containers. Member States must choose either a) 'This product contains nicotine which is a highly addictive substance'; or b) 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'. The Government is minded to require that e-cigarettes be labelled with the warning 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'. Do you agree?.....

Question 22 74

Should the Government charge the industry proportionate fees to recover costs associated with the TPD2.....

Question 23 84

Should retailers and importers be given the proposed transition period until May 2017 to sell through old stock?.....

Question 24 87

Do you have any comments on the drafting of the Regulations, including anything you want to draw to our attention on the practicalities of implementing the Regulations, as drafted?

Question 25 – Question concerning the Impact Assessment 90

4. Next steps93

Appendix A – Consultation questions94

Appendix B – Responses to the consultation98

Executive summary

European legislation governing the manufacturing, presentation and sale of tobacco products (*Directive 2001/37/EC*) has been in place for over a decade and has been revised to reflect scientific and market developments, and to introduce a regulatory framework for related products, including electronic cigarettes (also known as e-cigarettes). The Member States, including the UK, agreed revised harmonised provisions under Directive 2014/40/EU (TPD2), which Member States will transpose into domestic law by 20 May 2016. The subject matter of the legislation is largely reserved and concerns harmonising of trade, therefore the Department of Health has agreed to transpose the TPD on behalf of the Devolved Administrations in Scotland, Wales and Northern Ireland.

On 2 July 2015, the Department of Health published a nine-week public consultation on the draft implementation of the revised Tobacco Products Directive. The purpose of the consultation was to seek views on the options available to Member States under the TPD2. Draft regulations – *The Tobacco and Related Products Regulations 2016* – were provided to give clarity as to how the Directive might be translated into UK law.

The Department received 709 responses. This report provides an overview of the responses received and a summary of the main themes that emerged in answer to the specific questions asked in the consultation document. It also sets out how the Government intends to proceed in finalising the implementing regulations.

Following consideration of the information and views received the Government can confirm that the draft regulations transposing the TPD2 will:

- Provide for peer review of scientific studies provided by the tobacco industry in relation to certain additives contained in a priority list of additives;
- Require the warning '*Smoking kills – quit now*' for tobacco products;
- Require the warning '*This product contains nicotine which is a highly addictive substance.*' for e-cigarettes;
- Derogate individually wrapped cigars and cigarillos from the full labelling regime, requiring only the general warning '*Smoking kills – quit now*'; one of the text warnings from the combined warning list but no picture; and a reference to the smoking cessation information;
- Implement a notification (not an authorisation) scheme for novel tobacco products;
- Not ban cross border distance sales but introduce a registration scheme for such sales of tobacco products, e-cigarettes and refills;
- Adopt transition periods in TPD2, allowing the sell-through of old stock until 20 May 2017.

In addition the Government confirms that it will charge the tobacco and e-cigarette industry proportionate fees for certain services under the TPD2. These aspects will be taken forward in separate legislation and subject to further consultation.

The Government Impact Assessment has been updated and finalised taking account of information and evidence received in response to the consultation and submitted to the Regulatory Policy Committee for scrutiny. The statutory instrument will be amended as outlined in this document and laid before Parliament in spring 2016, with a view to bringing the regulations into force by 20 May 2016.

1. Overview of the consultation

Purpose of consultation

- 1.1. The Health Departments in England, Scotland, Wales and Northern Ireland have responsibility for improving public health, including the regulation of tobacco products. Directive 2014/40/EU (TPD2) was agreed by Member States, including the UK, and adopted on 29 April 2014. All Member States will transpose the TPD2 into their respective domestic laws by 20 May 2016. This forms part of a wider package of tobacco control measures to ensure the smooth functioning of the single market and a high level of health protection.
- 1.2. The aims of the TPD2 are to:
 - Update harmonised tobacco control legislation and establish a regulatory framework for related products including novel tobacco products and herbal products;
 - Tackle illicit trade by introducing an EU-wide tracking and tracing system for the legal supply chain and a security feature combining both visible and invisible elements;
 - Reduce smoking prevalence by ensuring that ingredients and the presentation of tobacco products do not encourage or facilitate smoking uptake by young people; and
 - Establish a regulatory framework for e-cigarettes to ensure they meet safety and marketing standards.
- 1.3. Directive 2014/40/EU maintains and strengthens many aspects of the current controls (Directive 2001/37/EC). The main new provisions of Directive 2014/40/EU:
 - a. Introduce a minimum pack size of 20 cigarettes and minimum weight of 30g for hand-rolling tobacco;
 - b. Continue, and enhance in some areas, the reporting of ingredients and emissions of tobacco products, including the introduction of a harmonised reporting format;
 - c. Increase the size of combined health warnings consisting of a text and photograph warning and cessation information, increased in size to cover 65% of front and back of pack (previously 30% on front of pack and 40% on back of pack);
 - d. Ban certain descriptors, such as “natural” or “organic”;
 - e. Ban cigarettes and hand-rolling tobacco containing characterising flavours such as menthol (with a transition period to 2020 for products whose Union-wide sales volumes represent 3% or more);
 - f. Introduce a traceability system and security features to track and trace tobacco products, to strengthen the fight against illicit trade;

- g. Regulate electronic cigarettes and associated refill cartridges;
 - h. Regulate herbal cigarettes; and
 - i. Introduce a notification (or authorisation) system for novel tobacco products.
- 1.4. The TPD2 is a harmonising directive, so there are few instances for the UK and other Member States to deviate from its provisions. It does, however, provide some limited options for Member States to consider when implementing, and formed the basis of the consultation exercise. These include:
- a. Option to require peer review of reports submitted by the tobacco industry in relation to certain additives present in tobacco products;
 - b. Choice of two textual health warnings to apply to tobacco products and e-cigarettes;
 - c. Option to derogate tobacco products other than cigarettes, RYO/Hand-rolling tobacco and waterpipe tobacco to a lesser labelling regime;
 - d. Choice on whether to ban cross-border distance sales of tobacco products and e-cigarettes, or put in place a registration scheme;
 - e. Choice of introduction of a notification or authorisation system for novel tobacco products;
 - f. Option to charge proportionate fees to recover costs associated with the TPD2 e.g. verification of emission levels of tobacco products and costs associated with notification of tobacco products and e-cigarettes; and
 - g. Option to apply a 12 month transition period to allow the sell through of old stock at retail.
- 1.5. The purpose of the consultation was to seek the views of interested people, organisations and businesses on the above options. The consultation included draft regulations to provide clarity as to how the Directive might be translated into UK law. The consultation also seeks views on the draft regulations and initial assessment of the impact on business. The consultation documents are available on the Department of Health's website.¹

Consultation exercise

- 1.6. On 2 July 2015, the Department of Health launched a nine-week public consultation on the draft implementation of the revised Tobacco Products Directive. Consultation respondents were invited to answer a number of questions on the approach to implementation, draft regulations and draft impact assessment (listed at Appendix A).

Purpose of report

- 1.7. This report has been prepared and published by the Department of Health. It gives an overview of the consultation responses received and summarises the main themes which emerged. It also sets out the Government's response to the points raised and how the Regulations will be amended.

2. Overview of responses

2.1. This chapter provides an overview of the responses received to this consultation.

Collation, analysis and interpretation of consultation responses

2.2. The Department of Health engaged TONIC Consultants Ltd to assist with undertaking initial collation and analysis of consultation responses. The Department of Health has undertaken further detailed analysis and consideration of the issues raised in consultation responses.

2.3. This report provides an overview of all the responses received and reflects the main themes that emerged in response to the specific questions asked in the consultation document.

Number of responses received

2.4. There were a total of 709 responses to the consultation, with the majority coming from members of the public and businesses associated with the production, sale and distribution of tobacco products and e-cigarettes. The breakdown of the responses is as follows:

- 536 members of the public
- 86 businesses and trade associations
- 65 health and other organisations
- 16 health or social care professionals
- 6 regulatory services professionals

2.5. For the purposes of the quantitative and qualitative analysis in this report, Stakeholder Groups have been created that bring together a number of respondent types in the following categories, shown below with the total number of respondents in each category:

Public = 536 (75.6%)

- Members of the public

Tobacco Stakeholders = 25 (3.5%)

- Tobacco importer
- Tobacco manufacturer
- Tobacco retailer (convenience store)
- Tobacco retailer (supermarket)
- Tobacco wholesaler

- Distributor of tobacco products
- Relevant trade or representative body

E-Cigarette Stakeholders = 56 (7.9%)

- Distributor of e-cigarette products
- E-cigarette importer (non-tobacco industry owned)
- E-cigarette importer (tobacco industry owned)
- E-cigarette manufacturer (non-tobacco industry owned)
- E-cigarette manufacturer (tobacco industry owned)
- E-cigarette retailer (specialist store)
- Other e-cigarette retailer
- Relevant trade or representative body

Other Businesses (including retailers) = 24 (3.4%)

- Other (Business) – including retailers
- Pharmaceutical industry
- Relevant trade or representative body
- Other business

Health & Other Organisations = 42 (5.9%)

- NHS Organisation
- Non-Government Organisation – health related
- Health/Social Care Professionals
- Other (Organisation)
- University or research organisation
- Non-Government Organisation – other

Enforcement Stakeholders = 26 (3.7%)

- Local Authority
- Local Authority enforcement body (i.e. trading standards, environmental health)
- Local tobacco control alliance

- Regulatory services professionals

- 2.6. Responses were received via Citizenspace, the Government's consultation portal, via email and by post. Appendix B sets out details of the organisations and businesses who responded to the consultation with the exception of any who wished to remain anonymous.
- 2.7. To meet our obligations under the World Health Organization's Framework Convention on Tobacco Control (FCTC), we asked all respondents to our consultations to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry and 37 respondents declared that they had such links.

Comments on the policy

- 2.8. Chapter 3 sets out the responses to the consultation questions. The consultation questions focussed on the options available to Member States and the Government approach to implementation on technical aspects of the regulations.
- 2.9. A summary of the key overarching points made by respondent groups is provided as follows.

The Tobacco Industry

- 2.10. Responses were received from all sectors of the tobacco industry, including the big four tobacco companies (British American Tobacco (BAT), Imperial Tobacco (IT) Japan Tobacco International (JTI), Philip Morris Limited (PML)) and specialist tobacco sector.
- 2.11. There were three overarching messages across the responses of the tobacco industry:
- A call for expedition of decisions on packaging requirements, to enable sufficient time to prepare for and to implement required changes.
 - A reminder that it is current Government policy not to go beyond the minimum requirements of the Directive ('gold plating'), which would go against the Better Regulation Principles.
 - A call for the Government to utilise the Article 11 derogation to its fullest extent and to only require full pictorial combined health warnings on cigarettes, roll-your own tobacco (RYO) and waterpipe tobacco and not on any other tobacco products.
- 2.12. Whilst the Government received comments from the tobacco industry, they also highlighted that they are currently challenging the validity of the TPD2 through the European Courts and that their responses to the consultation are given without prejudice to those actions.

E-cigarette stakeholders

- 2.13. The large majority of responses to the consultation were from businesses engaged in the production, distribution or sale of e-cigarettes. Some responses indicated that respondents thought that e-cigarettes are categorised as a 'Tobacco Product' under

the TPD2 and therefore need to comply with some of the tobacco product rules other than those set out in Article 20 of the Directive. Where this has influenced stakeholder views it is highlighted in Chapter 3.

- 2.14. Some key overarching comments from e-cigarette stakeholders, related not to the consultation questions but more generally reflected concern over the rules set out in the TPD2 and their impact on the market. The main themes included:
- That any regulatory regime recognises the harm reduction potential of e-cigarettes.
 - Many respondents referenced the Public Health England report ‘E-cigarettes: An Evidence Update’.
 - That TPD2 was not proportionate regulation for e-cigarettes and was incorrectly modelled on tobacco control legislation.
 - That non-nicotine products should be included with, or treated in the same way as, all vaping (inhalation) products. Reasoning given included that non-nicotine products should meet the same quality standards as equivalent nicotine-containing products, in terms of production and emissions generated from the device; prevent distortion to the market; and some respondents warned that a black-market in highly concentrated nicotine solutions could develop.
- 2.15. Whilst the Government received comments from PILLBOX 38 (UK) LIMITED (trading as “Totally Wicked”), they also highlighted that they are currently challenging the validity of Article 20 of the TPD2 through the European Courts and that their responses to the consultation are given without prejudice to those actions.

Health Organisations/professionals

- 2.16. Many health respondents were encouraging of further, tougher action on tobacco products – urging for more stringent legislation, recouping of costs from the industry and bringing in legislation as soon as possible.
- 2.17. Views were more diverse in relation to e-cigarettes, where the majority appeared to support fewer restrictions on e-cigarettes in order to capitalise on potential public health gains, whilst others argued for greater parity of legislation with tobacco products expressing concerns about unproven efficacy as a smoking cessation aid, product safety and potential to act as a gateway to smoking (e.g. by allowing advertising and marketing).

Enforcement

- 2.18. There were 26 responses from local authority enforcement services (Trading Standards or Environmental Health Departments) and professionals employed in this sector. A key concern for enforcers was that of resources.
- 2.19. The majority of respondents agreed with the proposed approach to implementation, citing the need for strengthened regulatory controls for the tobacco industry, which has employed creative means to circumnavigate existing tobacco control measures such as those on advertising and Point of Sale Regulations.

- 2.20. Whilst there was agreement on the proposed measures on e-cigarettes, there were some calls for caution and the need to review these measures given the likely benefits of these products to smokers.

Members of the Public

- 2.21. Members of the public expressed a diverse range of views. The majority of members of the public declared that they either currently use, or have previously used, e-cigarettes to help them quit smoking. Similar to respondents from the e-cigarette industry there are instances where this stakeholder group at times incorrectly assume that proposals that are aimed solely at tobacco products also applied to e-cigarettes. Where this is apparent this is highlighted in Chapter 3.
- 2.22. The majority of members of the public appeared to support fewer restrictions on e-cigarettes in order to capitalise on potential public health gains and safeguard consumer choice and availability of products currently on the market, whilst others argued for greater parity of legislation with tobacco products given concerns about unproven efficacy as a smoking cessation aid, product safety and potential to act as a gateway to smoking (e.g. by allowing advertising and marketing).

Limitations to elicit representative samples of public opinion

- 2.23. The consultation process was not intended or designed to elicit representative samples of public opinion, instead it sought information, comments and views on the draft regulation, impact assessment and equality analysis.
- 2.24. It is in the nature of open consultation exercises that, generally, it is only those who already have an interest in the subject who respond to the questions. The nature of consultation exercises means that respondents are self-selecting, and cannot therefore be considered to be a representative sample of public opinion.

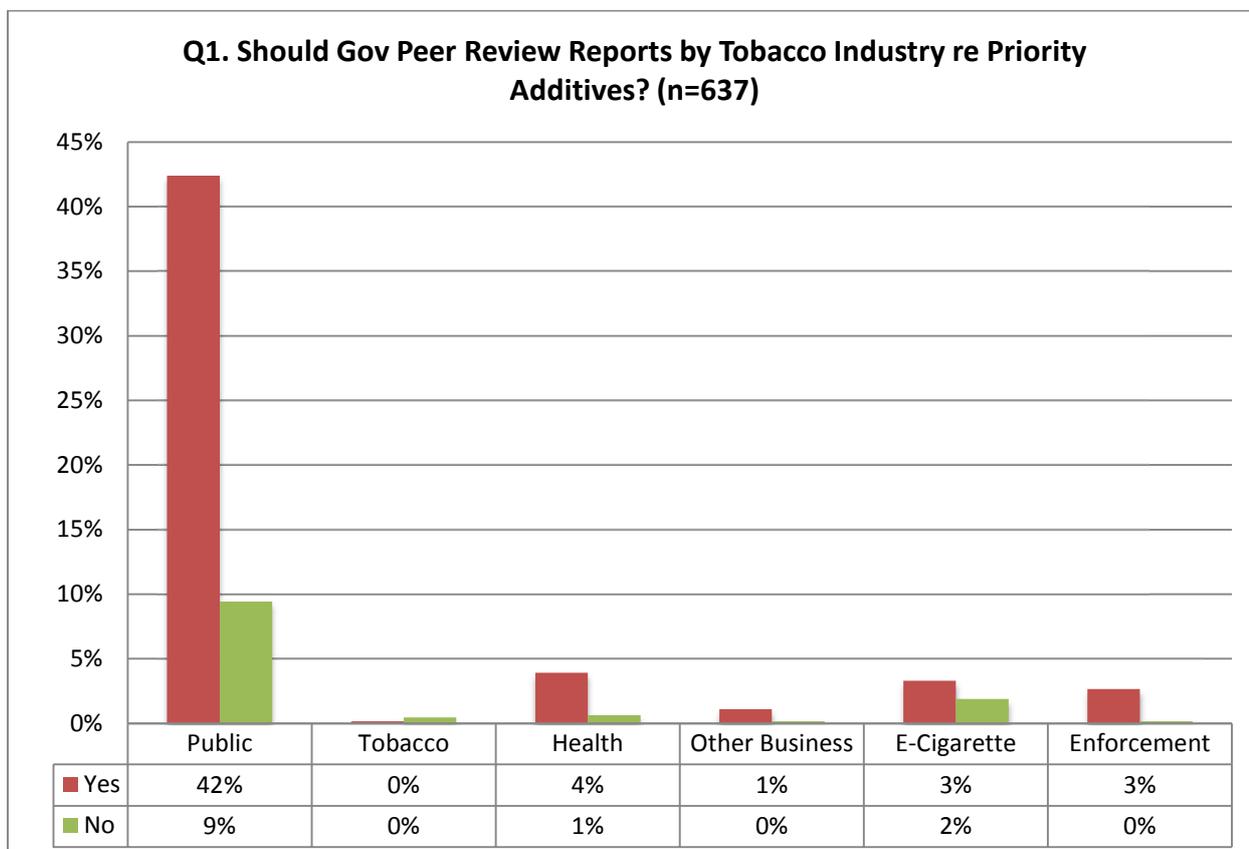
3. Responses to the consultation

3.1. Respondents were invited to answer a number of questions in the consultation document and this chapter summarises the key themes that emerged from the answers to each of these questions.

Question 1

Should the Government request peer review of any reports submitted by the industry in relation to certain additives contained in a priority list of additives?

3.1.1 All stakeholder groups, with the exception of the tobacco industry were generally in favour of the proposal, although a large number of businesses did not express a view. Details of the quantitative response are set out in the graph below:



TOBACCO STAKEHOLDERS

3.1.2 There was broad disagreement amongst tobacco stakeholders with some feeling that the proposals were either not appropriate or unnecessary - some reports will already have been subject to peer review or other method of ensuring sufficient scientific rigour, whilst others were of the view that peer reviews should be coordinated and overseen by the European Commission, rather than by Member States.

E-CIGARETTE STAKEHOLDERS

3.1.3 E-cigarette stakeholders that agreed with the proposal said it would ensure robust data and that there needed to be confidence in the quality of tobacco industry reports.

HEALTH STAKEHOLDERS

3.1.4 Health-Related Organisations (HROs) agreed with the Government proposal, and many called for a requirement to peer review all industry reports, on the basis that the tobacco industry had proved itself to be unreliable in the past. Stakeholders pointed to an alleged history of suppression and distortion of evidence and of commissioning biased research to support its policy positions or to resist regulation. It was suggested that in order to ensure consistency of approach and to ensure that peer review is carried out in the most efficient and effective way, that the European Commission should oversee this.

ENFORCEMENT/LOCAL AUTHORITIES

3.1.5 Local Authorities (LA) and Trading Standards (TS) departments agreed with the proposal. This group shared the views of the health stakeholders on the tobacco industry's past reliability and history of suppressing information. They thought that peer review would ensure accuracy, prevent inconsistencies, and should alleviate concerns that important information was being omitted or distorted by the tobacco industry.

3.1.6 Some also asked for the European Commission to oversee the process to ensure a consistent approach.

RETAILERS/OTHER BUSINESSES

3.1.7 While retailers and retail Trade Associations were mostly in agreement with this proposal, they offered little detail in support of their views.

MEMBERS OF THE PUBLIC

3.1.8 Members of the public who answered this question seemed to be in agreement that the implementation of peer reviews are a welcome measure. One reason behind this agreement was the lack of trust in the tobacco industry, which was a view shared by many respondents.

3.1.9 Peer reviews in this case were seen to offer a "guarantee" that information provided is honest and accurate. In doing so, it granted findings an air of legitimacy and value that they otherwise would not have; in the long-term ensuring safer tobacco products.

Government response

- 3.1.10 The majority of stakeholders support the proportionate use of peer review of reports submitted by the tobacco industry on the priority list of ingredients.
- 3.1.11 **The Government, therefore, intends to include measures in the implementing regulations requiring manufacturers to cooperate with a requirement for peer review. The UK will work with the Commission to ensure that such peer reviews are undertaken in the most economical way possible whilst assuring the accuracy and adequacy of industry's studies.**

Question 2

The Government intends to implement this provision of the Directive [TPD2 Article 8(8)] to mean images, targeted at consumers that are used to promote the sale of products, such as retailer websites offering products for sale. Do you agree with this approach?

- 3.2.1 Most respondents were in generally in favour of the Government proposal, to restrict the interpretation of TPD Article 8(8)², as applying solely to images used to promote the sales of products to consumers. There was some confusion that this provision would apply to e-cigarettes, which is not the case.

TOBACCO STAKEHOLDERS

- 3.2.2 The tobacco industry responses were mixed. Larger businesses see the Government proposal as a practical and sensible approach, and agree in principle, with the proposal that images of tobacco products at retail (whether on-line or otherwise) should carry the required health warnings. One large business did note that that these provisions should not apply to any UK-based website targeting non-EU consumers. Responses from the specialist tobacco sector highlighted concerns that this provision would place a significant burden on smaller retailers of other tobacco products (OTPs) (such as cigars, cigarillos and pipe tobacco), who would have to change a greater number of images due to greater variation in pack size and types of OTPs.

E-CIGARETTE STAKEHOLDERS

- 3.2.3 E-cigarette stakeholders supported the Government proposals with regards to tobacco products, but there was some confusion over whether the restrictions on images applied to e-cigarettes, which they do not.

HEALTH STAKEHOLDERS

- 3.2.4 Most respondents agreed with the Government proposal, or indicated that they were unsure/had no view. Some health organisations cautioned against possible loopholes allowing the tobacco industry to circumvent existing legislation that prohibit tobacco advertising and ensure that media regulators are aware of the Directive and monitor media content appropriately.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.2.5 Local Authorities and Trading Standards agreed with the proposed approach, noting that it would be difficult to enforce where retailer websites targeting UK consumers are hosted abroad (outside of the EU). They shared the concerns that the tobacco industry might use these provisions to circumvent existing legislation that prohibit tobacco advertising and asked that controls should ensure journalistic/editorial articles are not used for the promotion of tobacco products.

RETAILERS/OTHER BUSINESSES

3.2.6 In general, retailers and other businesses did not agree with the Government approach, however, it is apparent from the comments that they thought, incorrectly, that the restrictions apply also to images on e-cigarettes. One major supermarket retailer agreed that the Government approach is sensible and practical and asked for the Government to make it clear/remind retailers that they will need to update images on product lists with TPD2 compliant images.

MEMBERS OF THE PUBLIC

3.2.7 A large proportion of the public respondents did not answer this question, or responded in the belief that this measure applies to e-cigarettes, which it does not. However, those that did supported the Government's proposal citing that any health warning required on packs of tobacco products should be shown at point of sale and the public should be made aware of the dangers tobacco products pose.

Government response

3.2.8 In proposing that TPD2 compliant images only apply to situations where they are used to promote the sale of tobacco products, the Government believes it has struck a balance that is both practical and sensible. The Government does not wish to prevent freedom of expression or prevent the use of images of tobacco products in the media or other publications, for illustrative purposes, but believes that any images used to promote the sale of tobacco products, should be that of the product the purchaser receives – including relevant health warnings.

3.2.9 The suggested transition period of 12 months to allow sell through at retail, should allow retailers sufficient time to amend any on-line or product lists using images of products. As with other tobacco control legislation, we anticipate that enforcement agencies will take a compliance building approach, working with local retailers to assist them in implementing the legislation.

3.2.10 **The Government will implement TPD2 Article 8(8) to mean that any images of tobacco products targeted at consumers that are used to promote the sale of products, such as on a retailer's website or in a product list at point of sale, should be compliant with the TPD2.**

Question 3

The TPD2 stipulates where health warnings should appear on packs including that the general warning should appear on the lateral surface. The Government propose to transpose 'lateral' (Article 9) as 'secondary' (defined as the next two largest surfaces of the pack, after the front and the back surfaces) in our domestic legislation. Can you tell us of any packaging shapes where this interpretation would not be the most effective approach / would not work as intended?

TOBACCO STAKEHOLDERS

- 3.3.1 Two major tobacco manufacturers agreed with the Government proposal. The rest of the tobacco industry respondents disagreed. Disagreement centred on the view that this introduces inconsistency between the UK and the other EU Member States, which could impede the free movement of goods and introduce an obstacle to the smooth running of the internal market. Those respondents related to the manufacture and retail of cigars and specialist tobacco products indicated the proposal is impractical for some packaging types, but expressed more detailed views relating to the labelling of these products in response to Questions 5 and 8.

E-CIGARETTE STAKEHOLDERS

- 3.3.2 A large proportion of the respondents did not answer this question, or did not do so in a manner relevant to the question, citing that it should not apply to e-cigarettes, which it does not. Those that did answer the question had mixed views, with some not wanting any health warnings, others agreeing to warnings on the front and back of packets only, and some feeling that question 5 and 8 of the consultation document addresses this issue for more complex packaging.

HEALTH STAKEHOLDERS

- 3.3.3 Health-related organisations indicated that they had no relevant knowledge or were unsure of their view on this issue. However, many suggested that the industry should change the shapes of any packs that could not currently comply with the TPD2.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.3.4 Local Authorities agreed with the Government's proposal. One example was given of 2-sided packs such as single 'blunts' (rolled tobacco leave wrapper intended to be filled loose tobacco) where the proposed interpretation would not work. Similarly to the health stakeholders many suggested that if there are any packaging types that are non-compliant, the industry should change the shape or form of packaging.

RETAILERS/OTHER BUSINESSES

3.3.5 Respondents provided little substantive response to this question, but expressed more detailed views relating to the labelling of certain products/packaging in response to Questions 5 and 8.

MEMBERS OF THE PUBLIC

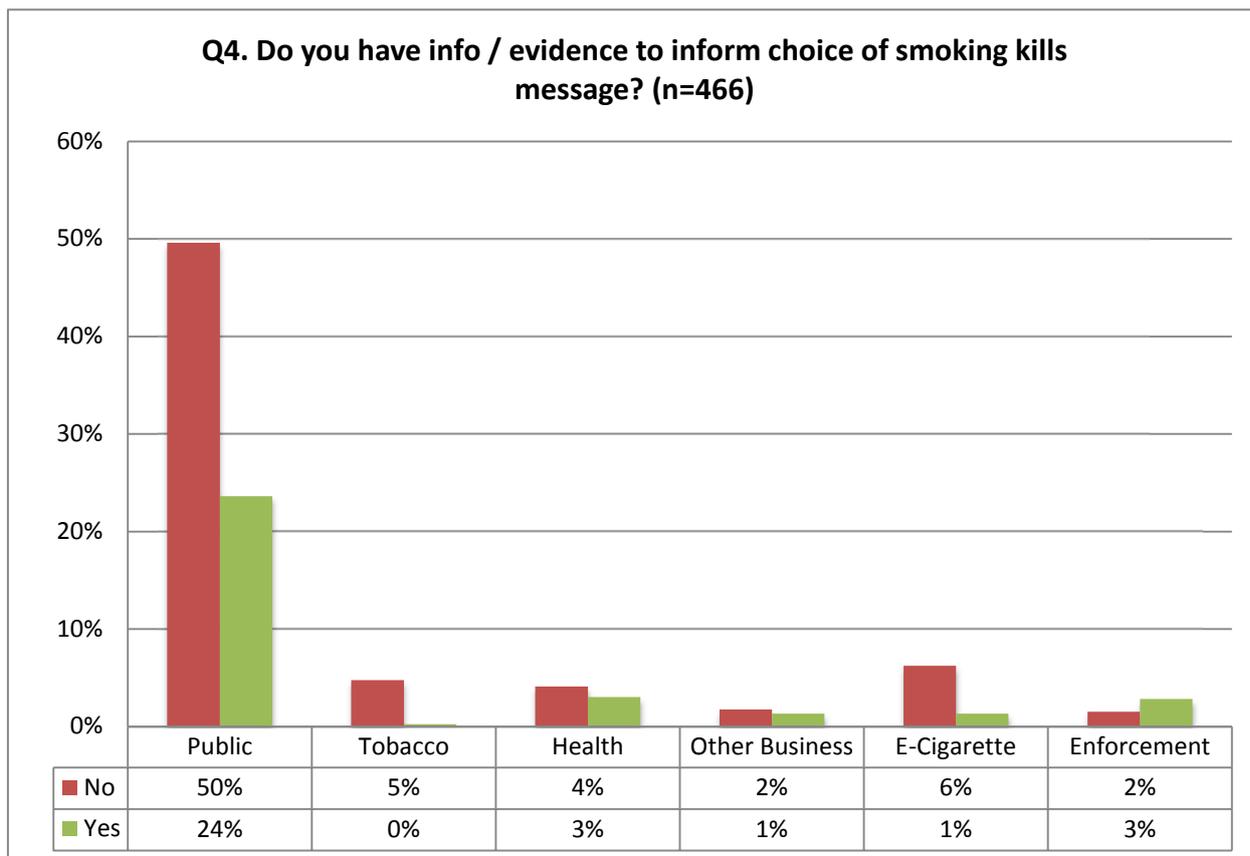
3.3.6 Members of the public largely did not respond to this question. One respondent urged the Government to issue legislation requiring health warnings on every surface and spherical or larger than usual surfaces to have multiple warnings, whilst others insisted that regulations such as these were overly burdensome and health warnings would be ultimately ignored by smokers.

Government response

- 3.3.7 The term 'lateral' is not defined in the TPD2, therefore, when applying to three dimensional packaging it is necessary to provide clarity for producers. In transposing EU legislation the Government is able to elaborate the text of the Directive by using alternative language in order to clarify its meaning. The proposed elaboration is supported by the majority of responses.
- 3.3.8 Further discussions at EU level have also clarified that TPD2 Article 9(3) does not restrict the placement of the general health warning and information message on other tobacco products, such as cigars, cigarillos and pipe tobacco, however does require these warnings to occupy 50% of the surface on which they are placed. The draft implementing regulations presented in the consultation required tobacco products other than cigarettes and hand-rolling tobacco to display the general warning on one of the secondary surfaces and the information message on the other secondary surface. The Government will, therefore, amend the implementing regulations to remove this requirement. This will allow industry greater flexibility in positioning of the general warning and information text messages on tobacco products other than cigarettes, hand-rolling tobacco and waterpipe tobacco.
- 3.3.9 **The Government intends to transpose 'lateral' as outlined in TPD2 Article 9 as 'secondary' (defined as the next two largest surfaces of the pack, after the front and back surfaces).**

Question 4

The TPD2 requires Member States to choose between the warnings ‘Smoking kills’ or ‘Smoking kills – quit now’. The Government is minded to require that tobacco products be labelled with the warning ‘Smoking kills – quit now’ to align with UK smoking cessation messaging. Do you have any information/evidence that would inform this choice?



3.4.1 The majority of respondent groups did not have evidence or information that would inform the choice of combined health warning (CHW) message. Many respondents did however express views on the choice of health warning, the majority of which supporting the Government proposal to require the warning ‘Smoking kills – quit now’.

TOBACCO STAKEHOLDERS

3.4.2 Industry respondents provided little information and either did not respond or indicated they had no information. However, some did state that whilst they had no strong preference on which health warning should be applied, a common theme was to request expediency on a Government decision, to enable the industry sufficient time to prepare production of compliant packaging.

E-CIGARETTE STAKEHOLDERS

- 3.4.3 Most did not respond to this question, as it is not applicable to e-cigarettes, however, some did support the Government proposal, wanting to encourage the “Quit now” message.

HEALTH STAKEHOLDERS

- 3.4.4 Health-related organisation responses indicated agreement with the proposal to include ‘quit now’, for two key reasons, this reinforces the cessation message and it adds a ‘call to action’. Some also expressed that the European Commission should put into place delegated acts to ensure health warnings are reviewed and updated in a timely manner, suggesting every 2-5 years.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.4.5 The majority of those that supported the proposal quoted the response from ASH, advocating the proposal to include ‘quit now’, while others posited anecdotal evidence, stating either that warnings to quit had little or no effect or suggesting the warnings acted only as a deterrent to would-be smokers, rather than in motivating smokers to quit.

RETAILERS/OTHER BUSINESSES

- 3.4.6 Retailers who responded put forward solely anecdotal evidence, stating either that warnings to quit had little or no effect, or perhaps acted only as a deterrent to would-be smokers, rather than in motivating smokers to quit.

MEMBERS OF THE PUBLIC

- 3.4.7 Members of the public who responded to this question cited concerns about the warning itself. Respondents argued that the warning was factually incorrect, citing anecdotal evidence that some people who smoke live well beyond those who do not and can still be healthier than non-smokers, recommending that “Smoking May Kill” would be a more apt choice. Another member of the public builds upon this point by suggesting the use of the words “Quit Now” may make the warning less effective, as it appears as an order and is perhaps more likely, therefore, to be ignored. One respondent drew from their own experiences to illustrate the ineffectiveness of warnings on them in the past, describing how they and fellow consumers became desensitized and apathetic to the warnings once the initial “shock factor” passed. To change this they suggest the images should be rotated on a frequent basis to maintain their impact, a measure which is included within TPD2.

FURTHER EVIDENCE CITED

Hammond, D. (2009). Tobacco Labelling & Packaging Toolkit. A Guide to FCTC Article 11. Waterloo, ON: Tobacco Labelling Resource Centre, 2009. Available from: <http://www.tobaccolabels.ca/tobaccolab/iatldtook> February 2009

Sambrook Research International (2009). A Review of the Science Base to Support the Development of Health Warnings for Tobacco Packages. A report prepared for the European Commission, Directorate General for Health and Consumers. Brussels: European Commission, 2009. Available at: http://ec.europa.eu/health/tobacco/docs/warnings_report_en.pdf

Strahan, E., White, K., Fong, G. et al., (2002). Enhancing the effectiveness of tobacco package warning labels: a social psychological perspective. *Tobacco Control*, 11: 183–190. doi: 10.1136/tc.11.3.183.

White, V., Bariola, E., Faulkner, A., Coomber, K. & Wakefield, M. (2015). Graphic health warnings on cigarette packs: how long before the effects on adolescents wear out? *Nicotine and Tobacco Research*, 17, 776-783. doi: 10.1093/ntr/ntu184

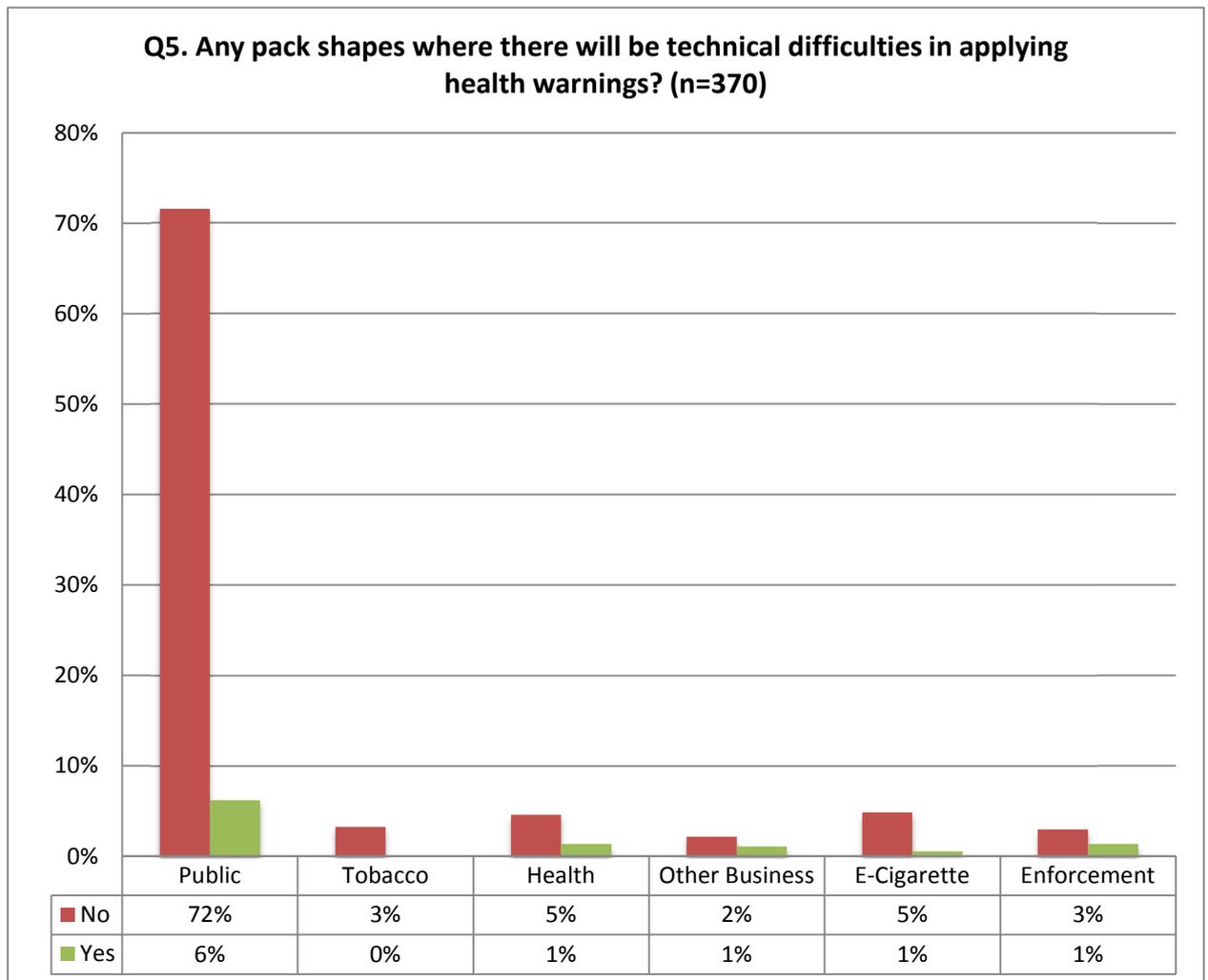
Government response

- 3.4.8 The majority of responses supported the Government proposal to require the warning 'Smoking kills - quit now'. Two thirds of current smokers want to quit and those that attempt to do so are four times more likely to stop smoking and quit for good if they use the personalised support offered by local stop smoking services. In transposing the TPD2 all tobacco products sold in the UK will be labelled with the mandatory smoking cessation information message 'Get help to stop smoking at www.nhs.uk/quit', providing access to cessation services across the UK. Supplementing this message with 'Smoking kills - quit now' reinforces the message to quit and seek help.
- 3.4.9 **The Government will require that tobacco products be labelled with the warning 'Smoking kills – quit now'.**

Question 5

Are there any other pack shapes for cigarettes, Roll Your Own (RYO/hand-rolling tobacco) and waterpipe tobacco on the market, other than pouches and squat cylindrical tins/tubs, where there may be technical difficulties in applying any of the new health warnings under Articles 9 and 10?

3.5.1 The majority of all respondent groups indicated they did not know of any pack shapes where there would be technical difficulties in applying the new health warnings under Articles 9 and 10. Details of the quantitative response are set out in the graph below:



TOBACCO STAKEHOLDERS

- 3.5.2 The majority of respondents had no knowledge of packs that would not be able to comply with the new regulations. Respondents from the specialist tobacco sector indicated the labelling provisions in Article 9 and 10 of the TPD2 would not work for certain hinged boxes and are uneconomical for smaller brands, effectively excluding them from the market. Some also stated that more complex packaging will not be able to accommodate the TPD2 labelling requirements in their existing form. One respondent provided a picture of a pack cigars that they believed may not be able to comply with the regulations due to incompatibility with the 16mm minimum height requirement of the lateral sides in TPD2. As stated above, the European Commission has now confirmed that the restrictions on the size and position of the general health warning and information message in TPD2 Article 9.3 (including the 16 mm rule) only applies to cigarettes and hand-rolling tobacco.
- 3.5.3 One respondent referred to draft tertiary legislation circulated during the consultation. This provides further detail on the position of the general health warnings and information message on pouches of hand-rolling tobacco. The respondent supported greater flexibility within the tertiary legislation for businesses to choose the solution which is best suited for the type of pouch and material used.
- 3.5.4 Respondents also used this question to raise some general labelling concerns:
- Regarding the lack of clarity about the terms 'Graphic Health Warning' (GHW) in the draft UK regulations and 'Combined Health Warning' (CHW) in TPD2.
 - One respondent also raised concerns that there is uncertainty about rounded corners and bevelled edges, as draft non-binding guidance circulated by the European Commission appears to suggest that Member States may prohibit packs where the CHW extends to bevelled edges/rounded corners.

E-CIGARETTE STAKEHOLDERS

- 3.5.5 Some respondents re-asserted that there should not be health warnings on e-cigarettes.

HEALTH STAKEHOLDERS

- 3.5.6 Health-related organisations suggested that the industry should change the shapes of any packs that could not currently comply with the new regime.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.5.7 Most respondents did not envisage any difficulties, however one respondent commented that thin rectangular cuboid shapes (so called perfume packs – see figure 2) of super-slim cigarettes would no longer be permitted as they could not accommodate the minimum width health warning and would need to be removed from the market or repackaged.



Figure 2: "Perfume Pack" submitted as part of the responses to this question (the example provided is Polish, but similar products can be found on the UK market)

RETAILERS/OTHER BUSINESSES

3.5.8 Retailers generally responded “no” in relation to this question, without providing further detail.

MEMBERS OF THE PUBLIC

3.5.9 There was no data of relevance provided for this question.

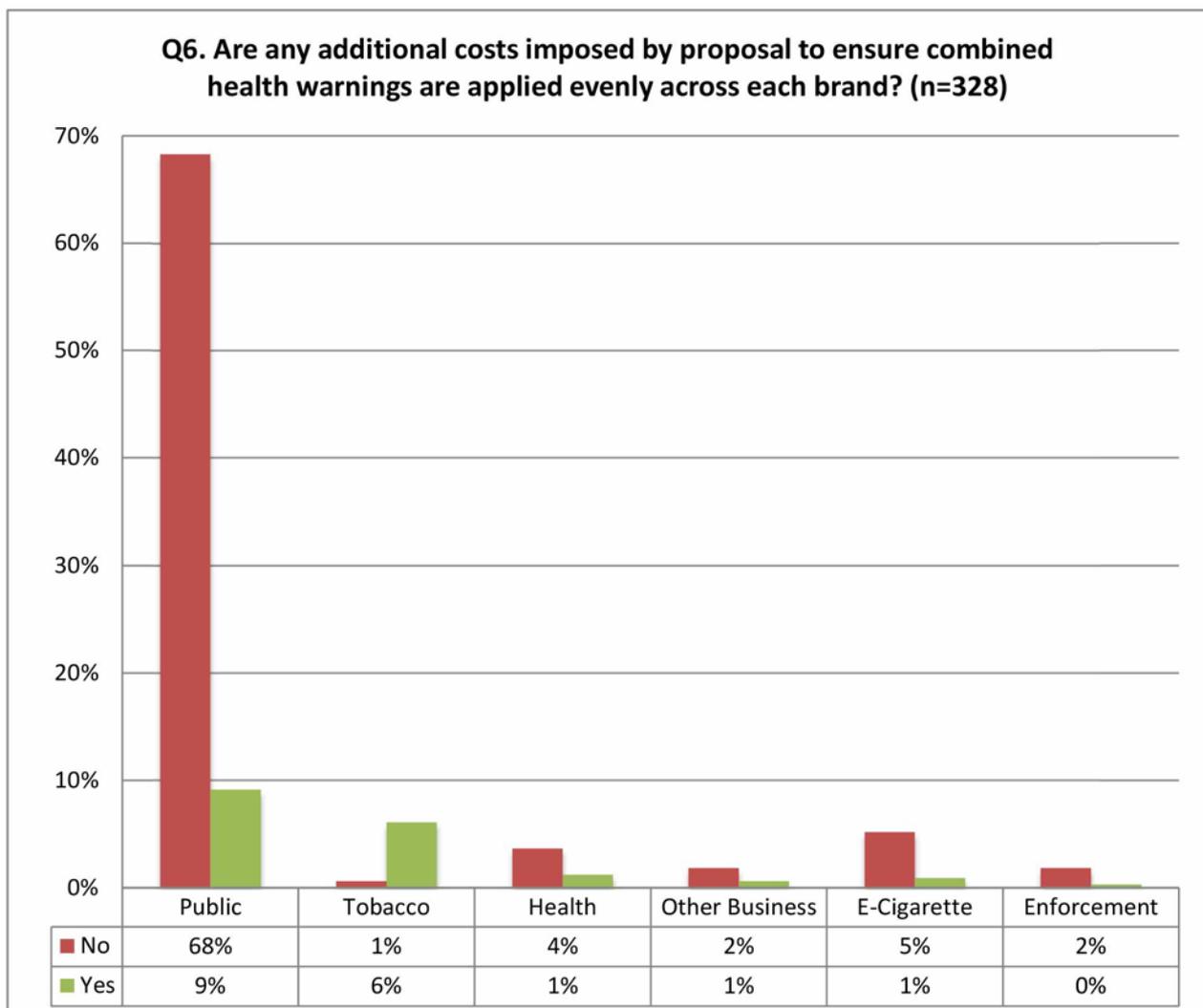
Government response

3.5.10 The Government has carefully considered the information provided. It is clear that the majority of tobacco products will be able to meet the new labelling requirements set out in the Directive. The European Commission has since the launch of this consultation adopted further tertiary legislation to clarify detailed labelling requirements on RYO/hand-rolling tobacco determining the precise positioning of the general warning and the information message on roll-your-own tobacco marketed in pouches, taking into account the different shapes of pouches and positioning of Combined Health Warnings on all tobacco products. In addition, in discussion with Member States it has been clarified that full flexibility should be given on the placement of the general warning and information message on tobacco products other than cigarettes and RYO/hand-rolling tobacco which will provide further flexibility to manufacturers of these products. Further information on the derogation of certain product types from the need to use pictorial health warnings is explored in Question 8.

Question 6

To ensure the combined health warnings are applied evenly across each brand of tobacco product, it is proposed that images should appear on between 1/24 (4.15%) and 1/12 (8.33%) of products and each set of images in the TPD2 picture library should be rotated on an annual basis. Are there any additional costs, above and beyond the current regime, imposed by this proposal?

3.6.1 Although the public and health related organisations clearly felt than no additional costs would be imposed by the combined health warnings proposal, businesses were evenly split between those who felt there would be additional costs and those who did not. Details of the quantitative responses are set out in the graph below:



TOBACCO STAKEHOLDERS

- 3.6.2 One respondent suggested that there would be no additional costs resulting from the new regulations. However, all other industry respondents indicated that costs would increase as a result of the new regulations. The extra costs would result from:
- Adding to design and print complexity
 - The increase in the number of images required (3 sets of 14 rotated annually compared to current 14), which requires the more regular replacement of print cylinders
 - The write-off of significant amounts of noncompliant material arising from the production process, occurring due to printed material stocks featuring health warnings from year 1, may not be fully used as year 2 material becomes mandatory, creating waste and costs
- 3.6.3 Respondents called for greater flexibility in the proportion of packs over which images appear (specifically, 1/28 – 1/7 of the product). Several requested that UK implementing regulations should not set a fixed percentage for all tobacco products for smoking, on the basis that for cigars, fine-cut tobacco and other tobacco products, the manufacturing and print processes are more complex. They indicate that a fixed percentage will result in greater waste and cost for the production of these types of products.
- 3.6.4 Some respondents elaborated that products with limited production/print runs, such as in the cigar sector, would be disproportionately affected. These products tend to have much smaller print runs (for example two per year), suggesting there will be significant difficulties in ensuring that these products meet the rotation requirements. They did, however, acknowledge that the TPD2 health warnings do not present significant challenges for larger volume products.
- 3.6.5 An example given was for a premium hand-made cigar manufacturer:
- “They have in their inventory over 330 hand-made cigar SKUs of different dimensions, all of which would require dressing with warnings tailored to specific sizes covering either 65% or 50% of the prescribed surfaces. The sheer number of self-adhesive labels required to ensure compliance with these SKUs is estimated to be c. 6,000 different items, let alone the logistical demands of ensuring that the correct sized warning labels are placed on the different packets. This whole operation would result in an extraordinary and exponential increase in packaging and manpower costs, which by any account would be totally unrealistic and unreasonable for small and micro-businesses”*
- 3.6.6 Other suggestions include that annual rotation should commence from January, rather than May and agreed with the Government’s proposal that the deadline for rotation should apply at point of manufacture only, allowing the sell through of old stock on the market. They stated that any other solution would be "totally impractical", leading to "significant costs related to product clearance in the supply chain and an unreasonable burden on manufacturers, wholesalers and retailers".

E-CIGARETTE STAKEHOLDERS

3.6.7 This question is of no relevance to e-cigarette stakeholders, therefore no information was provided.

HEALTH STAKEHOLDERS

3.6.8 Health stakeholders cited no knowledge of the costs of new regulations for industry. However, the main theme was of the importance of refreshing and rotating of images on a regular basis to avoid erosion of impact. Some respondents noted that it is not necessary to harmonise the rotation of images across the European Union (EU), as exposure to multiple different warnings is potentially beneficial to public health.

ENFORCEMENT/LOCAL AUTHORITIES

3.6.9 Most respondents answered, “no” or “don’t know”, however one respondent provided anecdotal information that manufacturers select the least off-putting pictures for the types of consumers that use their products and manufacturers should be obliged to provide evidence that the rotation of pictures is applied as per the regulations and that compliance checks are built into the enforcement regime.

MEMBERS OF THE PUBLIC

3.6.10 Members of the public’s responses for this question provided no relevant qualitative data, however, some mentioned that regulatory changes inevitably lead to increased costs, but gave no specific examples or reasoning to explain this viewpoint.

Government response

3.6.11 Current legislation requires that health warnings are applied evenly across each brand of tobacco product – each image should appear on between 1/24 (4.15%) and 1/12 (8.33%) of products. Responses to the consultation gave no justification to alter this approach. It is clear that there will be additional costs to businesses to comply with the TPD2 annual rotation of images in the TPD2 picture library. These will be accounted for in the final impact assessment. The Government believes that it is important to refresh these images to maintain the impact of the graphic health warnings and deter young people from taking up smoking.

3.6.12 **The Government will retain current draft provisions to ensure the combined health warnings are applied evenly across each brand of tobacco product – each image should appear on between 1/24 (4.15%) and 1/12 (8.33%) of products and each set of images in the TPD2 picture library will be rotated on an annual basis. The requirement to rotate images will fall to producers of tobacco products, and importers must use their best endeavours to ensure that these obligations are met. Sell through of old stock (with the previous image) will be permitted.**

Question 7

The draft regulations require producers to ensure the correct health warning is applied to tobacco products. We are minded to treat retailers who repackage tobacco products at the point of sale the same as producers. For example, individual cigars or loose tobacco packaged at point of sale, should comply with the full labelling provisions, including the rotation of the combined health warning. Do you agree with this approach?

We also seek further details on the costs and practicalities of such businesses meeting these requirements.

- 3.7.1 The majority of the public and of organisations agreed with the proposal. However, amongst businesses the response was equally split, with many businesses and organisations not expressing a view. Details of the quantitative response are set out in the graph below:

TOBACCO STAKEHOLDERS

- 3.7.2 There were mixed responses to this question. Some of the large tobacco manufacturers agreed with this approach, some were unsure or had no view and some were against this proposal, saying it was impractical and unreasonable, because the requirements are too complex for smaller retailers to reasonably implement and the cost would be borne primarily by smaller retailers, requiring staff time and training.

E-CIGARETTE STAKEHOLDERS

- 3.7.3 There were mixed views with little reasoning provided in support of those views.

HEALTH STAKEHOLDERS

- 3.7.4 Health related organisations agreed with the Government approach, with some suggesting that it is important not to create a potential loophole in the regulations and that there should be no difference between tobacco products packaged by a manufacturer and products repackaged by a retailer.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.7.5 Most respondents agreed with the Government proposal, with the few that disagreed not elaborating on the reasons for their decision. No further details were provided on costs and practicalities associated with the proposals.

MEMBERS OF THE PUBLIC

- 3.7.6 One respondent questioned the disproportionate effect of this measure on smaller businesses, noting that many of these businesses manufacture their own labels or engage closely with a specialist print production company who do it for them for the sale of loose tobacco. To bring in these measures therefore may be prohibitive and decrease the number of products on the market, and consequently reduce consumer choice. This was reported as a particular concern for those who mix different blends of tobacco for their own consumption.

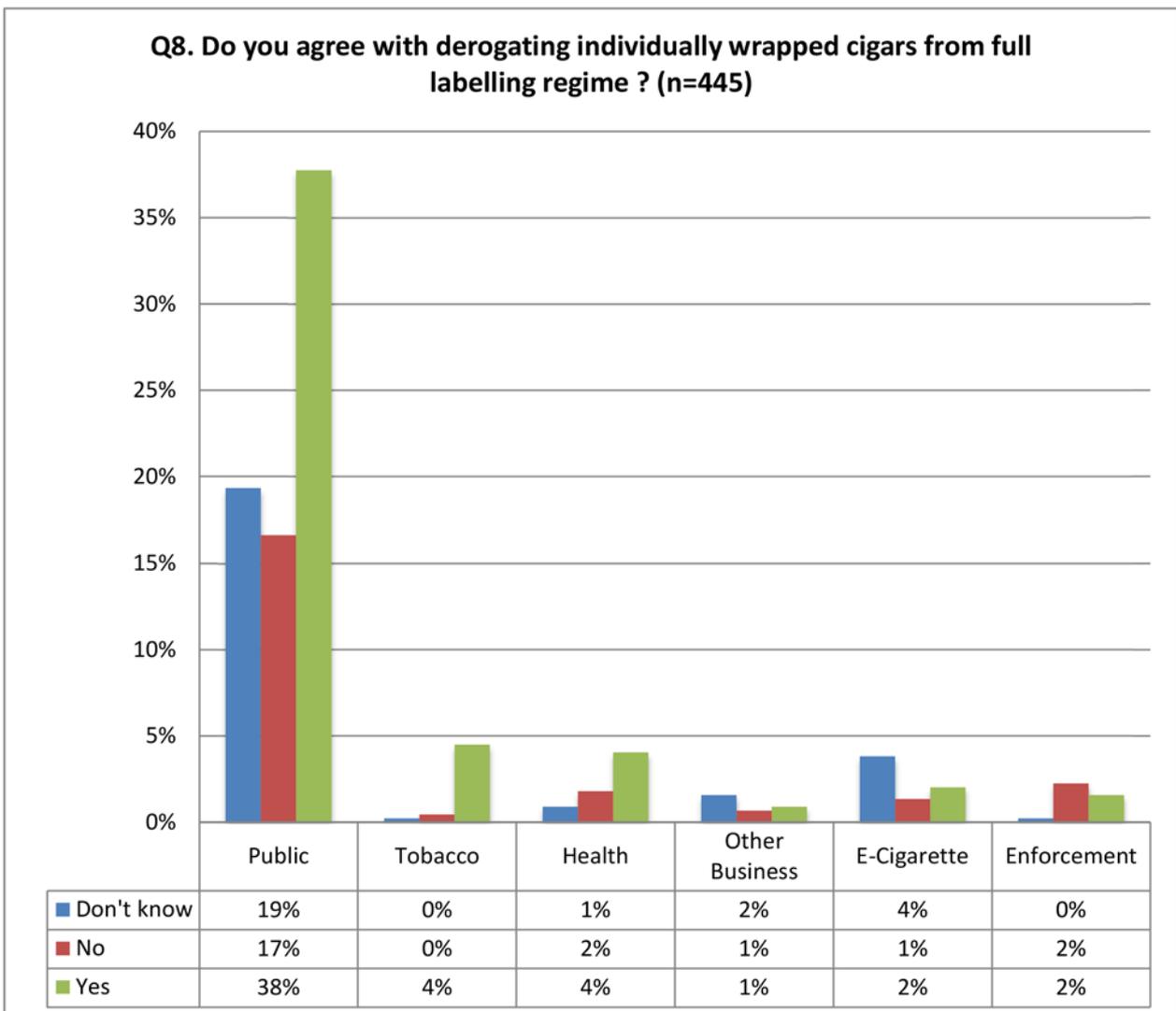
Government response

- 3.7.7 It is clear that the specialist tobacco sector generally regard the requirements of the TPD2 as disproportionate for tobacco products other than cigarettes and hand-rolling tobacco. The question posed relates to whether a retailer that repackages tobacco products at the point of sale should be required to apply health warnings to the products that they repackage for sale.
- 3.7.8 Retailers that package products at point of sale currently provide products with health warnings applied. This is achieved by the use of pre-printed outer packaging either provided by manufacturers or commissioned by the retailer. This level of consumer information should be maintained. Consumers should receive the same information on products, of the same type and nature and posing the same health risk, no matter whether they are labelled by a manufacturer or a retailer.
- 3.7.9 **The Government will retain the draft implementing regulations treatment of retailers who repackage tobacco products at the point of sale, as the same as producers.**

Question 8

The Government is minded to derogate individually wrapped cigars and cigarillos from the full labelling regime, requiring only the general warning ‘Smoking kills’ or ‘Smoking kills – quit now’; one of the text warnings from the combined warning list but no picture; and a reference to the smoking cessation information. Do you agree with this approach?

3.8.1 The majority in each stakeholder type was in favour of the proposal to derogate cigars and cigarillos from the full labelling regime. Details of the quantitative response are set out in the graph below:



TOBACCO STAKEHOLDERS

- 3.8.2 Tobacco industry respondents agreed with the Government proposal. The majority of industry respondents suggest that the proposal does not go far enough and called for all cigars, cigarillos and pipe tobacco to be derogated under Article 11. The main reasons given were that these products are suffering from falling product sales, are not used by young people, have a wider product range and are, therefore, disproportionately affected by the regulations and some package shapes cannot comply with full labelling requirements.
- 3.8.3 Manufacturers/importers of cigars and other specialist tobacco products cited that the large and varied product ranges in this sector mean that it is disproportionate to apply full labelling. This sector currently has a number of small batch and slow moving products, which if required to apply full labelling, would not be cost effective to maintain. Some respondents recognised that the lesser labelling regime under Article 11 is still challenging, for example, having the same requirement to print warnings on the inside of the hinged lid, but would thought would result in fewer product discontinuations.
- 3.8.4 Respondents asked that the implementing regulations are drafted to refer to “All individually wrapped cigars sold by the piece”.

E-CIGARETTE STAKEHOLDERS

- 3.8.5 E-cigarette stakeholders highlighted that cigars were no less harmful than other tobacco products, however, some did acknowledge the practical difficulties with labelling cigars/cigarillos in the same way, and believed the proposed labelling strengthens the current warnings.

HEALTH STAKEHOLDERS

- 3.8.6 Some respondents agreed with the Government proposal, but caution that the list of derogated products should not be expanded beyond that proposed.
- 3.8.7 Some respondents were against the proposal, as anything less than the full labelling regime could imply that individually wrapped cigars and cigarillos are safer, and could lead to an underestimation of harm by the consumer. Others suggested that it is essential to include smoking cessation information on all tobacco products, which would be the case under both options.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.8.8 Local Authorities generally disagreed with the approach, seeking a consistent approach across all tobacco products. Respondents recommended that no derogation should be given and that the tobacco industry be required to adapt existing packaging in order to comply with the full labelling regime in the TPD2, citing that all tobacco products are equally harmful, regardless of packaging.
- 3.8.9 One respondent that agreed with the Government proposal recognised even the rules required by the derogation would provide an enhancement over the current rules, but also suggested that where products in individual tubes are sold from a box at point of sale – e.g. tobacco ‘blunts’ – the box should be required to comply with the full labelling regime such that the consumer can see the picture warnings at point of sale.

RETAILERS/OTHER BUSINESSES

3.8.10 Most retailers agreed with this approach, stating that it is “the only practical way to get across the key information required in a legible fashion on products with such limited packaging surfaces”.

MEMBERS OF THE PUBLIC

3.8.11 This question drew a mixed response from the few members of the public who did respond specifically to it. The majority of respondents agreed with the Government’s proposal. Those that disagreed were mixed with some respondents suggesting that cigars should not be subject to health warnings as the consumption of cigars are not an entry to smoking for young people, contrastingly however other respondents who felt the ruling did not go far enough, citing that all tobacco products carry a similar levels of harm. Whilst one respondent felt that anything less than what the government was planning to implement would be “too small to have an impact.”

Government response

3.8.12 The Government has worked hard to reduce the prevalence of smoking and the health harms it causes to smokers and those affected by passive smoking. The Government recognise that producers of other tobacco products (OTPs) have a wider range of products and different packaging forms to relabel but do not wish to reduce the level of consumer protection offered by current legislation. It is recognised that picture health warnings have been demonstrated to be the most effective form of health warning, but it is difficult to apply them in a clear and effective manner to small products, such as individually wrapped cigars and cigarillos, as is acknowledged by the exemption in existing legislation. In addition, these products represent a relatively small proportion of the overall tobacco market and are products that tend to be used by existing smokers and not as an introduction to smoking.

3.8.13 **The Government intends to derogate individually wrapped cigars and cigarillos from the Directive’s requirements to label with picture warnings.**

Question 9

The Government is seeking evidence and information on the supply chains currently used to distribute tobacco products in the UK, such as the number of links in the chain and the number of businesses affected.

Question 10

The Government would welcome initial views on how track and trace and security markings may impact on business, and what the key issues for business will be.

- 3.9.1 As one might expect, the Tobacco industry was the only stakeholder group that provided detailed information in responses to these questions. Other stakeholder groups used these questions to raise general views in support of a track and trace system, with some citing opposition to any future use of 'Codentify' – an industry developed track and trace system.

TOBACCO STAKEHOLDERS

- 3.9.2 Those respondents from the tobacco industry that provided views on this question set out details of the supply used to distribution tobacco products. The main theme was recognition that the structure of the UK distribution network and the process of distribution differs significantly from other European countries such as Spain or France, where a single distributor/wholesaler manages the supply of products from manufacturers. Respondents said that it is imperative for any future EU proposals to recognise and be able to accommodate this complexity. Due to this complexity it is expected that there will be a higher number of tracking events through the UK supply chain, and, therefore, costs of the proposed traceability system to both the industry and the distributive supply chain could be significant.
- 3.9.3 Respondents also highlighted that the supply chain for the specialist tobacco market (cigars, cigarillos, pipe tobacco), tend to be shorter than that of the cigarette and hand-rolling tobacco sector, with a higher incidence of products supplied by the manufacturer/importer direct to the retailer.
- 3.9.4 Industry responses supported that any future track and trace system should allow individual manufacturers to decide on solutions meeting agreed EU technical specifications, citing that 'Codentify', the existing system used by the big four tobacco manufacturers, should be permitted.

HEALTH STAKEHOLDERS

- 3.9.5 In contrast to the industry, health related organisations opposed the use of ‘Codentify’, on the basis that it is a system developed by the tobacco industry. They considered that any track and trace system should be independent of the industry. Respondents also cited there has also been no assessment of Codentify’s efficacy as a track and trace system and that an industry developed system is not compatible with the Framework Convention on Tobacco Control (FCTC).

ENFORCEMENT/LOCAL AUTHORITIES

- 3.9.6 Track and Trace was universally welcomed, with respondents expressing positive expectations regarding the effects on crime, the community, and on ensuring the supply of authentic tobacco products.

RETAILERS/OTHER BUSINESSES

- 3.9.7 Whilst supportive of measures to tackle the supply and sale of illicit tobacco, larger businesses – wholesalers and retail chains, expressed concerns that any future system should be practical and manageable and not impede the speed of distribution or significantly increase costs. One example given was that it is unclear as to what extent specialist equipment will be required for tracking and tracing tobacco products and whether this would be one piece of equipment for all products, or whether different equipment would be required for different manufacturers. Each additional process would increase associated costs of scanning in and out of warehouses.

MEMBERS OF THE PUBLIC

- 3.9.8 Of those who responded to this question, views expressed were mixed. Some welcomed tighter controls to prevent illicit trade of tobacco. Others noted that track and trace might have implications with regards to consumer choice and would further increase prices on imported goods, suggesting such an increase would likely encourage an increase in illicit trade of tobacco products.

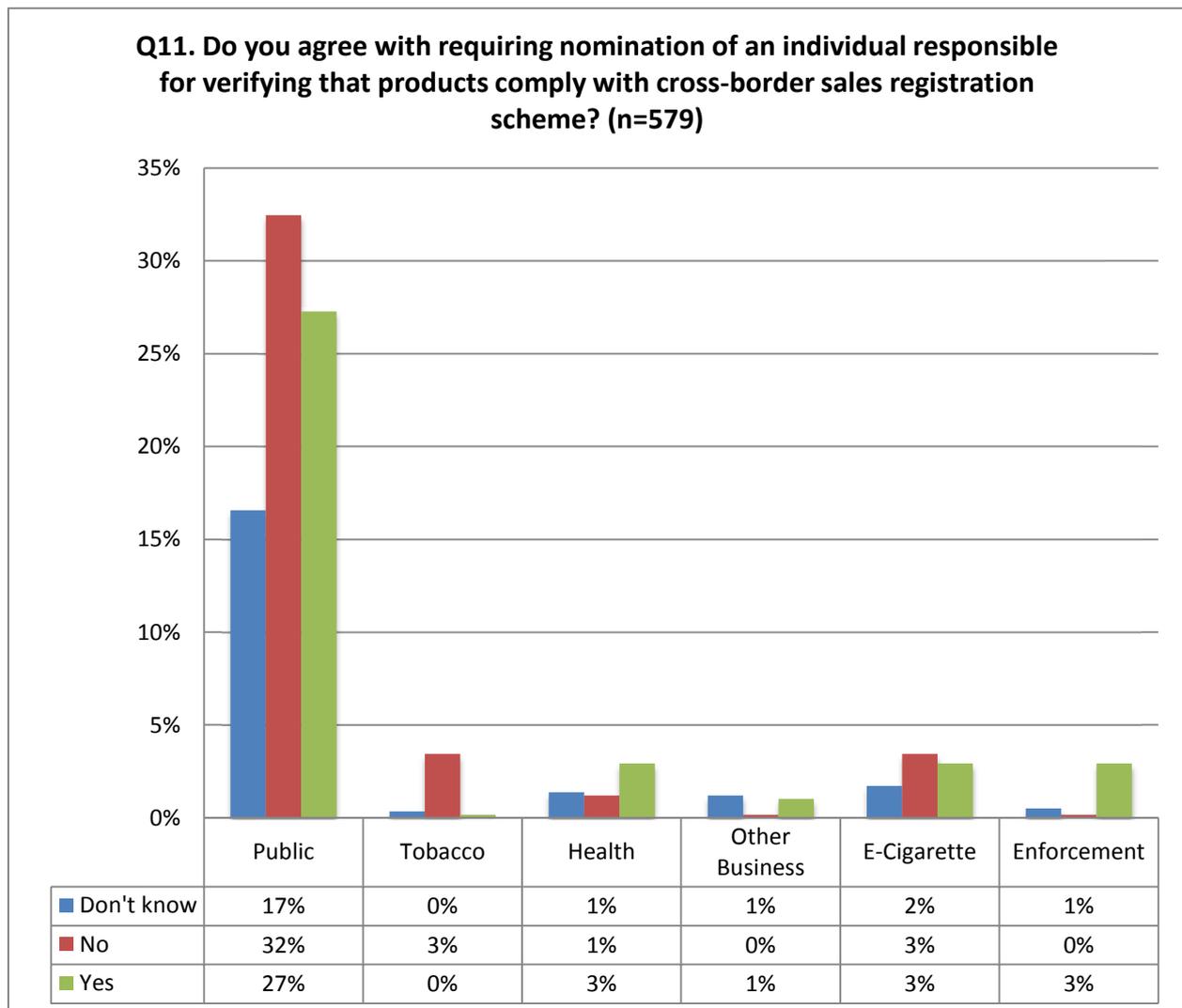
Government response

- 3.9.9 Proposals for tertiary legislation on track and trace and security features are being developed by the European Commission and are expected to be adopted in the first half of 2017.
- 3.9.10 **The Government is fully considering the information provided and will continue to listen to all businesses involved in the supply of tobacco products in the development of EU proposals in this area. HMRC is leading on this aspect of the TPD2 and will be transposing TPD2 Articles 15 and 16 in separate UK legislation, to apply to cigarettes and hand-rolling tobacco from 20 May 2019 and to all other tobacco products from 20 May 2024. Legislative proposals will be accompanied by an assessment of the estimated impact on businesses.**
- 3.9.11 **The Government is also making provision for the continued use of (until the new track and trace requirements take effect in 2019/2024) code markings that allow the identification of the place, date and, in the case of a product other than cigars, the time, of manufacture to be determined.**

Question 11

If a registration scheme were introduced for cross border distance sales, the Government is minded to require the nomination of an individual to be responsible for verifying that the product complies with the provisions in the UK regulations, before the product is supplied to the consumer. Do you agree with this approach?

3.10.1 Businesses were largely unsupportive of this proposal, the public had more mixed views, while organisations were in favour. Details of the quantitative response are set out in the graph below:



TOBACCO STAKEHOLDERS

- 3.10.2 Tobacco industry respondents mostly disagreed with the Government proposal to adopt the Directive's provisions to require a named individual to be responsible for checking legislative compliance, arguing that there is no good reason to go beyond the minimum requirements of the Directive that only require companies that engage in this activity to be registered, and that this, therefore, amounts to 'gold-plating'. More specific arguments included that this introduces unnecessary complexity and that the registration requirements are sufficient.

E-CIGARETTE STAKEHOLDERS

- 3.10.3 There were mixed opinions in this stakeholder group. Some agreed, but many were unsure or confused as to whether a supplier or retailer selling e-cigarettes is included in the definition of producer, which is the case.

HEALTH STAKEHOLDERS

- 3.10.4 Some Health related organisations agreed with the Government proposal, based on the tobacco industry's previous failure to comply with regulations and efforts to avoid liability, suggesting an independent regulator is required.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.10.5 Local Authorities and Trading Standards generally agreed with the proposal. One respondent believed that an individual not connected to the industry should be nominated and have powers to ensure that products are not available for supply until confirmation of compliance is given.

RETAILERS/OTHER BUSINESSES

- 3.10.6 Retailers and Retail Trade Associations were split equally between "yes", "no", and "don't know/unsure". Reasons for respondents' views were in the main not elaborated.

MEMBERS OF THE PUBLIC

- 3.10.7 Most members of the public did not directly address the question of the nomination of an individual to be responsible for verifying that the product complies with the provisions in the UK regulations. However, some respondents foresaw issues with a registration scheme, which are summarised in question 13.
- 3.10.8 More generally, one respondent took the view that any such changes would be "against the fundamental basis of the existing EU Trade Agreements".

Government response

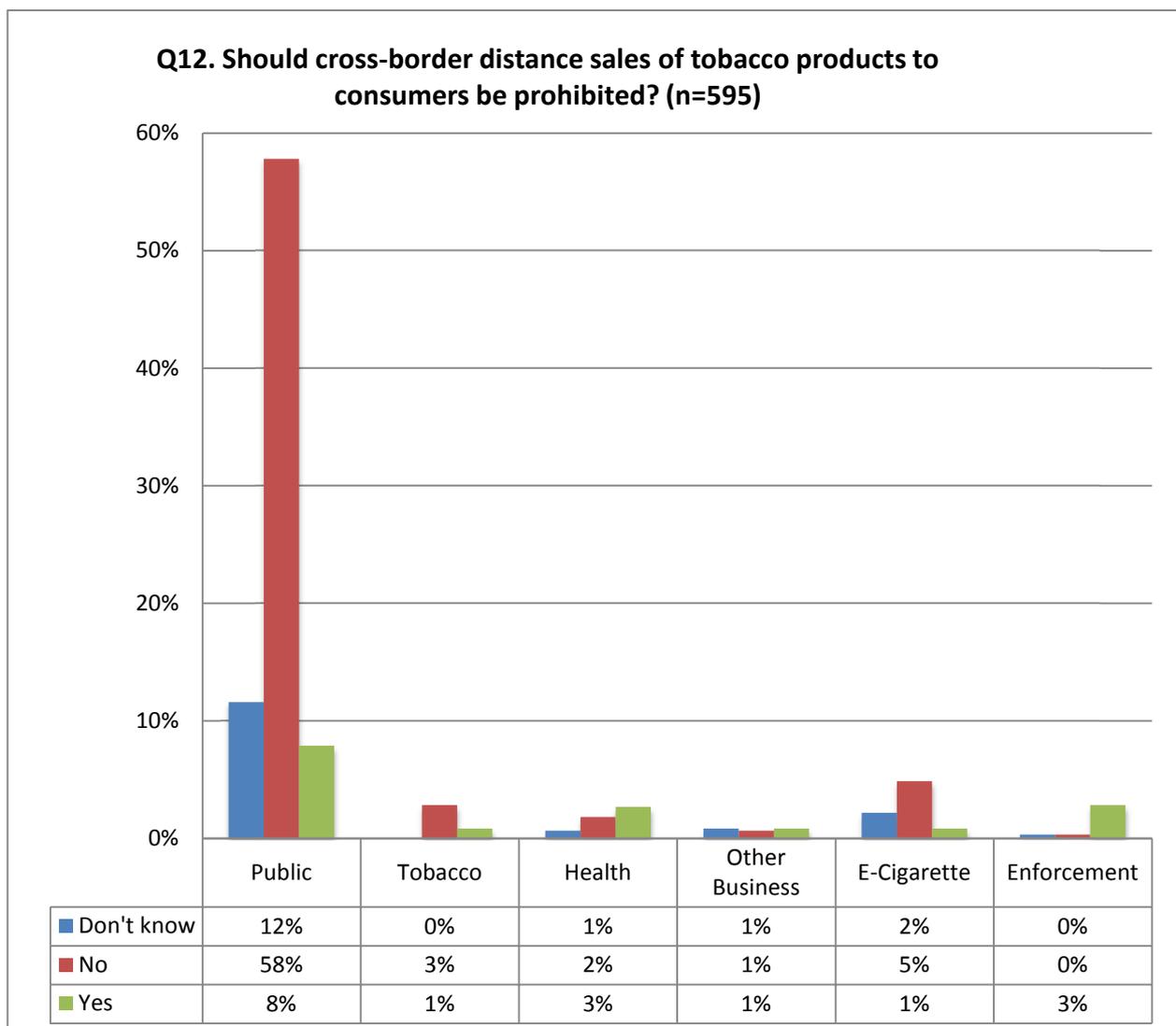
- 3.10.9 Consultation responses were mixed. Whilst only a very small percentage of sales of tobacco products to UK consumers are from EU-based companies, consultation responses indicate this is more significant proportion of the e-cigarette market. The Government believes that it would be disproportionate to ban cross-border distance sales of tobacco or e-cigarettes. A registration system requiring all UK and other EU-based businesses to provide a named person as part of the registration process will help to ensure products sold into the UK conform to UK law and assist enforcement authorities where retailers are not established in the UK, for example with consumer complaints, product recalls and withdrawals.

- 3.10.10 **The Government will implement regulations requiring, in the case of businesses established outside of the UK engaged in cross-border distance sales to UK consumers, the nomination of an individual to be responsible for verifying that products comply with the provisions in the UK regulations, before the product is supplied to the consumer.**

Question 12

Should cross-border distance sales of tobacco products to consumers be prohibited?

3.11.1 The majority of businesses and the public were against the prohibition of cross-border distance sales of tobacco, in contrast to the majority of health organisations which were in favour. Details of the quantitative response are set out in the graph below:



TOBACCO STAKEHOLDERS

3.11.2 Most tobacco industry respondents disagreed with a ban, suggesting that this was unwarranted and disproportionate. Five main arguments against the proposed ban were put forward:

- It breaches the EU Treaty as it undermines the foundation of the internal market
- It doesn't negate the need to establish a system of retail outlet registration for those countries that want to maintain cross-border sales
- Cross-border sales do not compromise the effectiveness of CHWs, which have to be in the language of the consumer to whom the product is sold
- Cross-border sales present no additional risk of underage purchasing when compared to intra-state distance sales or face-to-face retailer sales.

3.11.3 There was some misunderstanding on the part of some respondents who were unclear whether the TPD2 measures would apply to both EU and UK distance sales. They cited that the latter is an important growth area and serves areas of the country which do not have access to specialist tobacconists.

E-CIGARETTE STAKEHOLDERS

3.11.4 E-cigarette stakeholders were largely against the proposal, but it is clear that the majority of responses were in the context of the sale of e-cigarettes as opposed to tobacco products. These stakeholders do, however, make the same representation under question 13 on e-cigarettes.

HEALTH STAKEHOLDERS

3.11.5 The majority of health related organisations who responded to this question would prefer a ban on cross-border distance sales of tobacco products. Some also provided anecdotal views that such sales act as a means to avoid tobacco tax and regulation. Some also suggest that there could be difficulties distinguishing cross-border and domestic distances sales, therefore both should be banned.

ENFORCEMENT/LOCAL AUTHORITIES

3.11.6 The majority of Local Authorities and Trading Standards believe that cross-border distance sales of tobacco products should be banned. Reasons given included that it is difficult to regulate on-line sales and track who is responsible for websites; and similarly to health related organisations believed that there could be a problem in discriminating between cross-border and domestic distance sales, therefore, officers would prefer that all distance sales be prohibited.

RETAILERS/OTHER BUSINESSES

3.11.7 Retailers and Retail Trade Associations were split fairly equally between support, opposition and not having a view. Some of those supporting a ban expressed that it should not apply to smokeless tobacco products.

MEMBERS OF THE PUBLIC

3.11.8 The potential for a prohibition of cross-border sales was met with a considerably negative reaction from members of the public. Again a large proportion of comments were provided in the context of e-cigarettes, which are further explored

in question 13. Substantive responses argued that a ban would go against the ideals that the EU was based on, namely co-operation and free trade and question the legality of the provision under EU law.

Government response

- 3.11.9 It is clear that some respondents had understood that the TPD2 would ban all forms of distance sale, both domestic distance sale by companies in the UK to UK consumers and those to and from other MS (inter-community trade). This is not the case. The TPD2 requires the Government to choose one of two options, to ban cross-border distance sales or introduce a registration scheme for these sales. Based on the information received, sales of tobacco products to or from the EU are very small in the UK due to the comparatively high duty rates in the UK. On balance, a prohibition of this form of sales in and out of the UK would be disproportionate. A registration scheme represents the least burdensome option and will enable the continued sale of tobacco products to UK consumers by retailers established in the EU, and will provide enforcement authorities with greater information to carry out their duties.
- 3.11.10 The UK already has legislation prohibiting the sale of tobacco products to under 18s and retailers, whether on-line or person to person, will need to have taken sufficient steps to verify the age of their consumers. The Government will maintain the proposals included in the draft regulations at consultation and set up and maintain a register of all businesses engaged in cross-border distances sales.
- 3.11.11 The register will complement existing and planned registrations of retailers operating in the devolved administrations. In Scotland, any person carrying on a tobacco business must be registered on a national register held by the Scottish Ministers³. In Wales, there are provisions in the Public Health (Wales) Bill which cover the creation of a register for retailers of tobacco and nicotine products, which will create an offence for a person to carry on a tobacco and/or nicotine business in Wales without it being registered. The Bill also contains a provision which creates an offence for a person to knowingly hand over tobacco and/or nicotine products to a person under the age of 18 during the delivery or collection of those products in connection with a sale. It is intended that a tobacco retailers' register will be in operation in Northern Ireland from spring 2016. In England, we have no current plans to introduce a registration scheme for tobacco retailers. However, as announced at Autumn Statement, the government will be consulting on the provisions of Article 6 of the Illicit Trade Protocol and will examine options following this.
- 3.11.12 EU Member States are taking different approaches to implementation reflecting domestic policy on tobacco control. It will, therefore, be necessary to ensure that a list of all Member States banning cross-distance sales of tobacco products is established and made public.
- 3.11.13 **The Government intends to maintain the draft regulations introducing a registration scheme for businesses engaged in cross-border distances sales of tobacco products.**

Question 13

Should cross-border distance sales of e-cigarettes and refills to consumers be prohibited?

- 3.12.1 The majority in the business and public respondent groups were against the proposal, however, in organisations there was more of an even split between support and opposition. Details of the quantitative response are set out in the graph below:

TOBACCO STAKEHOLDERS

- 3.12.2 Tobacco industry respondents disagree with an outright ban, which they considered would be a disproportionate measure. They warn that a ban would stifle development of a product that has the potential to improve public health, restrict free movement of goods and contradict the 'Single Digital Market' initiative.
- 3.12.3 One respondent that stated their preference for a registration scheme agreed with the provisions in the TPD2 requiring sellers to verify the age of the consumer.

E-CIGARETTE STAKEHOLDERS

- 3.12.4 Almost all respondents to this question were against a ban on cross-border distance sales of e-cigarettes, stating anecdotally that many businesses in this sector trade solely on-line. Information from the consultation and other intelligence sources indicate that many businesses trade solely on-line. Respondents felt a ban would stifle innovation and development of e-cigarettes which could potentially carry less risk to health than tobacco products.
- 3.12.5 Those supporting a ban cited that on-line sales could be a gateway for underage sales, in part due to the absence of effective age verification systems.

HEALTH STAKEHOLDERS

- 3.12.6 The responses to this question reflect the diverse views on e-cigarettes that exist within the public health community. Some agreed with a prohibition of cross-border sales of e-cigarettes, on the basis, that the tobacco industry is using e-cigarettes to promote traditional cigarettes; the safety and efficacy of e-cigarettes as a smoking cessation aid is unproven; they may be a 'gateway' to smoking; and the absence of adequate age-verification systems.
- 3.12.7 Others disagreed with a ban and cited evidence that e-cigarettes are little used by people that have never smoked; e-cigarettes are less harmful than cigarettes and therefore warrant a lower degree of regulation; and it is not in the interest of public health to limit the availability of products that have the potential to help people stop smoking.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.12.8 Local Authorities and Trading Standards were largely against cross-border sales of e-cigarettes and refills to consumers. This was mainly due, as with distance sales of tobacco products, to concerns around the adequacy of current age verification systems.

RETAILERS/OTHER BUSINESSES

- 3.12.9 Retailers and Retail Trade Associations did not think there should be a prohibition, as they considered that it restricts the free movement of goods around the EU and any move to ban cross border sales would be unlawful.

MEMBERS OF THE PUBLIC

- 3.12.10 Almost all respondents to this question were against a ban on cross-border distance sales of e-cigarettes. The main themes were that consumer choice would be considerably reduced and deprive consumers of products they find useful as an alternative to smoking, which in turn may lead people to return to smoking; and a ban would be against the principle of free movement of goods in EU. Some

respondents suggested that any ban should apply to e-liquids/refills and not to the purchase of devices.

Government response

- 3.12.11 E-cigarettes are not risk free, but the latest evidence suggests these products are safer than smoking. The Government believes that it would be disproportionate to prohibit cross-border distance sales of e-cigarettes, which have the potential to help smokers quit. Information from the consultation and other intelligence sources indicate that many businesses in this sector trade solely on-line. The Government will, therefore, maintain the proposals included in the draft regulations at consultation and setup and maintain a register of all businesses engaged in cross-border distances sales. Domestic distance sales (UK retailers to UK consumers) are not affected.
- 3.12.12 England and Wales already has legislation prohibiting the sale of e-cigarettes products to under 18s and retailers, whether on-line or person to person, will need to have taken sufficient steps to verify the age of their consumers. Similar legislation is planned in Scotland and Northern Ireland. The Government will maintain the proposals included in the draft regulations at consultation and setup and maintain a register of all businesses engaged in cross-border distances sales.
- 3.12.13 The register will complement existing and planned registrations of retailers operating in the devolved administrations. In Scotland, the Scottish Parliament are considering the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill⁴ which, if passed, will require any person carrying on a nicotine vapour product business in Scotland to register on a national register held by Scottish Ministers. In Wales, there are provisions in the Public Health (Wales) Bill which cover the creation of a register for retailers' of tobacco and nicotine products, which will create an offence for a person to carry on a tobacco and/or nicotine business in Wales without it being registered. The Bill also contains a provision which creates an offence for a person to knowingly hand over tobacco and/or nicotine products to a person under the age of 18 during the delivery or collection of those products in connection with a sale. In England, we do not at this stage intend to implement a registration scheme for domestic sales.
- 3.12.14 EU Member States are taking different approaches to implementation reflecting domestic policy on e-cigarettes. It will, therefore, be necessary to ensure that a list of all Member States banning cross-distance sales of e-cigarettes and refill containers is established and made public.
- 3.12.15 **The Government will put in place regulations and operate a system requiring the registration of all businesses engaged in the cross-border distance sale of e-cigarettes.**

Question 14

What systems to verify the age of customers are available to, or currently used by, businesses involved in distance sales to other EU Member States?

TOBACCO STAKEHOLDERS

3.13.1 A number of age verification system checks were noted by tobacco companies, comprising:

- IP recognition
- Self-certification
- Payment mechanisms
- Third party software (including electoral register checks)
- Semantic verification

3.13.2 Respondents believe that all these methods should be acceptable under TPD for businesses engaged in cross-border distance sales. It was suggested that the Government should incorporate the work of the Digital Policy Alliance, who are collaborating with the British Standards Institution to develop a Publicly Available Specification for on-line age verification.

E-CIGARETTE STAKEHOLDERS

3.13.3 A number of respondents cited similar views to the tobacco industry suggesting that that it may be possible to collaborate with the work of the Digital Policy Alliance to develop new age verification standards. This would provide similar assurance on-line to existing schemes that operate at face-to-face retail including “Challenge 21” policy in stores, ‘No Sale to U18s’ on product labelling, point of sale materials, marketing and display stands.

HEALTH STAKEHOLDERS

3.13.4 One respondent noted that no ‘unambiguous’ system of age verification has yet been demonstrated. Others cited that any decision to require registration of tobacco products must be compatible with the provisions of the Illicit Trade Protocol (ITP) and demonstrate adequate to supply-chain control.

ENFORCEMENT/LOCAL AUTHORITIES

3.13.5 Most respondents provided similar views to other stakeholder groups, listing various age verification systems currently in use and suggesting that self-verification is an inadequate check. Respondents also agreed that there is no current age verification system which ‘unambiguously’ confirms the consumer’s age electronically.

RETAILERS/OTHER BUSINESSES

3.13.6 Most responses included references to credit card and self-age verification systems.

MEMBERS OF THE PUBLIC

3.13.7 This question drew a large number of responses, however, this gave only a few unique opinions. Some felt that current methods requiring users to state their age on websites to ensure they are 18 or over is sufficient, whilst others felt this was not likely to be effective at preventing underage sales.

3.13.8 One respondent's view related to e-cigarettes: "any burden associated with age-verification should be proportionate to risk, and any risks of material harm are low". Essentially indicating that due to the low levels of harm that e-cigarettes may cause, it does not need particularly strict restrictions. Respondents also note that credit cards or PayPal accounts are often required to complete a distance transaction, something that children and adolescents would find hard to access.

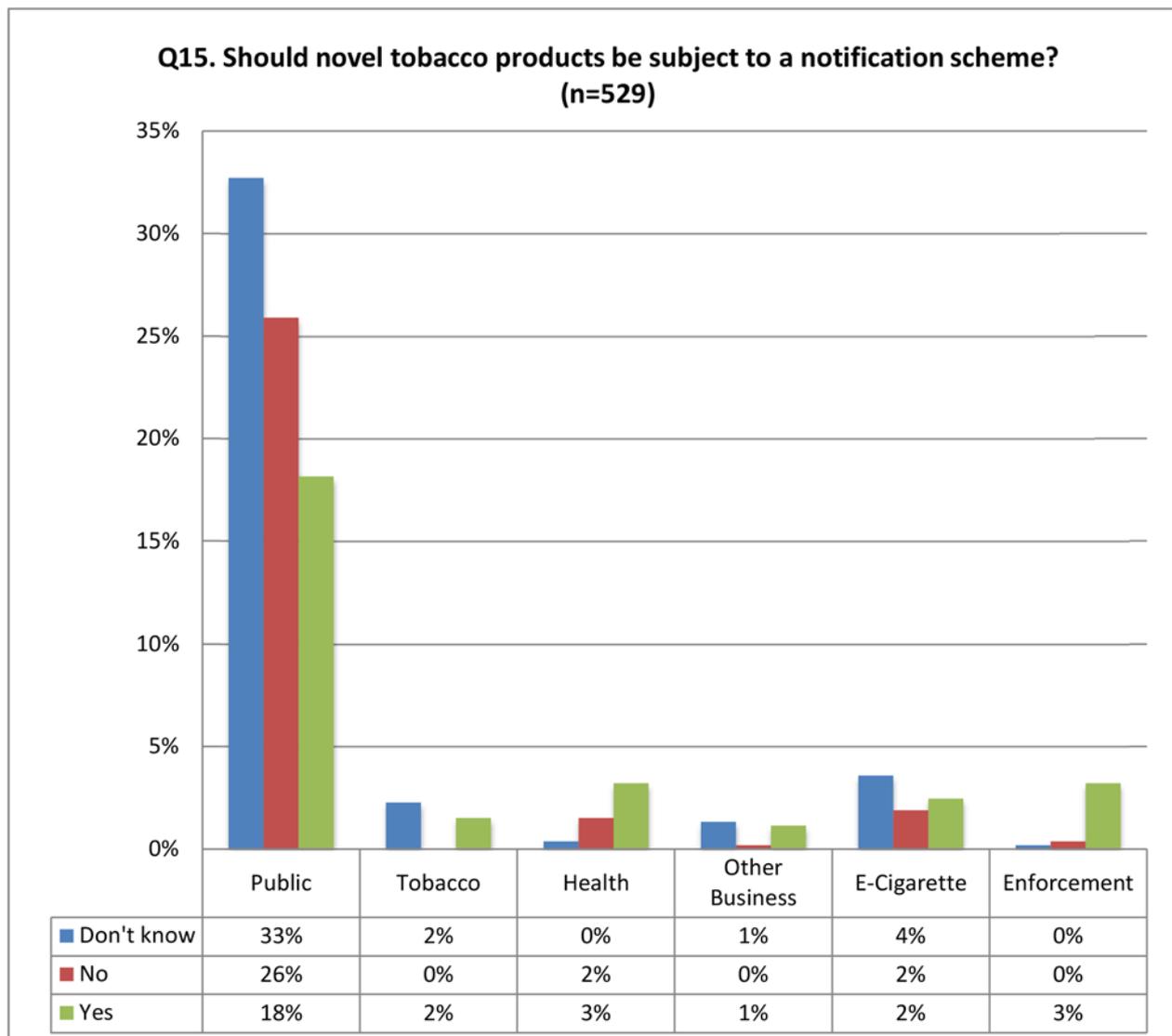
Government response

3.13.9 **The Government has carefully considered responses. This issue has been discussed at European level and Member States are taking different approaches dependent on existing mechanisms in their jurisdictions. It will be for companies selling into other Member States to establish and meet those requirements. For businesses selling into the UK they will need to demonstrate an electronic age verification scheme that unambiguously confirms the consumer's age. Enforcement authorities will wish to have regard of developments in age verification technologies, such as that under development by the Digital Policy Alliance and British Standards Institution.**

Question 15

Should novel tobacco products be subject to a notification scheme?
 If “No”, please explain why you think an authorisation scheme would be preferable?

3.14.1 Many respondents did not know or have a view on this question. Of those with a firm opinion, businesses and organisations supported the proposal, whilst the public were more opposed than supportive. However, both businesses and organisations were in favour. Details of the responses are set out in the graph below:



TOBACCO STAKEHOLDERS

- 3.14.2 All respondents who answered this question agreed with notification on the basis that this is simpler and more efficient than an authorisation scheme.
- 3.14.3 Respondents stated that an authorisation scheme would be problematic because it would be an obstacle to the free movement of goods and stifle commercial freedom, innovation and be contrary to EU competition law principles.

E-CIGARETTE STAKEHOLDERS

- 3.14.4 There was a mixed response from this stakeholder group, with many demonstrating a lack of understanding of what constitutes a Novel Tobacco Product (NTP⁵) and a misconception that e-cigarettes would fall in this category. Some respondents requested better definition of NTP and that the regulation should separate and group all products that contain tobacco, both traditional and 'novel' tobacco products, from products like e-cigs. Subsequently, there was support of a regulatory regime that recognises that novel tobacco products are still tobacco products and should be subject to tobacco regulation.

HEALTH STAKEHOLDERS

- 3.14.5 All respondents who answered this question agreed with a prior notification procedure, on the basis that authorisation would imply that authorised products are safe.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.14.6 Local Authorities unanimously agreed, with little further information supplied.

RETAILERS/OTHER BUSINESSES

- 3.14.7 Retailers and Retail Trade Associations disagreed that a notification scheme was necessary, though strongly agreed that a notification scheme would be preferable to an authorisation scheme, due to the costs and times involved.
- 3.14.8 Furthermore, it was assumed that, producers would be required to have notified competent authorities before they approached retailers to sell the product. Obligations should be placed upon the producer to confirm that products had been notified rather than creating a further burden upon retailers to check that notification had occurred.
- 3.14.9 Similarly to other stakeholder groups, some respondents mistakenly understood that e-cigarettes are classified as NTP.

MEMBERS OF THE PUBLIC

- 3.14.10 A large number of respondents used this question to express concerns over what they see as excessive regulation of e-cigarettes and disagreement with the notification procedures in TPD2 Article 20. These comments are considered in the summary of Question 18 which relates to the notification of e-cigarettes. Many members of the public confused the NTP scheme with that for e-cigarettes and disagreed with the introduction of both notification and authorisation schemes. Some suggested that current regulations applicable to e-cigarettes would suffice as they reflect the level of control necessary for a low harm product.

- 3.14.11 Substantive comments raised concerns that many people would be unfamiliar with the term NTP and suggested an explicit exclusion of e-cigarettes should be made in the definition, others suggested that the definition should include, but not be limited to, heated tobacco.

Government response

- 3.14.12 The TPD2 allows Member States to implement a notification scheme or a prior authorisation scheme for novel tobacco products. Consultation responses overwhelmingly support a notification scheme over an authorisation scheme for NTP. This supports the Government proposal at consultation, which detailed how a notification scheme would operate under UK law. A prior authorisation scheme would introduce significant costs to businesses and the Government. The establishment of a notification scheme will provide the Government with sufficient additional information to monitor innovations in the tobacco market such as heat-not-burn products.
- 3.14.13 **The Government will implement procedures for the notification of novel tobacco products.**

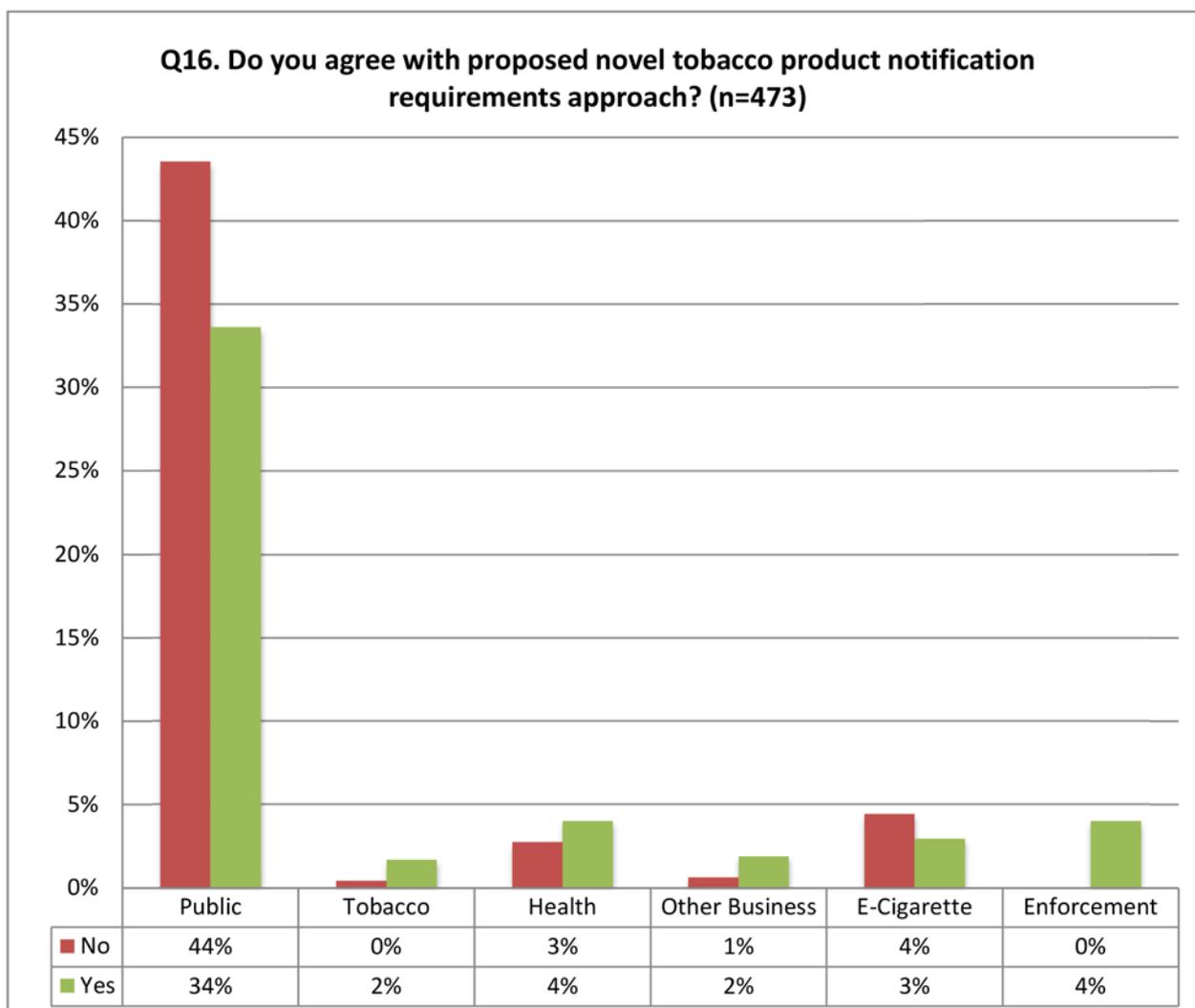
Question 16

Under a notification scheme the Government is minded to include provision to require manufacturers or importers of novel tobacco products to provide, with any notification, information on:

- the toxicity of the product, its ingredients and emissions;
- the addictiveness of the product, its ingredients and emissions;
- the expected effects of the product on the cessation of tobacco consumption by existing users of tobacco products; and
- the perception of the product by consumers or potential consumers (or predictions as to how the product will be perceived), including the attractiveness of the product.

The Government believes that this information should and will be available to manufacturers and importers prior to launching all new products. Do you agree with this approach?

3.15.1 Responses to the Government proposal by businesses were relatively evenly split between support and opposition. The public was more opposed to the proposals. Organisations, however, were overwhelmingly in favour. Details of the quantitative response are set out in the graph below:



TOBACCO STAKEHOLDERS

- 3.15.2 Some agreed with the proposal, citing that the Government should require product risk profile information. However, most of the industry respondents disagreed in some way with the list, indicating that the information required in the proposal would not be readily available to the producer, and getting it would represent a significant additional burden on tobacco manufacturers. Notably, they recalled that the information in points (a)-(c) will already be required under Article 5 (general reporting requirements), and this would appear to be unnecessary duplication. Respondents also cited that providing information on (c) the expected effects of the product on the cessation of tobacco consumption by existing users of tobacco products; and (d) the perception of the product by consumers or potential consumers (or predictions as to how the product will be perceived), including the attractiveness of the product, would amount to a pre-authorisation of products. These requirements were seen by tobacco stakeholders as 'gold-plating' and therefore they suggested against the UK Government's better regulation principles. Others raised concerns that 'addictiveness' and 'attractiveness' are not definable scientific concepts, as they cannot be measured objectively, and disagreed with their inclusion.
- 3.15.3 One respondent also considered the proposals as gold plating the Directive, as a result of the failure to make clear throughout that only 'available scientific studies' are required and that manufacturers are not required to commission new studies ahead of notification.

E-CIGARETTE STAKEHOLDERS

- 3.15.4 Some e-cigarette stakeholders gave responses in this section, which related only to e-cigarettes – these are included in the analysis of responses to question 18, which relates directly to the e-cigarette and refill notification scheme.

HEALTH STAKEHOLDERS

- 3.15.5 Those health related organisations that responded to this question agreed with the Government proposal, suggesting NTP should be treated as existing tobacco products. Respondents also requested that information notified should be made publicly available.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.15.6 Local Authorities and Trading Standards Agencies were in support of the Government proposal, without adding significant detail.

RETAILERS/OTHER BUSINESSES

- 3.15.7 Retailers and Retail Trade Associations were mostly against these requirements, arguing it was unfair that a product that might be demonstrably less harmful than traditional tobacco cigarettes e.g. a heat-not-burn product should be treated equally – or even more strictly.
- 3.15.8 They expressed the belief that mandatory notification requirements for novel tobacco products should not exceed those for existing tobacco products such as cigarettes, and that to impose greater burdens on manufacturers or importers of novel tobacco products than on cigarettes would breach the EU principle of non-

discrimination ("equal treatment") and be unlawful under the treaties and relevant EU jurisprudence.

- 3.15.9 This respondent group agreed with the comments from the tobacco industry that the requirements (c) and (d) are impossible to provide in advance of release on to the market and even then given the difficulty in defining the terms used. They also questioned how this information would be used by regulators.
- 3.15.10 There was one response from the pharmaceutical sector. This stated that manufacturers and importers should be required to provide the additional information on :
- The preferences of consumer groups, including young people and current smokers, in respect of the product
 - The risks and benefits of the product
- 3.15.11 They believed that such information is important to safeguard consumers and public health and provides valuable information that can inform future action or policy.

MEMBERS OF THE PUBLIC

- 3.15.12 Again, a large number of responses from members of the public gave responses in this section, which related only to e-cigarettes, therefore, these are included in the analysis of responses to question 18. Some respondents suggested that the TPD2 provisions on novel tobacco products would breach the EU principle of non-discrimination (equal treatment) and be unlawful under the EU treaties.
- 3.15.13 Some respondents were also unsure about how realistic some of the information requirements are in points (c) and (d) and shared other stakeholder's views on the difficulty of objectively measuring concepts like "addictiveness".

Government Response

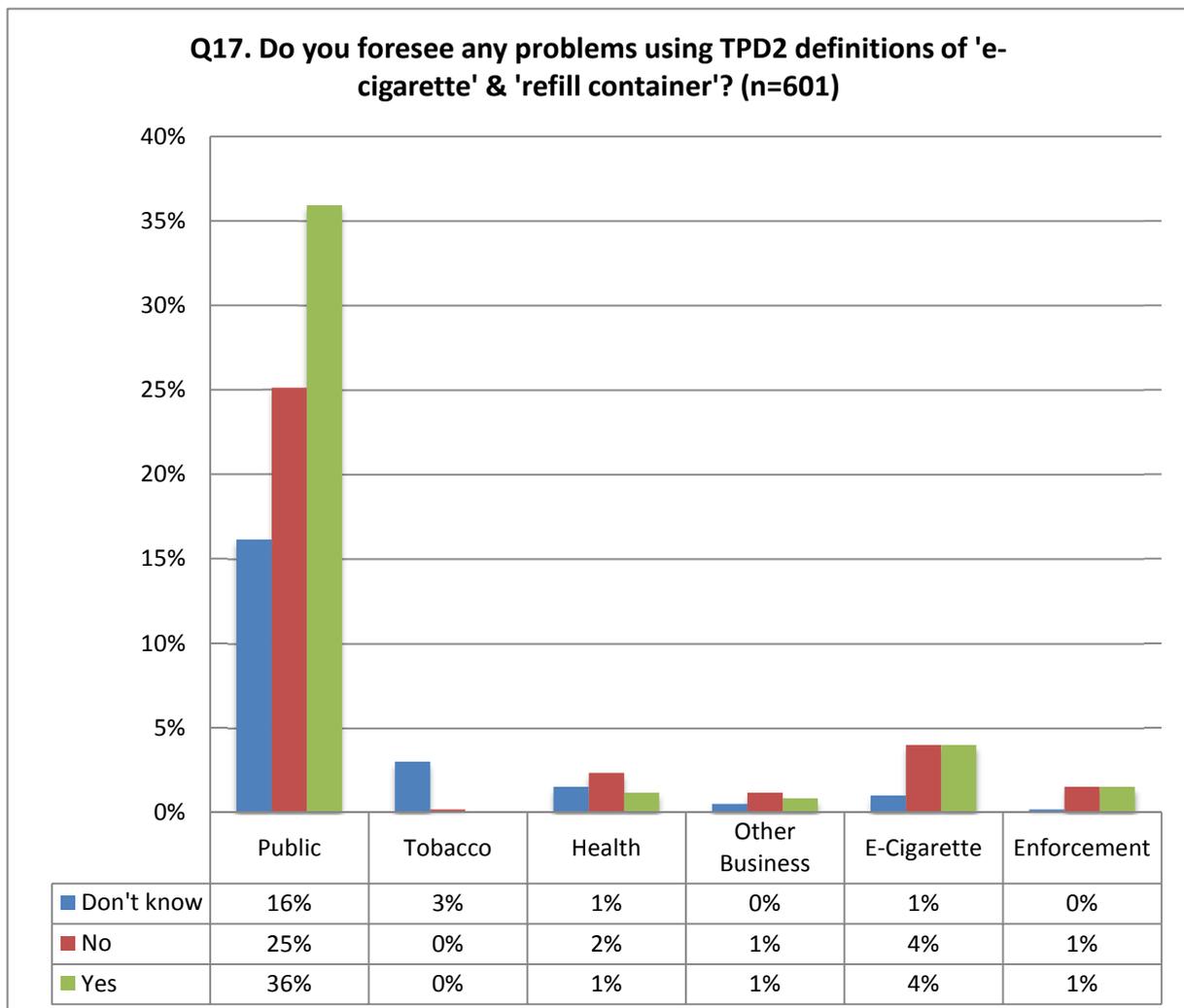
- 3.15.14 The Government has carefully considered the points raised. Respondents have rightly pointed out that there is duplication in the information required in the notification of NTP and that required of all tobacco products under the Article 5 reporting requirements, albeit to different timescales; novel tobacco products need to provide the information 6 months in advance of placing on the market. The development of the tertiary legislation on reporting for tobacco products, which has been undertaken since the publication of the consultation, has made it clearer how reporting requirements and notification requirements will be managed. The Government intends to use the central portal system being developed by the Commission for the submission both of information related to existing tobacco products and for notification of novel tobacco products. We will work with the Commission on the reporting and notification system to minimise any duplication of information required.
- 3.15.15 **Having considered the responses, the implementing regulations will make clear that in submitting data on novel tobacco products only studies that are available at the time of submission are required and that manufacturers are not required to carry out additional studies on toxicity, addictiveness,**

attractiveness or undertake additional market research. The Government will also work with the Commission to minimise any duplication.

Question 17

The Government is minded to use the TPD2 definitions of an 'electronic cigarette' and 'refill container'. Do you foresee any problems with inconsistency with the definitions in The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations?

- 3.16.1 Organisations and businesses were roughly equal in foreseeing problems with this proposal. Whilst the majority of the public felt that this would lead to confusion, common problems cited by all groups were that the TPD2 definitions exclude non-nicotine products, and the inclusion of a reference to component parts of e-cigarettes, results in illogical labelling and notification of components parts which are often sold separately to the nicotine liquid e.g. tank. Details of the quantitative response are set out in the graph:



TOBACCO STAKEHOLDERS

- 3.16.2 Respondents had mixed views on this question. Whilst some gave no response, others foresaw problems, stating that this would cause confusion.
- 3.16.3 There were several suggestions to amend the definitions in the UK age of sale legislation to bring it into line with the TPD2 definitions, others suggested removing the reference to component parts from the definition of e-cigarettes (in the TPD2 definition), as this was considered problematic, implying that it is necessary to put health warnings concerning nicotine (saying this product contains nicotine) on components that do not contain nicotine.
- 3.16.4 There were also calls to include in regulations e-liquids that do not contain nicotine, as well as those that do, noting that this would go beyond the scope of TPD2.

E-CIGARETTE STAKEHOLDERS

- 3.16.5 E-cigarette stakeholders provided a variety of views. Some respondents were concerned there is significant ambiguity in the TPD2 definitions namely:
- ““Electronic cigarettes” means a product that – a) can be used for the consumption of nicotine-containing vapour...”. Use of “can” in definition of e-cigarettes in the TPD2, captures other products not intended for vaping
 - Some suggested a further exception that “c) does not contain tobacco” to ensure that products that generate vapour from heating (not burning) tobacco are not covered. The definition would read:
“Electronic cigarette” means a product that—
 - a) can be used for the consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank (regardless of whether it is disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges), but
 - b) is not a medicinal product or medical device;
 - c) ***does not contain tobacco***
 - Some suggested that the definitions in BSI PAS 54115 (industry developed standard on guidance and best practice for producers of e-cigarettes) should be used, such as “vaping product” rather than “electronic cigarette”. “Vaping product” covers non-nicotine products, thereby capturing the whole vaping market, which they feel would benefit and provide clarity for enforcement officers, the industry and consumers.
- 3.16.6 Others stated that they do not fully agree with either definition and think that the application of certain restrictions to refill tanks and e-cigarettes lack any logical basis.

HEALTH STAKEHOLDERS

- 3.16.7 Health stakeholders did not anticipate any problems. However, it is worth noting some suggested that differences in terminology are also emerging between UK nations.

ENFORCEMENT/LOCAL AUTHORITIES

3.16.8 While many respondents answered that they did not foresee any major problems with this inconsistency, most found it perplexing and frustrating, and called for the definitions to be standardised.

RETAILERS/OTHER BUSINESSES

3.16.9 Whilst many respondents answered that they did not foresee any major problems with this inconsistency, most called for definitions to be standardised and criticised the fact that two Regulations made so closely together should propose to use different definitions.

MEMBERS OF THE PUBLIC

3.16.10 Whilst views were mixed, the majority of responses opposed the Government's proposal to use different definitions for e-cigarettes. Many criticised the wording of the definitions, opposing the use of either definition. Some reiterated that the TPD2 definition used in the UK draft regulations as they stand would consider components of e-cigarettes, e.g. a cartridge, to be defined as an e-cigarette.

Government Response

3.16.11 **Having considered all the responses carefully, the Government has decided to use the TPD2 definitions of an 'electronic cigarette' and 'refill container'.**

3.16.12 Retailers and enforcement authorities who would have to deal with both sets of regulations did not foresee major problems.

3.16.13 We do not intend to extend the definition to include any additional products that go beyond the TPD2 requirements, such as liquids that do not contain nicotine, as this would impose an additional burden on manufacturers and importers. Products that are not within the TPD2 definition will continue to be regulated under the General Product Safety Regulations.

3.16.14 The Government will maintain the definition in The Nicotine Inhaling Product (Age of Sale and Proxy Purchasing) Regulations which is drawn wider than the TPD2 definition, to capture all devices capable of delivering nicotine by inhalation, with the intention that these Regulations cover existing and future developments in technology providing protection for those under the age of 18. Scotland will maintain the definition of nicotine vapour products in respect of the provisions contained in the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill. The definition in the bill covers all devices and e-liquids whether they contain nicotine or not.

Question 18

The Government intends to handle notifications of e-cigarettes and refill containers electronically and make all information contained in notifications automatically available to the public unless this information can be considered truly commercially confidential. What information contained in the notifications should be considered commercially confidential?

TOBACCO STAKEHOLDERS

3.17.1 All four of the big tobacco companies felt that notifications required information that is commercially confidential, comprising:

- Data that describes recipes or supports formulations
- Details of production processes
- Identities of suppliers and sub suppliers
- Market research
- Measured emissions
- Sales volumes that are not publicly available
- Technological innovations that are not patented
- Filing of notifications and the notifications themselves

3.17.2 Respondents did not provide rationale for the list of information that they considered to be commercially confidential, but stated that competitors and other companies should not be able to directly mimic and replicate proprietary information and data, for example e-liquid recipes which are considered trade secrets and valued intellectual property.

E-CIGARETTE STAKEHOLDERS

3.17.3 E-cigarette stakeholders felt that there were a number of things that should remain confidential:

- Detailed ingredients lists from which a recipe could be reproduced
- Flavouring mixture
- E-liquid recipes
- Manufacturing techniques
- Construction
- Design

- 3.17.4 As expressed by the tobacco industry, there was concern that allowing the sharing and publication of certain information would enable overseas manufacturers to gain a competitive advantage by learning about recipes, manufacturing techniques and the supply chain.

HEALTH STAKEHOLDERS

- 3.17.5 Health organisations indicated that they had no relevant knowledge or were unsure of their view on this issue. However, they agreed that notifications should be made publicly available and burden of proof of the commercial sensitivity of the information should rest on the notifying party.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.17.6 The Local Authority and Trading Standards responses called for as much information as possible to be made available to the public, with an acknowledgement and expectation that businesses would want protection against others using their recipes, as is the case in the food sector. Nonetheless, they felt that the burden of proof should be placed on the party making the notification to show that requested information should properly be considered confidential.

RETAILERS/OTHER BUSINESSES

- 3.17.7 Retailers responded that information to be considered confidential included:

- Amount of ingredients, either by weight or percentage
- Flavours
- Formulations
- Any new data generated from toxicology and pharmacokinetics testing
- Any other information that would make it easy to replicate the product by a third party

- 3.17.8 Several respondents believed that supporting confidentiality would aid innovation and that manufacturers should not be penalised by making their information public.

MEMBERS OF THE PUBLIC

- 3.17.9 Respondents reiterated similar views to other respondent groups urging that certain information be kept confidential in order to prevent counterfeiters copying their product and taking their intellectual property. One respondent said that to avoid this, the full percentage of flavourings must not be disclosed. Another recommended extending this confidentiality to some aspects of the production, noting that manufacturers often make product using “sophisticated technologies” and processes, i.e. temperature management, and to disclose them would provide potential counterfeiters more significant information.

- 3.17.10 Respondents did however want the Government to balance the amount of confidentiality allowed. Substances that are known to harm the public must be disclosed and this is information the consumer has the right to know. One respondent summed up that the goal of commercial confidentiality: “The principle for disclosure should be to disclose information about risks or benefits to consumers, but to protect the intellectual property of manufacturers and vendors to support innovation.”

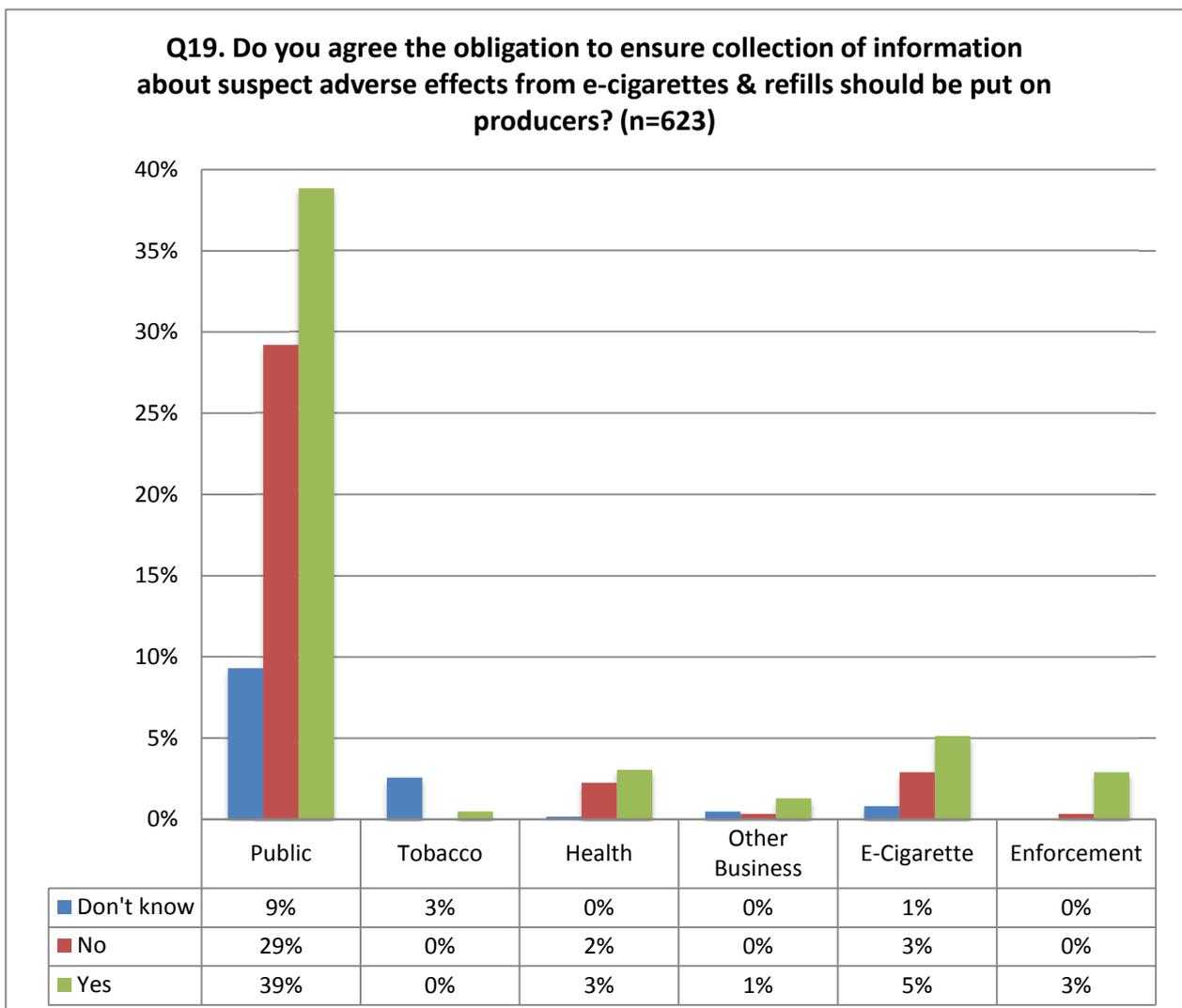
Government Response

3.17.11 The Government considers that it is an important facet of TPD2 that consumers should have access to information about e-cigarette products on the market to enable them to make an informed choice. **When a notification has been completed, MHRA will publish all non-confidential information on a designated website in-line with the requirements of TPD2 Article 20(8). Manufacturers and importers will have the opportunity to specify information that they consider to be confidential when they submit a notification.**

Question 19

The Government is minded to put the obligation on ‘producers’ (which includes manufacturers, importers into the UK and those that rename a product) in the transposing regulations which will ensure that there will always be a person in the UK who collects information about suspected adverse effects in relation to e-cigarettes and refill containers. Do you agree?

3.18.1 The majority of respondent groups were in favour of the proposal. Details of the quantitative response are set out in the graph below:



TOBACCO STAKEHOLDERS

- 3.18.2 There were very few responses to this question, the majority responding as 'Don't know/no view'. Only two respondents expressed further views, stating that the obligation should apply to all EU manufacturers and all those importing e-cigarettes outside of the EU into the EU, some were not against, but thought this unnecessary and other some felt this was burdensome. One respondent suggested that the TPD2 should instead cross-refer to the General Product Safety (GPS) regulations, so that there would be only one set of regulations to follow.

E-CIGARETTE STAKEHOLDERS

- 3.18.3 There was a mix of views amongst e-cigarette stakeholders. Some were against the proposal, stating there is no evidence of adverse effects from e-cigarettes and refills and therefore no need to set up a system to collect this information.
- 3.18.4 Some were supportive, stating this is the most cost effective and proportionate way of proceeding. Some wanted lower obligations for small/medium enterprises and that any costs should be proportionate to the size of businesses.
- 3.18.5 Some wanted a delay on the introduction of this (e.g. 2 years) and requested that retailers should be provided with protocols for reporting adverse events.

HEALTH STAKEHOLDERS

- 3.18.6 Health related organisations were generally in agreement with this proposal, adding that it will be important to collect and communicate information about any adverse health effects of these products.
- 3.18.7 Some respondents warned that e-cigarettes are still relatively new products, and that the possibility exists that such products could, in the future, be shown to have adverse effects on health. Conceding that this is a possibility, and being aware of the investment made in these products by the industry, they suggest that it is imperative that information about any negative effects on health is collected and communicated by an independent person/body.

ENFORCEMENT/LOCAL AUTHORITIES

- 3.18.8 Local Authorities agreed with the Government proposal and highlighted the importance that the collection of information about adverse effects should be operated by either the Government or an independent body and that producers should support the cost of this service.

RETAILERS/OTHER BUSINESSES

- 3.18.9 Retailers and Retail Trade Associations were mostly in agreement with the Government proposal, with them most commonly offered feedback being that retailers should be provided with guidance on the reporting of adverse events.

MEMBERS OF THE PUBLIC

- 3.18.10 Once again members of the public seemed to be largely against the policy proposed. One respondent argued that this was an unnecessary and unfair burden on the e-cigarette industry, arguing that combustible tobacco products industry which causes more health harm has no such regulations to meet.

- 3.18.11 Other respondents did not dispute that someone to collect information about suspected adverse effects was required, however, queried why this person had to be on member-state level. They argued that this role should be centralised at EU level to minimise unnecessary red tape and expense, the costs of which will inevitably be passed on to the consumer.
- 3.18.12 Finally there was some opposition to the Medicines and Healthcare products Regulatory Agency (MHRA) being named as the competent authority for the notification of e-cigarettes. One respondent believed the MHRA had a conflict of interest given their role in regulating medicines and others were concerned that they would impose a higher level of regulation than necessary.

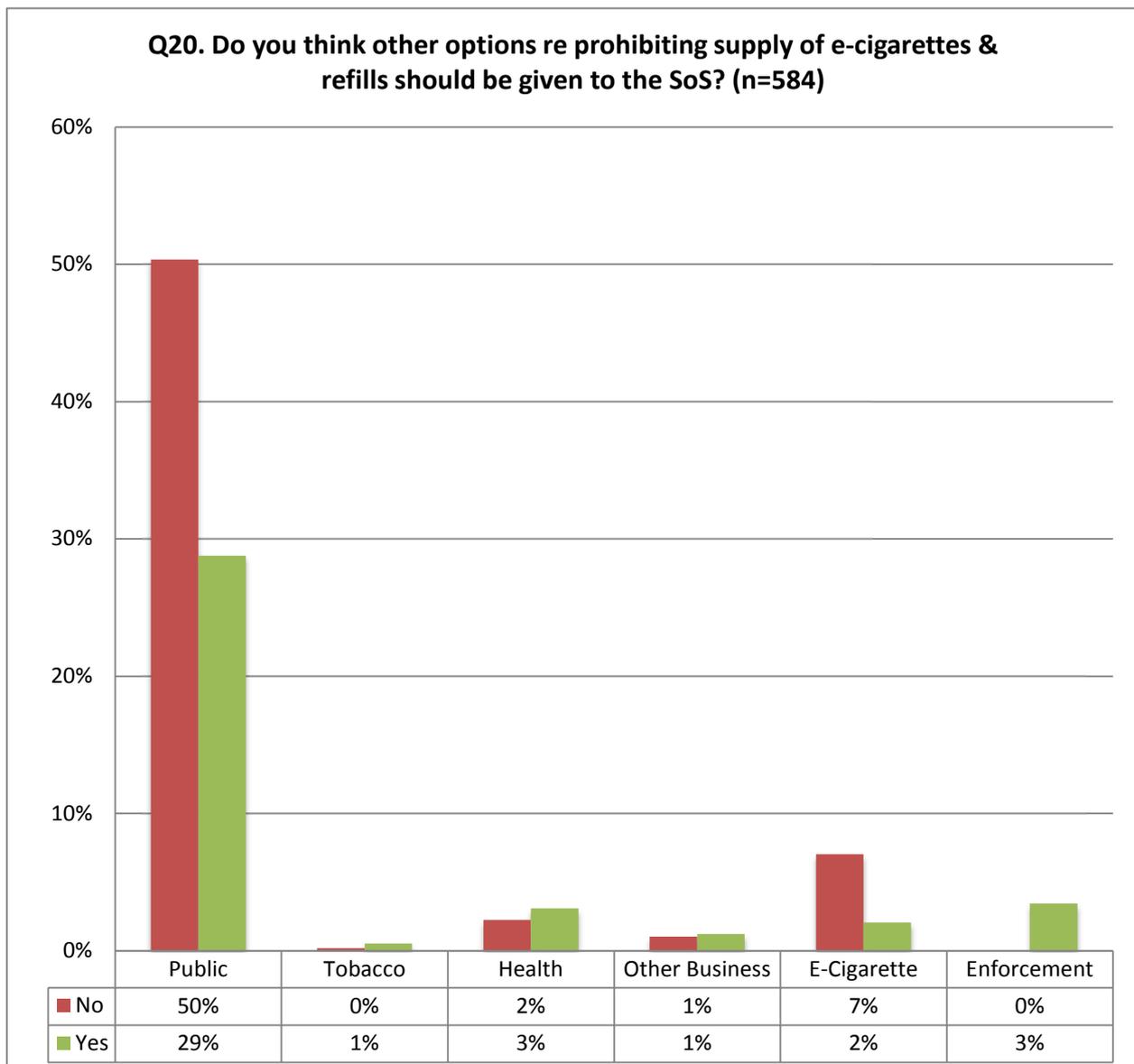
Government Response

- 3.18.13 The Government believe an important aspect of the TPD2 is that 'producers' will be expected to put in place a system for collecting and investigating adverse incidents. We are reassured from responses received during consultation that incidents reported to date are small in number when compared to the numbers of products sold. The National Poisons and Information Service and the MHRA have also received only small numbers of reported incidents, the large majority of which relate to accidental exposure.
- 3.18.14 It is reasonable to assume some consumers will wish to report adverse incidents to a relevant enforcement body. MHRA will facilitate the reporting of such adverse events through a dedicated reporting channel on the Yellow Card portal. The reporting channel will ensure that concerns are directed to the relevant enforcement body for assessment and action.
- 3.18.15 We will take appropriate provisional measures where we think there is a serious risk to human health in keeping with the obligations set out in the TPD2.
- 3.18.16 **Having considered the consultation responses the Government will not require businesses to nominate a named person to collect any adverse events information. The Regulations will, however, obligate businesses to investigate and report such incidents to the Competent Authority along with the outcome of any action they may have taken in line with current requirements in TPD2 Article 20(9).**

Question 20

The Government is minded to give the Secretary of State for Health (SoS) the power to prohibit the supply of an e-cigarette or refill container or to require producers and suppliers to recall a product if he/she considers them a serious risk to public health. Do you think there are other options that should be provided to the SoS, for example the power to require modification of a product or to require enhanced monitoring and/or reporting of company data?

3.19.1 Businesses and the public were against this proposal, with organisations being in favour. Details of the quantitative response are set out in the graph below:



TOBACCO STAKEHOLDERS

3.19.2 Whilst one major manufacturer was in general agreement with the proposal – albeit with a qualification to their response, adding a condition that the action must be proportionate and substantiated - other companies disagreed, stating that this is unnecessary, as the provisions of the General Product Safety (GPS) Directive achieve the same end.

E-CIGARETTE STAKEHOLDERS

3.19.3 Most felt further powers were unnecessary and reiterated comments made by the tobacco industry that there are already robust systems in place – e.g. GPS Directive and the RAPEX alert system. They felt this would lead to increased financial burden on smaller businesses by increased bureaucracy and expressed concerns regarding potential business closures.

HEALTH STAKEHOLDERS

3.19.4 Health related organisations were in agreement with this proposal, with one respondent warning that the provisions of the GPS Directive are inadequate.

3.19.5 There were calls for wider powers to be given to the SoS, comprising powers to require:

- Modification of products
- Disclosure of relevant information and data on product safety if this is believed to exist and has not been provided
- Disclosure of sales and marketing information when relevant to potentially dangerous products
- Appropriate remedial action by companies engaged in the sale, distribution or marketing of such products if they are shown to pose a serious risk to public health

ENFORCEMENT/LOCAL AUTHORITIES

3.19.6 Local Authorities and Trading Standards Agencies were in support of the Government proposal, requesting wider powers as expressed by health related organisations.

3.19.7 One respondent also stated that the SoS should also have the ability to require destruction of products where it is felt that neither recall nor modification will be sufficiently effective to reduce the risk to UK consumers.

RETAILERS/OTHER BUSINESSES

3.19.8 Retailers and Retail Trade Associations were unanimously against such proposals, feeling that current legislation was sufficient, again cited the GPS Directive. One respondent highlighted that most manufacturers issue a recall request for faulty products and saw no need for anything different concerning e-cigarettes. Others were concerned that a route for appeal against decisions made by the SoS would need to be implemented if any new powers were introduced.

MEMBERS OF THE PUBLIC

3.19.9 Many members of the public who responded rejected the need to extend the SoS powers. There were suggestions that the current mechanisms already in place are sufficient, citing that manufacturers are obligated to meet the requirements of the GPS Directive. Some expressed views that e-cigarettes pose little risk to health and that industry standards should be sufficient to safeguard these products and that the industry should be able to carry out necessary changes and recalls without the need of the SoS.

Government Response

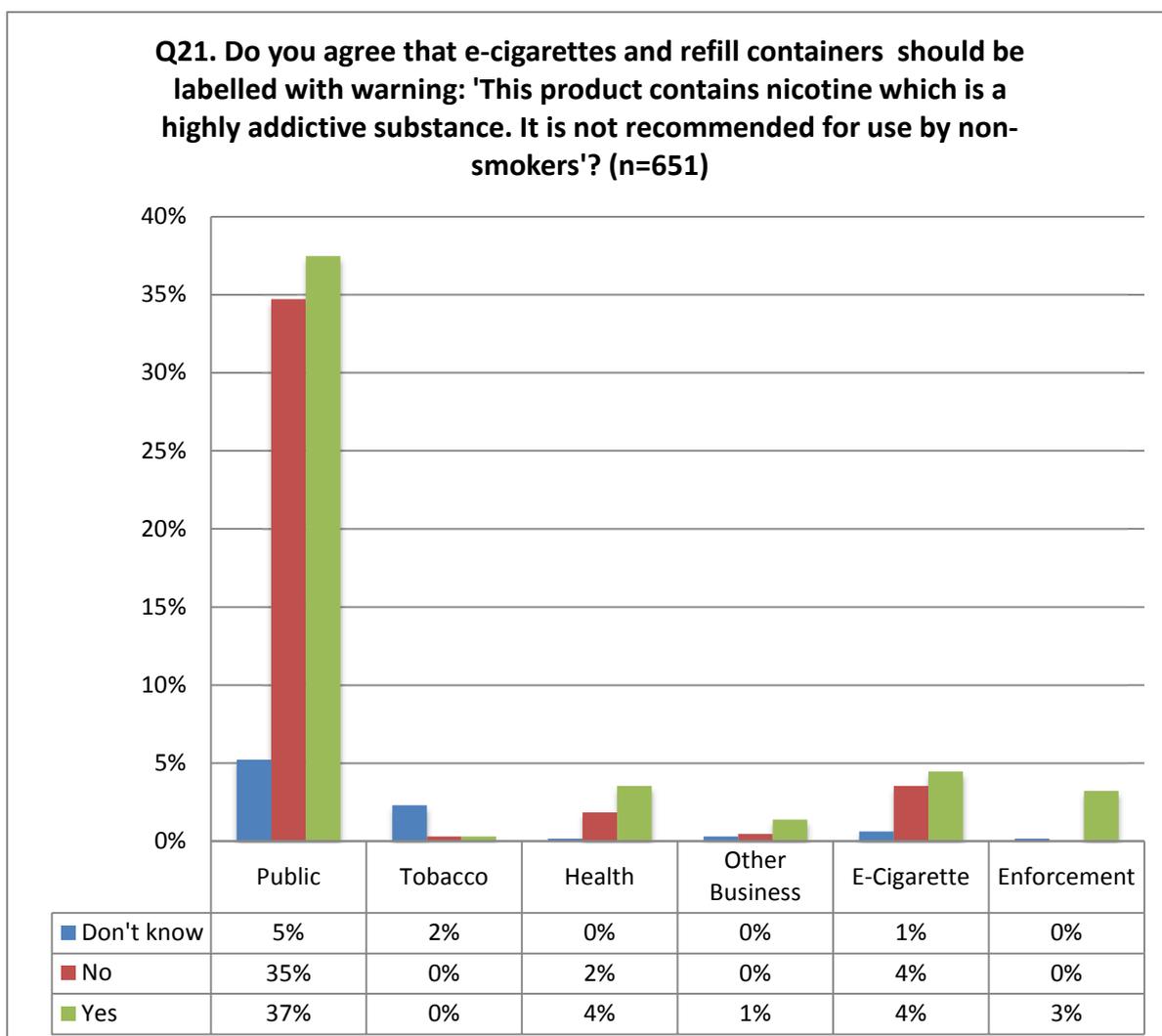
3.19.10 The GPS Directive applies to e-cigarettes, but only where the product is defective in some way and not in respect of its inherent risks. The latest evidence suggests that e-cigarettes are safer than smoking, but they are not risk free. The Government included the provision in regulation 41 (action to protect human health) of the draft regulations to reflect TPD2 Article 20(11) and cover the situation where a product conforms to all the product safety standards in the TPD2, but despite this, the product is found to be a serious risk or potential serious risk to human health, for example due to one of the substances inhaled.

3.19.11 **The Government has decided to give the Secretary of State for Health the power to take measures including action to prohibit the supply of an e-cigarette or refill container or to require producers and suppliers to recall a product if he/she considers them a serious risk to public health.**

Question 21

The TPD2 provides Member States with two options on the wording prescribed in the health warnings to appear on packs of e-cigarettes and refill containers. Member States must choose either a) 'This product contains nicotine which is a highly addictive substance'; or b) 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'. The Government is minded to require that e-cigarettes be labelled with the warning 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'. Do you agree?

3.20.1 All respondent groups expressed mixed views on the Government proposal, with a similar number of responses for and against the proposal. Details of the quantitative response are set out in the graph below:



TOBACCO STAKEHOLDERS

- 3.20.2 All industry respondents disagreed with the use of the longer warning, as they felt this was unnecessary as the TPD2 requires a reference to unsuitability for non-smokers in leaflets to be provided with all packs of e-cigarettes and refill containers. Respondents also stated that the longer warning is impractical, as the longer warning will not fit on some packs, and that many e-cigarette users are 'ex-smokers', but would now describe themselves as 'non-smokers'.
- 3.20.3 One respondent felt that both sets of wording in TPD2 were inconsistent with the regime for licenced nicotine replacement therapies, but acknowledge that HMG is required to implement one of the two warnings.

E-CIGARETTE STAKEHOLDERS

- 3.20.4 A number disputed that nicotine was 'highly addictive' (some provided evidence to support their view), questioning why other products they considered to be highly addictive, such as sugar and caffeine, were not also subject to such regulations.
- 3.20.5 There were similar concerns expressed regarding the use of the term "non-smokers" as not being suitable for those who have switched away from tobacco and some respondents foresee an issue with fitting the longer warning on packs e.g. 10ml bottles.
- 3.20.6 Some respondents felt the health warning was not needed for non-nicotine containing products or e-cigarette components – expressing concern that this could be misleading when the product in question does not contain nicotine.
- 3.20.7 One respondent felt that the proposal in regulation 37(5) of the draft regulations went further than was required by TPD2 and that it is not a legal requirement to apply the same requirements, in terms of the size, positioning and font used as those for tobacco products (TPD2 Article 12(2) & by reference 9(4)).

HEALTH STAKEHOLDERS

- 3.20.8 Again there were mixed views in this respondent group. The largest number of responses agreed with the Government proposal, stating that e-cigarettes should be labelled with a warning that they are not suitable for non-smokers. Whilst others recognise the importance of preventing non-smokers from using these products, a number of respondents disagreed with the proposal for the longer health warning, stating that the suggested wording is confusing, citing that recent evidence indicates there is growing confusion amongst the public on the safety of e-cigarettes and the harms of nicotine. They expressed concern that this confusion, alongside growing public misunderstanding around the safety of non-tobacco nicotine containing products, has the potential to discourage smokers from moving to safer sources of nicotine, such as e-cigarettes.
- 3.20.9 Suggested alternative wording include '*This product contains nicotine which is an addictive substance. E-cigarettes are a safer alternative to tobacco smoking and designed for use only by smokers and former smokers*'.
- 3.20.10 One respondent strongly supported the notion that e-cigarettes should only be treated as medicinal products and regulated by the Medicinal Healthcare products Regulatory Agency (MHRA).

3.20.11 Respondents also urged the Government to monitor whether the warnings deter smokers from moving to e-cigarettes and whether the warnings encourage non-smokers to use e-cigarettes.

ENFORCEMENT/LOCAL AUTHORITIES

3.20.12 Local Authorities and Trading Standards Authorities were unanimously in agreement, but caution was urged by those who felt that the warning label may discourage smokers of tobacco cigarette from switching to e-cigarettes. It was also suggested that the Government should monitor whether the health warning deters smokers from using these products within the first year of the warning coming into effect.

RETAILERS/OTHER BUSINESSES

3.20.13 Retailers expressed mixed views. Some respondents urged caution, as it was felt that the warning label might discourage smokers of tobacco cigarette from switching to e-cigarettes. Some disputed that nicotine was, in fact, highly addictive, and also questioned why other highly addictive products, such as sugar and caffeine, were not also subject to such regulations.

3.20.14 Respondents also cautioned that the longer health warning would not fit on refill containers and on this basis the short warning 'This product contains nicotine which is a highly addictive substance' should be adopted for these products.

MEMBERS OF THE PUBLIC

3.20.15 Public views on this proposal were equally split. A common theme in responses, both those for and against the proposal, was criticism of the wording of the health warnings in the TPD2, with many of the view that these are factually incorrect. Criticism was mainly around the wording on the highly addictive nature of nicotine, arguing that it would therefore be incorrect to place such warnings on the products. Others also expressed concerned that the warnings could lead to users going back to smoking and discourage uptake by current smokers. Some respondents urged regulators to adopt alternative warning messages such as "*Warning contains Nicotine – Not recommended for non-smokers*" or "*Should only be used as an alternative to smoking*".

Government Response

3.20.16 The Government has carefully considered the responses to this question. Non-nicotine e-cigarettes are outside of the scope of the TPD2, therefore will not be required to carry these warnings.

3.20.17 The Government acknowledges that there was no clear view on which of the health warnings should be required on the labelling of e-cigarettes and refill containers. This was reflected in discussions between the four countries in the UK with Welsh Ministers stating that they wanted, and Scottish Ministers also showing a preference for, the longer warning. All four Governments are clear that e-cigarettes should be positioned as alternatives to smoking and not a product that introduces non-smokers to the use of e-cigarettes or to smoking. However, we recognise the arguments on which health warning to use are finely balanced. It is true that the shorter statement would be more appropriate for the small refill bottles; and avoid any possible confusion amongst ex-smokers using these products who may view

themselves as non-smokers, who we do not want to see turn back to smoking. Whilst we recognise that the longer message is in line with current Government messaging that e-cigarettes are not suitable for non-smokers/never smokers, this messaging alongside messaging about not being suitable for children and other information on contra-indications must be included in the information leaflet mandated for all products. This approach would appear to be a more informative way of providing full information about the suitability of these products. On balance the Government has concluded that the shorter health warning will be required in the UK implementing regulations.

- 3.20.18 The Government will amend the implementing regulations to require the warning ‘This product contains nicotine which is a highly addictive substance’ on e-cigarettes and refill containers. The Government will continue to explore with other Member States and the Commission the scope for interpreting the labelling requirements of TPD2 to apply only to products/refills/components containing nicotine at the time of sale.**

Question 22

Should the Government charge the industry proportionate fees to recover costs associated with the TPD2

Including the following activities:

- a. The verification of the levels of tar, nicotine and carbon monoxide (TNCO) in cigarettes (Article 4);
- b. The receiving, storage, handling, analysis and publishing information on ingredients and emissions of tobacco products including novel tobacco products (Article 5);
- c. The peer review of scientific studies and additives undertaken by the tobacco industry (Article 6);
- d. Assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the carcinogenic, mutagenic or reprotoxic (CMR) properties of the tobacco product concerned (Article 7);
- e. If the UK chooses to implement an authorisation system for novel tobacco products then a fee can be charged for that authorisation (Article 19); and
- f. The receiving, storing and handling and analysing information submitted to them on e-cigarettes (Article 20).

Please provide further comment.

3.21.1 The data for the six quantitative parts to this question are shown in the qualitative feedback below:

TOBACCO STAKEHOLDERS

3.21.2 One major tobacco manufacturer agreed with the proposal as long as fees are proportionate and reflect the actual cost to Government. However, most industry respondents are against the proposal, on the basis that:

- Most of the charges relate to issues that are the statutory responsibility of the Department or the Commission
- It sets a precedent which could make the UK a less attractive investment location
- Tobacco companies have been disproportionately affected by regulation over the past five years, incurring significant costs and being subject to a duty escalator policy
- Producers of cigar and other tobacco products (cigarillos and pipe tobacco) would be disproportionately affected by the proposal, and these charges could close down these small businesses
- The charging regime outlined in the Impact Assessment is difficult to forecast

- The fees are essentially a tax

E-CIGARETTE STAKEHOLDERS

3.21.3 E-cigarette stakeholders expressed the following views:

- “If the Government want to conduct tests then the Government should pay for them. If however the Government instructs the industry to carry out tests then the manufacturer should pay for them”
- “The principle that firms should bear the cost of regulation is sound providing the regulation is well-founded. The making of article 20 of the TPD violated all legal requirements and principles of good policy making. There was no consultation, no impact assessment, no scientific basis for the measures and negligible scrutiny. It is not fair to ask companies to assume burdens associated with such poor policy-making, over which they have had little or no say”
- This should be proportionate to the size of the business: “The cost of emissions tests alone can be up to £10,000 per product. A company can have over 100 variants. Are the Government asking that each one be individually tested?”
- They have wide range of products with very small variations – “such as the flavour concentrates used, and differing nicotine content and diluent make up. 1,000 notifications for what is essentially the same product with small differences in its major constituents represents an undue burden, and will certainly not give regulators the clarity to distinguish products”
- Some felt that tobacco industry had had 10 years to prepare for this and that the e-cigarette market should be given a longer preparation period.

HEALTH STAKEHOLDERS

3.21.4 A number agreed with the proposal to charge fees to the industry, arguing that tobacco companies are extremely profitable and are responsible for public health damage and its associated costs.

ENFORCEMENT/LOCAL AUTHORITIES

3.21.5 Local Authorities and Trading Standards authorities responded positively, expressing the view that: “TPD2 is designed to protect consumers from the extremely dangerous products manufactured by the tobacco industry. It is therefore only reasonable that the manufacturers of the dangerous products should pay for those protections, rather than the victims”.

RETAILERS/OTHER BUSINESSES

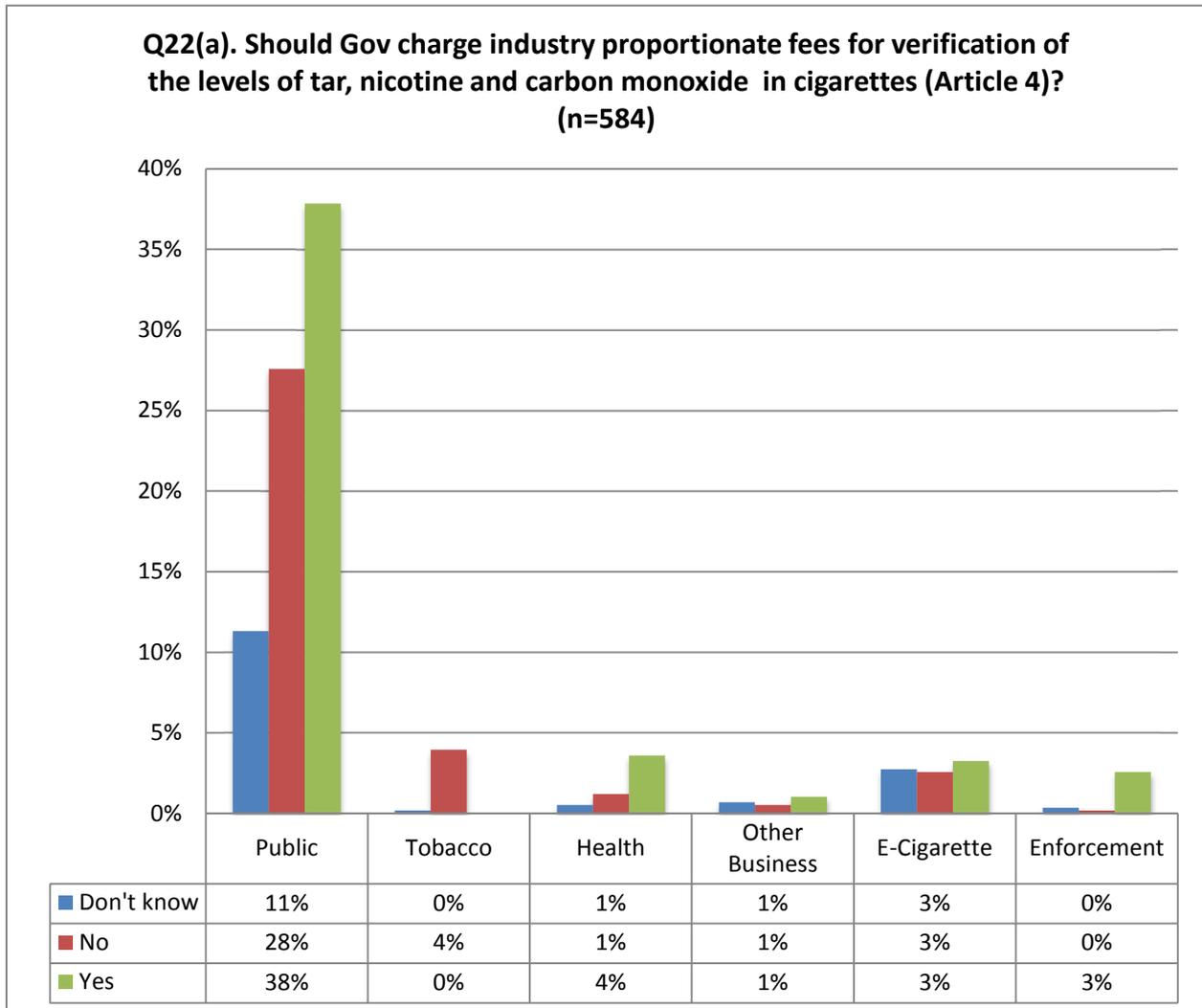
3.21.6 Retailers and other businesses were mostly in opposition to the Government recovering costs and fees from the tobacco industry, as it was felt that the legislative process was unfair. Responses suggested that costs to small businesses would be disproportionate, forcing many to close.

MEMBERS OF THE PUBLIC

3.21.7 Respondents were very concerned of the implications of this measure both on smaller businesses and on consumers. Many feared that testing required to adhere to the new rules would require clinical trial type studies likely to impose significant and disproportionate costs to businesses. There were also suggestions that such testing was unnecessary for products which are substantially less harmful than tobacco and that additional costs were likely to be passed onto consumers and many feared that the TPD2 would result in reduced choice.

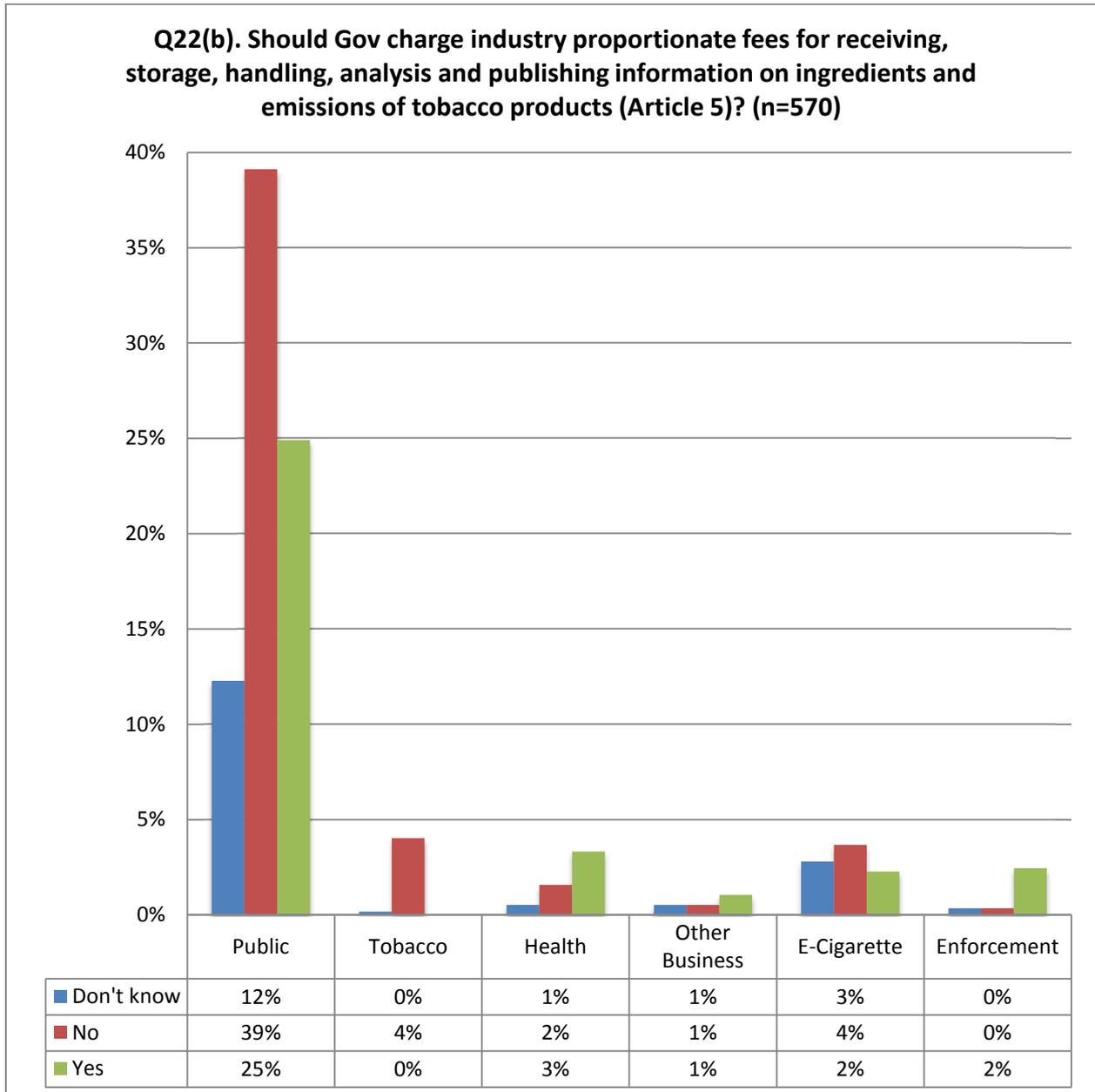
22(a). The verification of the levels of tar, nicotine and carbon monoxide (TNCO) in cigarettes (Article 4)

3.21.8 There was agreement in most stakeholder groups, with the exception of businesses who were against the proposal.



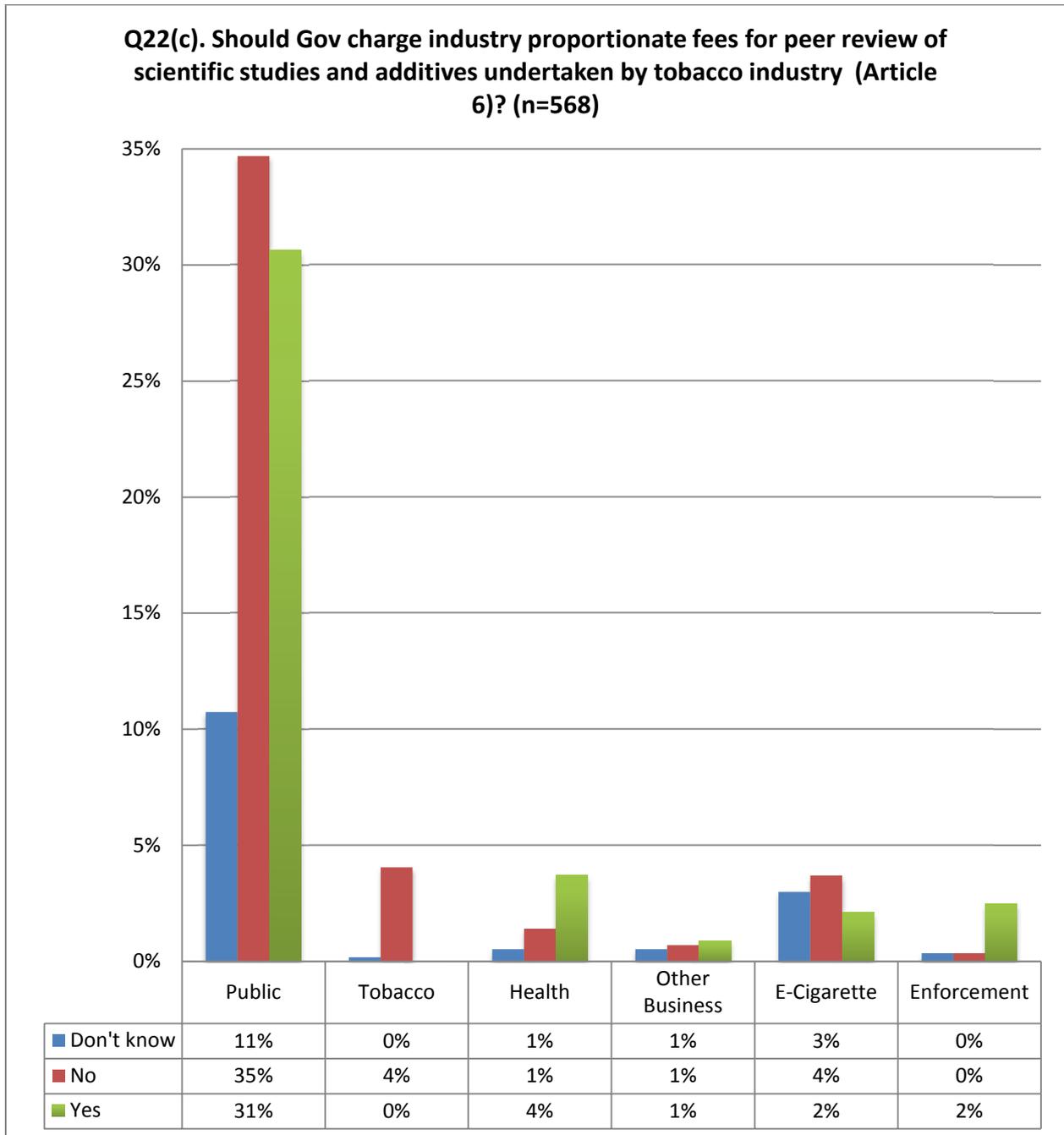
22(b). The receiving, storage, handling, analysis and publishing information on ingredients and emissions of tobacco products including novel tobacco products (Article 5)

3.21.9 Most groups were against this proposal, with the exception of health organisations and enforcers where the majority were in favour.



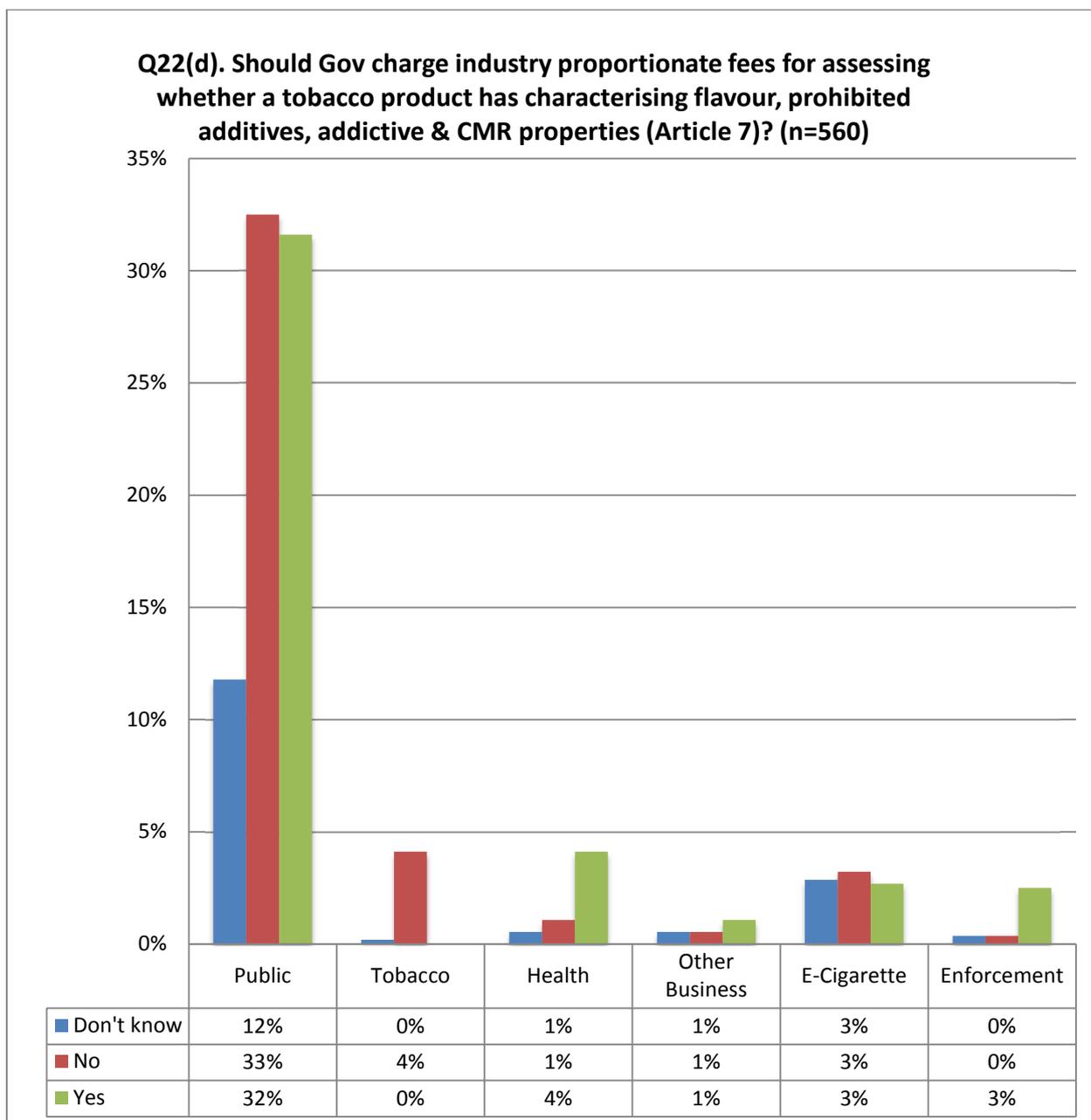
22(c). The peer review of scientific studies and additives undertaken by the tobacco industry (Article 6)

3.21.10 Most groups were against this proposal, with the exception of health organisations and enforcers where a majority were in favour.



22(d). Assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the carcinogenic, mutagenic or reprotoxic (CMR) properties of the tobacco product concerned (Article 7)

3.21.11 The public were evenly split between support and opposition for this proposal. Businesses were against, and organisations were in favour.

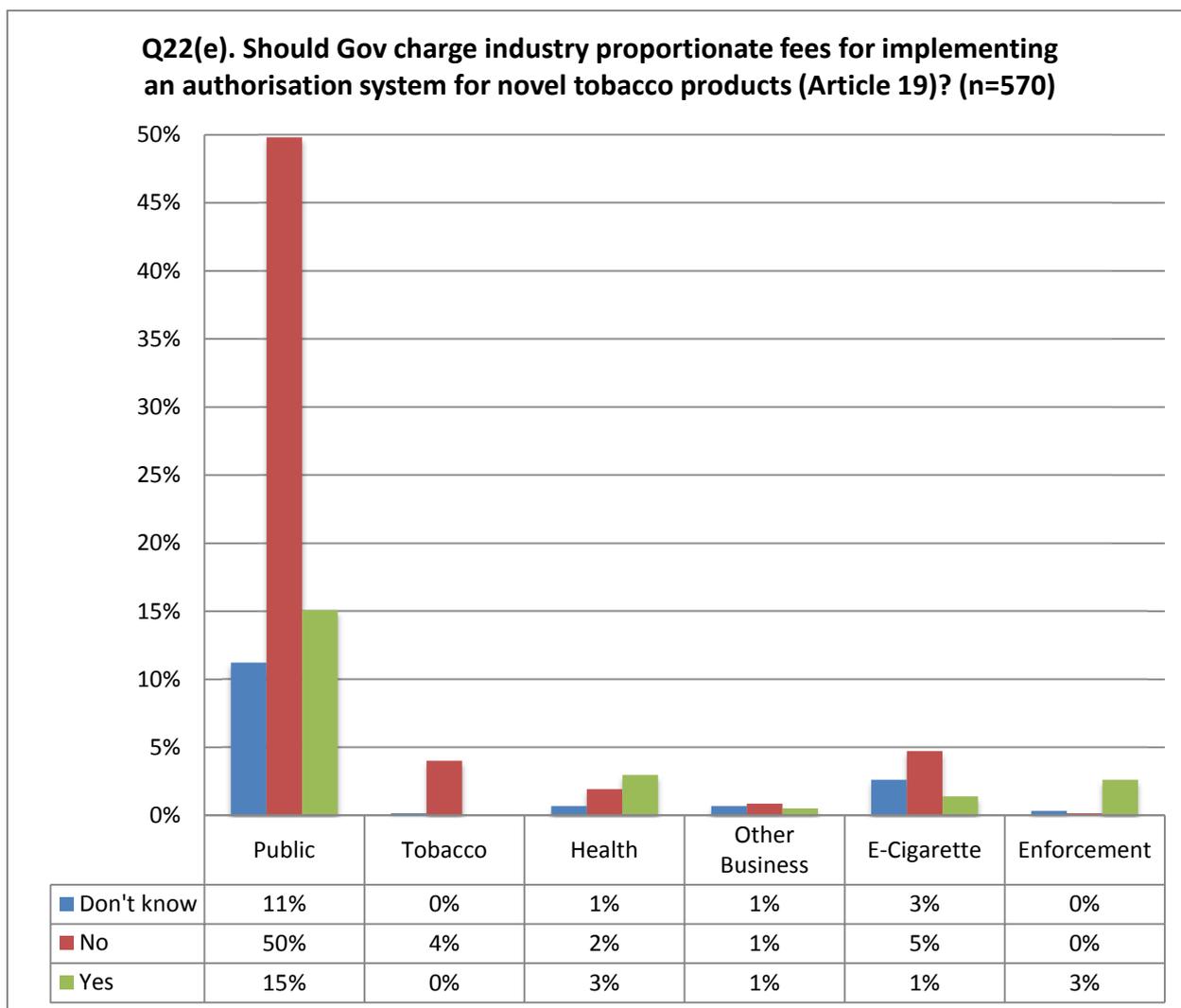


22(e). If the UK chooses to implement an authorisation system for novel tobacco products then a fee can be charged for that authorisation (Article 19)

3.21.12 The majority of businesses and the public were against this proposal, whereas organisations were in support.

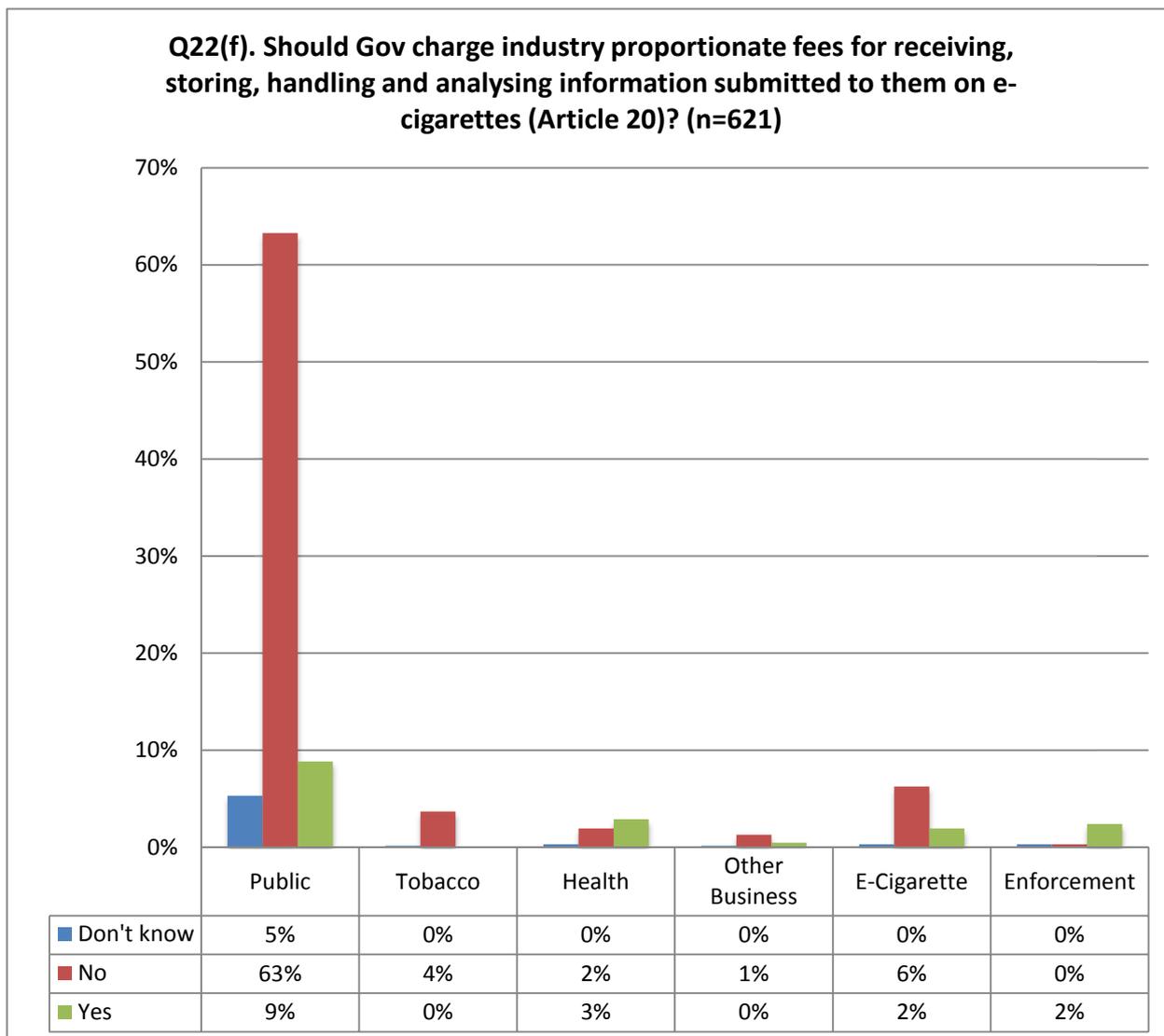
3.21.13 There was a relative scarcity of responses that directly recognised the implications of Article 19 and why they felt them to be unreasonable. It should be noted, however, that there were a considerable amount of responses in the context of e-cigarettes, which this question does not apply to.

3.21.14 Those that did respond to this question with relevant information suggested that fees may limit innovation in this sector, particularly in the field of harm reduction products.



22(f). The receiving, storing, handling and analysing information submitted to them on e-cigarettes (Article 20)

3.21.15 The majority of businesses and the public were against this proposal, whereas organisations were in support.



Members of the Public

3.21.16 It is important to first note that the responses received largely voiced wider concerns with Article 20. Those that provided specific comments with regard to charging believed that these charges are an excessive measure for e-cigarettes. There were numerous reasons put forward as to why this is - for instance, they argued that the proposals go against logic as e-cigarettes represent a healthier alternative to combustible tobacco products, that they would be disproportionate to smaller businesses and ultimately costs would be passed on to the consumer and may discourage uptake by smokers.

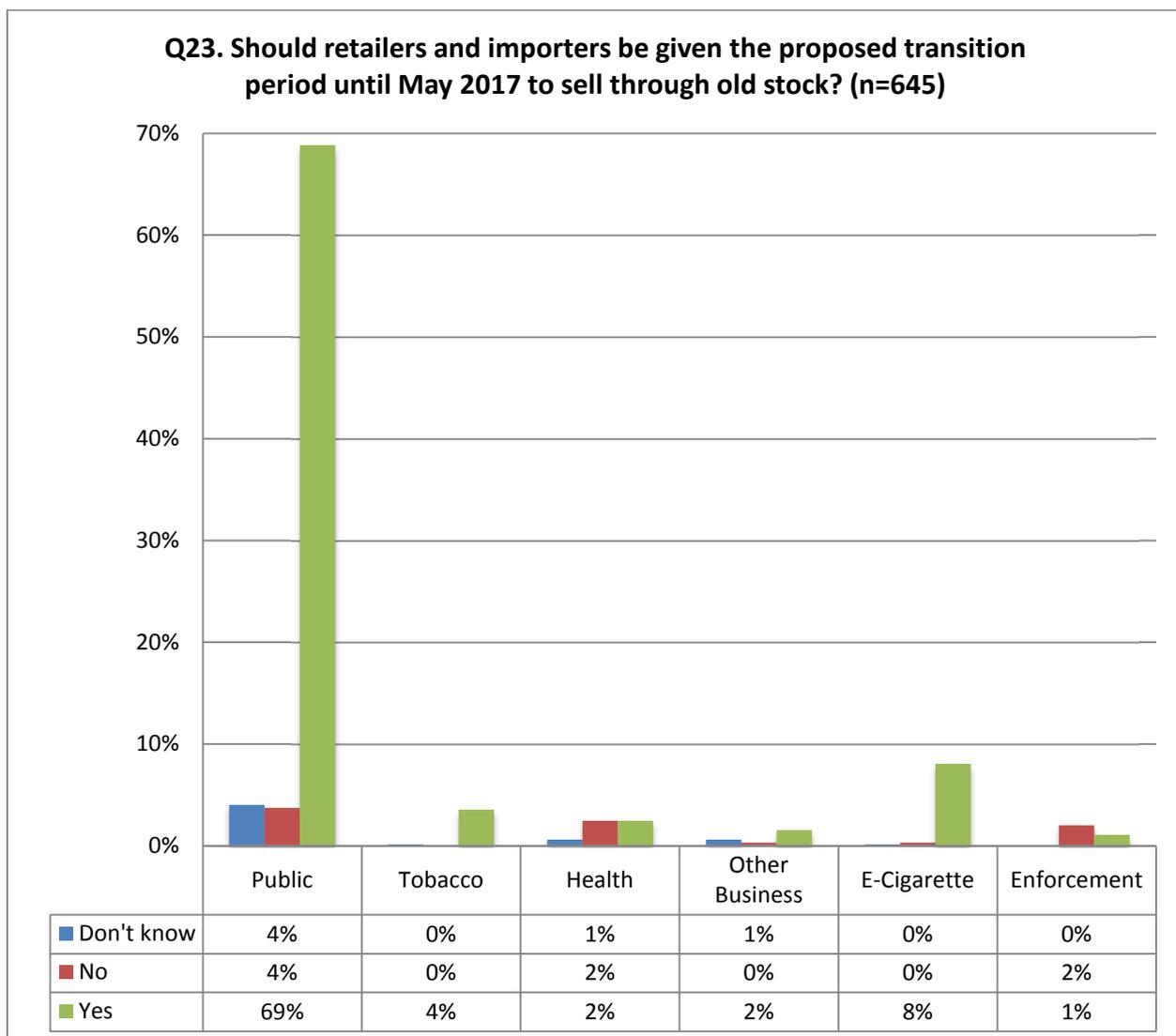
Government Response

- 3.21.17 The Government has noted the views expressed in response to the consultation and opposition by the tobacco industry. The Government is of the view that the tax payer should not fund verification and monitoring services provided to the industry under the TPD2 and that it is in the public interest to recover its costs. The Government will introduce proportionate fees for services provided by HMG in meeting the obligations concerning tobacco products. Health Departments will work with HMT to clearly set out the basis for any proposed fees and undertake further targeted stakeholder engagement in 2016.
- 3.21.18 The Government notes the broader opposition on charging fees in relation to services provided to producers of e-cigarettes and concerns that this may limit innovation in a sector largely dominated by small/medium businesses. The Government has asked the MHRA to act as the UK competent authority for the notification of e-cigarettes because of its existing expertise in handling notifications and monitoring adverse events under other regulatory regimes. In line with its status as a Government Trading Fund, MHRA will undertake full cost recovery through the charging of fees for the work involved in checking notifications are complete, correct and compliant and undertaking vigilance, reporting and compliance work. In undertaking this work the MHRA are planning a light touch regime to minimise costs to industry whilst meeting the UK's obligations under the Directive. The MHRA will shortly conduct a separate targeted consultation on a proposed fee structure, with a view to implementation before 20 May 2016. Proposals will detail the estimated impact on businesses, with particular regard to small and medium businesses and seek further views and evidence to inform and refine fees.
- 3.21.19 The Government will introduce proportionate fees to recover its costs of meeting its obligations under the TPD2, for tobacco products (including novel products) and e-cigarettes. Proposals to establish fee structures will be subject to separate consultation.**

Question 23

Should retailers and importers be given the proposed transition period until May 2017 to sell through old stock?

3.22.1 The majority of respondent groups were in favour of giving retailers and importers the proposed transition period until May 2017 to sell through old stock.



TOBACCO STAKEHOLDERS

3.22.2 Tobacco industry respondents agreed with the proposal, and suggested that there would be a large and negative impact on the industry should the periods be reduced. Tobacco industry respondents proposed a number of suggestions in response to this question including suggestions that:

- The transition periods must match those in the Standardised Packaging Regulations;
- Cigar and OTP companies need longer to sell their stock, which is slower moving; and
- Article 30 of TPD2 should not be an option for member states, but a unilateral requirement.

3.22.3 Some tobacco industry respondents raise concerns that any change to the sell-through period outlined in the TPD2 would result in substantial and unquantifiable cost to the industry and would compromise their ability to comply with the TPD2.

E-CIGARETTE STAKEHOLDERS

3.22.4 All e-cigarette stakeholders agreed with the proposal and wanted to ensure that these transitional periods include manufacturers and distributors. Some e-cigarette industry respondents wanted a longer transition period (e.g. post July 2017).

HEALTH STAKEHOLDERS

3.22.5 The health stakeholders that responded to this question were divided over whether retailers and importers should be given the proposed transition period until May 2017 to sell through old stock. A number of health related organisations were against the proposed transitional periods, arguing that the transition period undermines the potential public health gains of the regulations. Suggestions provided by health stakeholders include that the Department follows the Australian model used on the introduction of standardised packaging, giving a 6-12 week transition period, or that the transition period should be no more than 150 days, in line with Government's response to the consultation on Tobacco Anti-Forestalling Restrictions.

ENFORCEMENT/LOCAL AUTHORITIES

3.22.6 Local Authorities and Trading Standards respondents were more divided in their response to Question 23. They felt that the transition period of twelve months was either agreeable or unnecessarily long, with several also referencing Australia's move to introduce standardised packaging in 2012 which gave a 6-12 week transition period, considering this timescale reasonable and appropriate.

RETAILERS/OTHER BUSINESSES

3.22.7 Retailer and Retail Trade Association respondents felt that the proposal for a twelve-month transition period was either the right length or not long enough. A number of respondents highlighted the different factors to consider for wholesalers and retailers, given that retailers sell stock at a later date than wholesalers, and

urge the Government to encourage tobacco companies and wholesalers to sell through their old stock earlier than the proposed year.

- 3.22.8 Some respondents in this category questioned whether a twelve-month transition period would be long enough for e-cigarettes and there were also questions as to how the transition period would work with regard to menthol cigarettes. A concern expressed by some is that some manufacturers could, theoretically, import substantial amounts of low quality product and flood the market with it prior to May 2016.
- 3.22.9 Whilst several Local Authorities and Trading Standards Agencies referenced Australia's 2012 move to introduce standardised packaging in support of a shorter transitional period, a detailed response from Australia warned against this, stating that the transition to plain packaging had significant negative impacts on retailers and strongly recommending a twelve-month transition period.

MEMBERS OF THE PUBLIC

- 3.22.10 Members of the public who responded to this question largely agreed that a transition period be put into place to help businesses adapt to the new regulations and shift old stock. Respondents believe that these regulations will have a significant impact on the market and require substantial preparation time to develop compliant products. Despite the public support for this measure, many respondents appeared to offer this support only as it was felt to mitigate the concerns they have with other aspects of the regulations. A few members of the public responded by saying that e-cigarettes should be the only beneficiaries of the transition period, as they are a less harmful product and usage of them as an alternative to smoking should therefore be encouraged.

Government Response

- 3.22.11 Given the Commission's timetable to adopt tertiary legislation to supplement the TPD, it would be reasonable to provide the industry with the one year transitional period, to allow the sell-through of old stock.
- 3.22.12 **The Government will adopt the transition periods to allow the sell through of old stock until May 2017 for tobacco products, e-cigarettes and herbal products for smoking.**

Question 24

Do you have any comments on the drafting of the Regulations, including anything you want to draw to our attention on the practicalities of implementing the Regulations, as drafted?

3.23.1 A wide range of comments were provided on the drafting of the Implementing Regulations. These can be grouped into six themes:

- Requests for further engagement
- Emphasising key points
- Alignment of wording with tertiary legislation
- Potential for misinterpretation
- Expedition in clarifying labelling requirements
- Other issues

Emphasising key points

3.23.2 A number of businesses used their response to this question to emphasise key points that had been made to earlier questions in their consultation response. These were calls for expedition in decision-making; calls for derogation from the full labelling regime of cigars, cigarillos and pipe tobacco under Article 11; the position that the Regulations and Directive are unlawful; problems with the concept of 'addictiveness'; and a request for stipulation of a timeline for action by the SoS in relation to Regulations 30, 33 and 3 (the requirement for the manufacturer and/or importer of an electronic cigarette to provide complete data if the original notification is considered incomplete).

Alignment of wording with tertiary legislation

3.23.3 A number of responses to this question reference the wording used in the draft Implementing Regulations, asking them to be aligned for the Government to transpose the original text of the Directive to prevent any risk of going beyond the minimum requirements. Other concerns related to the level of protection afforded to the commercially sensitive information of tobacco businesses.

3.23.4 Responses also referenced tertiary legislation that was draft at the time of the consultation expressing concern that the proposed common reporting format for the reporting of tobacco products went above and beyond the requirements of the Directive

Potential for misinterpretation

3.23.5 Some stakeholders expressed concern in relation to the regulation of characterising flavours stating that the UK's draft Implementing Regulations repeat imprecise language used in the Directive itself. They called for better definition in the UK regulations of terms such as: "young people", "current smokers" and "non-smokers".

Expedition in clarifying labelling requirements

- 3.23.6 There were some requests for clarification of some aspects of the regulations, including the precise wording of the cessation information that will be required on tobacco products. This has subsequently been provided to businesses.
- 3.23.7 Other requests related to the location of the fiscal mark on tobacco products and how that fits with the new labelling requirements.

Others

- 3.23.8 There was a call for consolidation of legislation concerning the packaging, marketing and labelling of tobacco products which stakeholders identified was spread across several pieces of legislation and queries on whether the new rules would apply to products sold duty free.

Government Response

- 3.23.9 We have considered carefully the comments and suggestions on the drafting of the Regulations and are making a number of changes with a view to laying the Regulations before Parliament in spring 2016.
- 3.23.10 The main amendments resulting from the consultation and developments at EU level will be:
- To make provision (until the new track and trace requirements take effect in 2019/2024) for code markings that allow the identification of the place, date and, in the case of a product other than cigars, the time, of manufacture to be determined;
 - To make clear that there is no legal requirement on the positioning of the general and information warnings other than on cigarette and hand rolling tobacco packaging;
 - To make clear that in submitting data on novel tobacco products only studies that are available at the time of submission are required and that manufacturers are not required to do additional studies on toxicity, addictiveness, attractiveness or undertake additional market research;
 - To align our terminology with that in the further tertiary legislation that has been published since the time of the consultation; and
 - To limit the offence of supplying false and misleading information to persons doing so knowingly or recklessly.
- 3.23.11 The TPD2 contains a number of powers for implementing and delegated acts, conferring powers to the European Commission to develop further detailed rules in defined areas, such as standardising reporting mechanisms. Whilst some of these implementing and delegated acts have already been published, others are yet to be finalised. The Government is committed to conducting targeted stakeholder engagement during the development of these acts and the Implementing

Regulations will be amended as necessary to incorporate these provisions and to ensure they are fully aligned.

Question 25 – Question concerning the Impact Assessment

To better understand the likely costs and benefits of implementing the TPD2, and to develop the consultation-stage impact assessment, we are seeking further evidence on the following questions:

What is the likely cost of reassigning or retiring capital and adjusting manufacturing processes in response to the restrictions on certain product lines and requirements for additional health warnings?

What are the likely marginal impacts of implementing the TPD2 on e-cigarette manufacturers?

We are aware that tobacco products that benefit from transitional arrangements (menthol), or are exempt from the ban on characterising flavours, will no longer be able to provide a reference to the flavour on the packet. We would be interested to receive views on the impact of this provision.

Do you have any further information that may inform the calculations in this IA, specifically in those areas outlined in Annex E?

Do you have any further comments on the approach taken in this IA?

- 3.24.1 A substantial number of responses were received in response to Question 25 regarding the Impact Assessment (IA).
- 3.24.2 In response to part (a) of this question, many respondents thought that there would be a high cost to e-cigarette manufacturers, particularly small businesses. Some respondents commented that the costs to cigar manufacturers would be significant given the large number of low volume SKUs (Stock keeping Unit) sold in the industry, with some providing estimates of these costs. These costs were expected to be considerably higher if the option to exempt cigars is not taken up. Some also stated that the requirement for health warnings to rotate annually may result in additional costs. None of the respondents provided any specific estimates of the likely costs for retiring capital or adjusting machinery as a result of the requirements.
- 3.24.3 In response to part (b) of Question 25, the likely marginal impacts of implementing the TPD2 on e-cigarette manufacturers, many respondents suggested that the cost to e-cigarette manufacturers would be high, particularly to small businesses, without providing any figures. In particular the costs for toxicology and emissions tests were expected to be too high for many small businesses to incur, and would therefore cause many to close down. This was expected to lead to a reduction in the variety of products available to consumers and increase prices as the costs are passed on by manufacturers. It was therefore expected that some consumers will

stop using e-cigarettes, potentially returning to smoking tobacco. Some respondents did provide a breakdown of the likely costs, whilst stating that there remained substantial uncertainty around these due to the lack of clarity on the finalised requirements.

- 3.24.4 Many respondents reported, in response to part (c), that this would likely lead to confusion for consumers and retailers, and therefore incorrect transactions. This was thought to be a particular problem for tobacco products other than cigarettes & hand-rolling tobacco, due to the wide variety of products available. Other respondents thought that it would be unproblematic as green packaging or labelling is widely understood to represent menthol flavouring. The question was often misinterpreted as referring to e-cigarettes, rather than just tobacco products.
- 3.24.5 Most respondents did not provide any further information, as requested in part (d) of Question 25. Some respondents provided estimates of the costs in some of the areas outlined in Annex E of the IA.
- 3.24.6 For part (e) which asked for any further comments on the approach taken in this IA, many respondents used this question to criticise the policy in general rather than providing specific comments on the IA. Some respondents suggested that there may be an increase in illicit tobacco trade which the IA had not considered, as a result of the restrictions on tobacco products, in particular the ban on menthol cigarettes. It was also suggested that retailers will face costs due to this increase in illicit trade and also reduced footfall as customers will make fewer trips to the shops with the minimum pack sizes. Some respondents thought that the sell-through period of one year would be insufficient for the cigar industry, due to the slow moving nature of the market, and that stock would therefore have to be written off. Some concerns were expressed regarding the labelling requirements, specifically for packs with bevelled edges and certain packs of hand-rolling tobacco. The approach taken to estimate the impact of the e-cigarette provisions was criticised by some respondents for not providing a full reflection of the likely costs. The likely impact of the e-cigarette provisions on smokers using e-cigarettes as an aid to quitting was also mentioned. Some respondents expressed concern with the One-In-Two-Out (now one-in-three-out) methodology used in the IA, suggesting that it works against important public health measures. Some respondents also disagreed with the IAs assessment of the proportion of economic activity that is UK based for the tobacco and e-cigarette industries.

Government Response

- 3.24.7 Some of the estimates made in the Consultation Impact Assessment were revised in light of the responses received in the consultation:
- The methodology used to estimate the costs of the labelling requirements on other tobacco products for smoking (cigars & pipe tobacco) has been updated to incorporate concerns expressed by the industry in consultation responses. Evidence supplied by the industry is used to estimate the cost under both Option 1 (implement the TPD2 at minimum cost to business) and Option 2 (implement some selected optional elements (preferred option)).

- Additional costs relating to an expected small increase in the illicit tobacco trade, prior to the introduction of the track and trace and security feature provisions in 2019/24, have been included in this impact assessment. This may result in reduced profits to business and further losses in tax revenue to the exchequer. The Government has, however, recently published a refreshed strategy to tackle the illicit tobacco trade. This includes a wide range of initiatives, including implementation of the TPD2 provisions on track and tracing of tobacco products, which are designed to reduce the illicit trade. The impact of the strategy and track and trace provisions are not covered by this Impact Assessment.
- The cost of reporting on the list of priority additives has been changed to reflect concerns expressed during the consultation that the IA had underestimated this cost.
- A full assessment of the cost to the e-cigarette industry due to TPD2 has been made.
- The impact of restricting advertising of e-cigarettes has been revised. Estimates of the proportion of economic activity that is UK based for cigars & e-cigarettes have been changed to reflect new information & the consultation responses.

4. Next steps

- 4.1. We are grateful to all who took the time to respond to the consultation. The Government response confirms its approach to transposition of the Directive and the implementing regulations will be amended as outlined in this document. We recognise that not all the required tertiary EU legislation is currently available and will continue to engagement with interested parties as proposals are published by the European Commission.
- 4.2. The Government has amended its Impact Assessment taking account of the information received and the decisions outlined in this document. The Impact Assessment has been submitted to the Regulatory Policy Committee (RPC) for scrutiny. The implementing regulations will be revised and laid before Parliament and will come into force on 20 May 2016.

Appendix A – Consultation questions

1. Should the Government request peer review of any reports submitted by the industry in relation to certain additives contained in a priority list of additives?
2. The Government intends to implement this provision of the Directive to mean images, targeted at consumers that are used to promote the sale of products, such as retailer websites offering products for sale. Do you agree with this approach?
3. The TPD2 stipulates where health warnings should appear on packs including that the general warning should appear on the lateral surface. The Government propose to transpose 'lateral' (Article 9) as 'secondary' (defined as the next two largest surfaces of the pack, after the front and the back surfaces) in our domestic legislation. Can you tell us of any packaging shapes where this interpretation would not be the most effective approach / would not work as intended?
4. The TPD2 requires Member States to choose between the warnings 'Smoking kills' or 'Smoking kills – quit now'. The Government is minded to require that tobacco products be labelled with the warning 'Smoking kills – quit now' to align with UK smoking cessation messaging. Do you have any information/evidence that would inform this choice?
5. Are there any other pack shapes for cigarettes, Roll-your-own/hand-rolling tobacco and waterpipe tobacco on the market, other than pouches and squat cylindrical tins/tubs, where there may be technical difficulties in applying any of the new health warnings under Articles 9 and 10?
6. To ensure the combined health warnings are applied evenly across each brand of tobacco product, it is proposed that images should appear on between 1/24 (4.15%) and 1/12 (8.33%) of products and each set of images in the TPD2 picture library should be rotated on an annual basis. Are there any additional costs, above and beyond the current regime, imposed by this proposal?
7. The draft regulations require producers to ensure the correct health warning is applied to tobacco products. We are minded to treat retailers who repackage tobacco products at the point of sale the same as producers. For example, individual cigars or loose tobacco packaged at point of sale, should comply with the full labelling provisions, including the rotation of the combined health warning. Do you agree with this approach?

We also seek further details on the costs and practicalities of such businesses meeting these requirements.

8. The Government is minded to derogate individually wrapped cigars and cigarillos from the full labelling regime, requiring only the general warning 'Smoking kills' or 'Smoking kills – quit now'; one of the text warnings from the combined warning list but no picture; and a reference to the smoking cessation information. Do you agree with this approach?

9. The Government is seeking evidence and information on the supply chains currently used to distribute tobacco products in the UK, such as the number of links in the chain and the number of businesses affected.
10. The Government would welcome initial views on how track and trace and security markings may impact on business, and what the key issues for business will be.
11. If a registration scheme were introduced for cross border distance sales, the Government is minded to require the nomination of an individual to be responsible for verifying that the product complies with the provisions in the UK regulations, before the product is supplied to the consumer. Do you agree with this approach?
12. Should cross-border distance sales of tobacco products to consumers be prohibited?
13. Should cross-border distance sales of e-cigarettes and refills to consumers be prohibited?
14. What systems to verify the age of customers are available to, or currently used by, businesses involved in distance sales to other EU Member States?
15. Should novel tobacco products be subject to a notification scheme? If “No”, please explain why you think an authorisation scheme would be preferable?
16. Under a notification scheme the Government is minded to include provision to require manufacturers or importers of novel tobacco products to provide, with any notification, information on:
 - a. the toxicity of the product, its ingredients and emissions;
 - b. the addictiveness of the product, its ingredients and emissions;
 - c. the expected effects of the product on the cessation of tobacco consumption by existing users of tobacco products; and
 - d. The perception of the product by consumers or potential consumers (or predictions as to how the product will be perceived), including the attractiveness of the product.

The Government believes that this information should and will be available to manufacturers and importers prior to launching all new products. Do you agree with this approach?

17. The Government is minded to use the TPD2 definitions of an ‘electronic cigarette’ and ‘refill container’. Do you foresee any problems with inconsistency with the definitions in The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations?
18. The Government intends to handle notifications of e-cigarettes and refill containers electronically and make all information contained in notifications automatically available to the public unless this information can be considered truly commercially confidential. What information contained in the notifications should be considered commercially confidential?

19. The Government is minded to put the obligation on 'producers' (which includes manufacturers, importers into the UK and those that rename a product) in the transposing regulations which will ensure that there will always be a person in the UK who collects information about suspected adverse effects in relation to e-cigarettes and refill containers. Do you agree?
20. The Government is minded to give the Secretary of State for Health (SoS) the power to prohibit the supply of an e-cigarette or refill container or to require producers and suppliers to recall a product if he/she considers them a serious risk to public health. Do you think there are other options that should be provided to the SoS, for example the power to require modification of a product or to require enhanced monitoring and/or reporting of company data?
21. The TPD2 provides Member States with two options on the wording prescribed in the health warnings to appear on packs of e-cigarettes and refill containers. Member States must choose either a) 'This product contains nicotine which is a highly addictive substance'; or b) 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'. The Government is minded to require that e-cigarettes be labelled with the warning 'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'. Do you agree?
22. Should the Government charge the industry proportionate fees to recover costs associated with the TPD2, including the following activities:
 - a. The verification of the levels of tar, nicotine and carbon monoxide (TNCO) in cigarettes (Article 4);
 - b. The receiving, storage, handling, analysis and publishing information on ingredients and emissions of tobacco products including novel tobacco products (Article 5);
 - c. The peer review of scientific studies and additives undertaken by the tobacco industry (Article 6);
 - d. Assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the carcinogenic, mutagenic or reprotoxic (CMR) properties of the tobacco product concerned (Article 7);
 - e. If the UK chooses to implement an authorisation system for novel tobacco products then a fee can be charged for that authorisation (Article 19); and
 - f. The receiving, storing and handling and analysing information submitted to them on e-cigarettes (Article 20).

Please provide further comment.

23. Should retailers and importers be given the proposed transition period until May 2017 to sell through old stock?

Question concerning the draft regulations

24. Do you have any comments on the drafting of the regulations, including anything you want to draw to our attention on the practicalities of implementing the regulations, as drafted?

Questions concerning the draft Impact assessment

25. To better understand the likely costs and benefits of implementing the TPD2, and to develop the consultation-stage impact assessment, we are seeking further evidence on the following questions:
26. What is the likely cost of reassigning or retiring capital and adjusting manufacturing processes in response to the restrictions on certain product lines and requirements for additional health warnings?
27. What are the likely marginal impacts of implementing the TPD2 on e-cigarette manufacturers?
28. We are aware that tobacco products that benefit from transitional arrangements (menthol), or are exempt from the ban on characterising flavours, will no longer be able to provide a reference to the flavour on the packet. We would be interested to receive views on the impact of this provision.
29. Do you have any further information that may inform the calculations in this IA, specifically in those areas outlined in Annex E?
30. Do you have any further comments on the approach taken in this IA?

Appendix B – Responses to the consultation

Note: Those respondents who indicated that they wanted their response to remain anonymous are not included in this list.

Organisations

20-20 Voice Cancer

Action on Smoking and Health (ASH)

Acvoda

Advertising Standards Authority

ASH Wales

Association of Convenience Stores (ACS)

Association of Independent Tobacco Specialists (AITS)

Australasian Association of Convenience Stores

Bolton Community and Voluntary Services

British Dental Association BDA

British Heart Foundation

British Medical Association BMA

Cancer Research UK (CRUK)

Central England Trading Standards Authorities

Chartered Trading Standards Institute (CTSI)

Consumer Packaging Manufacturers Alliance (CPMA)

Counterfactual

Dudley Trading Standards

EECBA (European Electronic Cigarette Business Association)

European Cigar Manufacturers Association (ECMA)

Federation of Wholesale Distributors

FOREST

Fresh

Hull City Council

Hywel Dda University Health Board

Institute of Economic Affairs (IEA)

Lancashire County Council

Liberty Flights
Middlesbrough Council Trading Standards
Middlesbrough Smokefree Alliance
MRC/CSO Social and Public Health Science Unit SPHSU, University of Glasgow
National Federation of Retail Newsagents (NFRN)
NETSA
New Nicotine Alliance UK
News Media Association
Nottingham City Council
Nottingham Crime & Drugs Partnership
Nottinghamshire Strategic Tobacco Alliance Group (STAG)
Petrol Retailers Association's (PRA)
Proprietary Association of Great Britain (PAGB)
Public Health Action
Rochdale Tobacco Free Alliance
Royal College of Midwives
Royal College of Physicians
Royal College of Psychiatrists
Royal Society for Public Health
Smoke Free Newcastle
Smokefree County Durham Tobacco Alliance
Smokefree Yorkshire and the Humber
The Electronic Cigarette Industry Trade Association (ECITA)
The Imported Tobacco Products Advisory Council
The Libertarian Alliance
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Tobacco Free Futures
Tobacco Manufacturer's Association (TMA)
Trading Standards North West
UK Faculty of Public Health (FPH)
UK Health Forum
Wakefield Smokefree Alliance
Worcestershire Tobacco Control Alliance

Businesses

A G Parfett & Sons Ltd
Alauna Vapour Store
Benkert UK
Berkshire Vapers Ltd
Blue Tiger vapes
Blue Label Vapour Ltd
British American Tobacco (BAT)
Broughton LABORATORIES
Cambridge Vaping
CiggyJuice Ltd
Cloudz Vapour
Compañía Canariense de Tabacos, S.A.U.
Custom Vaping Company Ltd
Cuts Ice Ltd
Dannemann Cigarrenfabrik GmbH
Davidoff Distribution (UK) Ltd
Decadent Vapours Ltd
Ecigbubble Ltd (Trading as EcigZoo)
ecigwizard.com
Electro Mist
E-Vapor8 Ltd
Fontem Ventures
Forum Retail Ltd
Gawith Hoggarth &Co
Generals Juices
Go Vapour UK Ltd
Gower Enterprises
Grit & Partners Ltd
Habanos SA
Hunters & Frankau
Imperial Tobacco
J.Cortès Cigars
Japan Tobacco International (JTI)

John Sully's Ltd
Johnson & Johnson Ltd
Karelia Tobacco Company K Ltd
Liquid Smoke Ltd
Lonjas UK (E-Quits Ltd)
Nerudia Ltd
NJOY
Oettinger Davidoff AG
P G Liquid (Trading as Cig-liquid)
Philip Morris Ltd
Ritmeester Cigars UK Ltd
Rojeans
Royal Agio Cigars
Scandinavian Tobacco Group
Senior Vape Ltd
SICPA
Smokey Jo
Southampton Vaping Centre
Standpoint Electronic Technology Shanghai Ltd
Tabacalera SLU
Tann UK
That's Nice Ltd (Trading as FlavourArt UK)
The Co-operative Group
The Vapor Room
The Vapour Bar Ltd
Tor Imports Ltd
Totally Wicked Ltd
Triple Eight Vape (888 Vape)
Undecided
V for vaping ltd
VapeGrid BV
Vapingliquid Ltd
Vapour Dreams
Vapour Mill Ltd

Vapourium Ltd
Vapouriz Ltd
Yorkshire Biotec Ltd
ZDVapes
Zeus Industry Ltd

¹ <https://www.gov.uk/government/consultations/draft-regulations-on-the-sale-and-manufacture-of-tobacco-products>

² TPD2 Article 8(8) - Images of unit packets and any outside packaging targeting consumers in the Union shall comply with the provisions of this chapter [Chapter II – Labelling and Packaging provisions].

³ <http://www.legislation.gov.uk/asp/2010/3/contents>

⁴ <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx>

⁵ TPD” Definition of ‘novel tobacco product’ - means a tobacco product which: (a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and (b) is placed on the market after 19 May 2014;