

Hunters & Frankau

EST. 1790

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Regulatory Policy Committee
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Dear [REDACTED]

Subject: Consultation Stage Impact Assessment – standardised packaging and combined health warnings for handmade cigars

I am writing on behalf of Hunters & Frankau Limited (H&F) regarding the Department of Health and Social Care's July 2026 consultation stage Impact Assessment concerning the proposed extension of standardised packaging and other packaging requirements to tobacco products beyond cigarettes and hand-rolling tobacco.

H&F is a medium-sized British business and the UK's principal importer and distributor of premium handmade cigars from Cuba and other countries in the Caribbean and Central America. We supply specialist tobacconists and other retailers throughout the UK and do not distribute tobacco products other than cigars. H&F currently employs approximately 50 people and has annual turnover of approximately £55 million.

We have undertaken a detailed review of the Impact Assessment insofar as it relates to the proposed application of standardised packaging and combined picture health warnings to handmade cigars. A copy of that analysis is enclosed.

Our principal concern is a foundational one. The IA does not identify or assess handmade cigars as a distinct product category, despite published evidence, including analyses authored or commissioned by the US Food and Drug Administration and National Institutes of Health, identifying materially different consumer characteristics, patterns of use, and purchasing behaviours among premium-cigar consumers compared with users of other cigars and cigarettes. Instead, they are subsumed within broad cigar and tobacco categories, despite material differences in consumer profile, frequency and patterns of use, purchasing behaviour, specialist retail channels, price points, and exposure to packaging. The significance of this choice extends throughout the assessment. It affects the baseline population, the evidence relied upon to predict behavioural effects, the

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quantitative assumptions used to estimate benefits, and the assessment of impacts on specialist tobacconists.

The resulting analysis relies almost exclusively on evidence concerning cigarettes and other non-cigar tobacco products to predict the effects of the proposed measures on handmade cigars, without demonstrating that the relevant behavioural mechanisms can reliably be transferred to this materially different category. The IA identifies no direct cigar-specific evidence showing that standardised packaging or combined picture warnings will materially change cigar consumer behaviour. Its central prevalence assumption is ultimately derived from cigarette-focused expert elicitation undertaken before direct real-world evidence was available, while the IA does not test that assumption against handmade-cigar-specific experience in jurisdictions where comparable packaging requirements already apply.

We are also concerned that these evidential deficiencies carry directly into the IA's assessment of benefits and its Small and Micro Business Assessment. The aggregate benefits analysis does not identify the incremental benefit attributable to handmade cigars, while the SaMBA relies on broad business classifications and uniform-sales assumptions that produce an estimated average profit loss of just £584 per small or micro retailer per year. That figure is strikingly low in a premium category where individual handmade cigars commonly retail for £20 - £100 each and illustrates how the methodology risks averaging away the concentrated impact on genuine specialist tobacconists. The enclosed analysis also identifies an unexplained inconsistency in the IA's headline estimate of retailer costs.

These concerns are particularly striking because the need to consider handmade cigars separately was raised directly with DHSC during parliamentary scrutiny of the Tobacco and Vapes Bill. Peers specifically drew attention to the distinct characteristics of handmade cigar consumers, patterns of use and specialist retail market, and challenged the adequacy of applying broad regulatory powers to handmade cigars without evidence directed to that category. In response, the Minister pointed to the consultation and impact assessment process that would accompany the subsequent exercise of those powers. The present IA nevertheless does not address that underlying category problem.

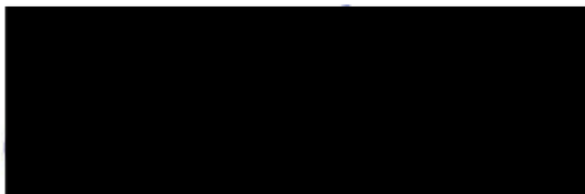
We recognise that the RPC previously found DHSC's options assessment fit for purpose at that earlier stage. Our concern is that the consultation stage analysis has not resolved the evidential and methodological issues relevant to handmade cigars and that several of the deficiencies identified in our analysis closely resemble weaknesses that the RPC has previously treated as material in its scrutiny of other impact assessments.

Given the potential significance of these issues for the final Impact Assessment, we would greatly appreciate the opportunity to meet with you and colleagues from the Secretariat to discuss our analysis and the appropriate scope for further RPC scrutiny as the proposal progresses.

We would be very happy to work around your availability and to provide any additional evidence or information that would assist the Committee or Secretariat.

Thank you for considering the enclosed analysis. I look forward to hearing from you.

Yours sincerely,

A large black rectangular redaction box covering the signature and name of the sender.

Hunters & Frankau Limited

Analysis of DHSC's Consultation Stage Impact Assessment for Standardised Packaging and Combined Health Warnings for Tobacco Products

Executive summary:

Handmade cigars are a distinct and niche part of the tobacco market. Their consumers, frequency and patterns of use, price points, purchasing environment, specialist retail channels, and exposure to packaging differ materially from those associated with cigarettes and many other tobacco products, including other types of cigars. These differences are not novel or peripheral considerations. Differentiated treatment of handmade cigars is already embedded in the existing regulatory framework: the current labelling regime provides a distinct treatment for individually wrapped cigars and packs of cigars weighing more than 3 grams, reflecting a regulatory framework that expressly recognised that such tobacco products were principally consumed by older consumers and relatively small groups of the population and should be subject to product-specific labelling rules.¹

Against that background, the July 2026 consultation stage Impact Assessment's (IA) failure to assess handmade cigars as a distinct product category is particularly striking. The issue had also been raised directly with DHSC only months earlier during parliamentary scrutiny of the Tobacco and Vapes Bill. Peers highlighted the distinct consumer profile, patterns of use, specialist retail channels and economic characteristics of handmade cigars, and challenged the adequacy of applying broad regulatory powers to them without evidence directed to that category. In direct response to those concerns, the responsible DHSC Minister confirmed that further impact assessments would precede secondary legislation and, specifically in relation to new packaging restrictions for cigars, that consultation and an accompanying impact assessment would be undertaken.²

Despite those ministerial commitments, the resulting consultation stage IA nevertheless again subsumes handmade cigars within the broader cigar category rather than assessing them separately. It therefore fails to provide the product-specific scrutiny that both the existing regulatory distinction and the recent parliamentary debate called for. It does not establish a handmade-cigar-specific baseline, identify direct evidence that the proposed measures will materially change handmade cigar consumer behaviour, or demonstrate that applying those measures to this distinct segment is justified by the resulting benefits. The consequences of that foundational category error run through the IA's evidence base, causal and quantitative analysis, assessment of benefits, and Small and Micro Business Assessment (SaMBA).

First, having failed to identify handmade cigars as a distinct category, the IA does not establish a reliable handmade-cigar-specific baseline. It treats handmade cigars within broad cigar or tobacco categories despite material differences in their consumers, frequency and patterns of use, purchasing environment, and exposure to packaging. It therefore cannot establish the size or characteristics of the handmade cigar population to which its assumptions are being applied, or the scale of the problem the proposed measures are intended to address within that segment.

Second, the evidence does not demonstrate a handmade-cigar-specific behavioural effect. The IA relies almost exclusively on evidence concerning cigarettes and other non-cigar tobacco products,

¹ Tobacco and Related Products Regulations 2016, reg. 9; Directive 2014/40/EU, recital 26 and art. 11.

² House of Lords Hansard, *Tobacco and Vapes Bill*, Committee, 11 November 2025, debate on amendments concerning handmade and hand-rolled cigars and impact assessment; see in particular the contributions of the Earl of Lindsay, Lord Johnson of Lairston, Lord Mendelsohn and Baroness Mairon.

uses general evidence of health harm as though it supported the effectiveness of the proposed packaging interventions, and selectively presents some sources without material qualifications or product-specific findings. It does not demonstrate that cigarette-related changes in noticing, recall, perceptions, or stated intentions will translate into sustained changes in handmade cigar initiation, consumption, or cessation.

Third, the quantitative analysis does not cure that evidential gap. The central 1.9% prevalence-reduction assumption originates in cigarette-focused expert elicitation undertaken before direct real-world evidence was available. Applying it to products in scope produces estimates of fewer cigar users but does not establish an effect for handmade cigars. The sensitivity analysis varies the assumed effect rather than testing whether the causal mechanism or any non-zero effect is supported for this category.

Fourth, the IA's aggregate benefits and break-even calculations cannot establish the case for including handmade cigars. They combine products and interventions and do not identify the incremental behavioural or health benefit attributable to handmade cigars. The calculations therefore cannot show what benefit would be lost if handmade cigars were excluded or treated differently, or whether any such benefit is proportionate to the costs imposed.

Finally, the SaMBA averages away the businesses most exposed. DHSC derives approximately 1,700 'specialist tobacconists' from a broad industrial classification without establishing how many satisfy the narrower statutory definition, then assumes sales are distributed uniformly across retailers. Industry evidence indicates that the number of businesses meeting the statutory definition of a specialist tobacconist is substantially smaller than the approximately 1,700 businesses identified by DHSC, and that handmade-cigar sales can represent a very high proportion of turnover for genuine specialists. The resulting averages cannot reveal the severity of the impact on those businesses or the risk to their commercial viability. The SaMBA also contains an unexplained inconsistency in its headline retailer cost estimate and does not meaningfully assess targeted, less burdensome alternatives.

The RPC's earlier options-assessment opinion found the analysis fit for purpose at that stage, while identifying areas requiring further development through consultation and in the final IA, including uncertainty around benefits and the interaction of different measures.³ The present concern is that, insofar as handmade cigars are concerned, the consultation stage analysis has not resolved the underlying evidential and methodological weaknesses identified in this paper. These are not minor deficiencies capable of being resolved through additional explanation. The RPC has previously treated materially analogous failures, including unsupported assumptions about distinct affected groups, unsuitable proxy evidence, inadequate uncertainty testing, deficient comparison of alternatives, and aggregate treatment of concentrated small-business impacts, as capable of rendering other IAs not fit for purpose. Taken together, they mean that the evidence and analysis do not support the case for applying the preferred option to handmade cigars. The IA should therefore not be regarded as fit for purpose in its treatment of that category.

³ Regulatory Policy Committee, *Options for standardised packaging and pack inserts for tobacco products*, RPC-DHSC-25096-QA(1), 26 November 2025.

Failure to identify and assess handmade cigars as a distinct product category:

The IA's foundational analytical error is its failure to identify and assess handmade cigars as a distinct, niche component of the broader cigar category. The proposals detailed in the IA are intended to apply standardised packaging to all 'cigars' and cigarillos. They would also introduce picture health warnings on individually wrapped cigars and on packs of larger cigars that are currently subject only to text warnings. Handmade cigars are therefore directly affected, yet the IA does not identify, disaggregate, or analyse them separately from other cigars.

This is not a distinction that was unavailable to, or unfamiliar to, DHSC. Existing tobacco labelling rules already differentiate between categories of cigars.⁴ The need for specific consideration of handmade cigars had also been raised directly with the Department during parliamentary scrutiny of the Tobacco and Vapes Bill only months before this IA was published.⁵ The decision nevertheless to analyse handmade cigars only within the broader cigar category therefore requires justification. None is provided.

Instead, the IA treats 'cigars' as a broad and largely undifferentiated category, without identifying or analysing material differences within it. It does not identify or assess the material differences between handmade cigars and other cigar products, their consumers, or the way they are bought and used. There is no separate analysis of patterns and frequency of use, purchasing behaviour, the role of specialist retailers, the sale of individual cigars, or the frequency and nature of consumers' exposure to packaging and warnings. This omission is material: published evidence, including analyses authored by staff of the US Food and Drug Administration's (FDA) Center for Tobacco Products and an FDA- and National Institutes of Health-commissioned review by the National Academies, identifies markedly lower frequency of use, and distinct consumer characteristics, use patterns, and purchasing behaviours among premium-cigar consumers compared with users of other cigar products and cigarettes.⁶ These differences may also affect packaging exposure, including where cigars purchased individually or by the box are subsequently removed from external packaging and stored in a humidor. Even the IA's underlying usage data provide only a single figure for cigar use, with no separate information about the handmade segment.⁷

This is not a technical classification issue. The choice of product category determines the population, evidence and assumptions on which the IA's assessment rests. The proposed interventions are intended to operate through packaging. Their likely effect therefore depends on the role packaging plays in selecting and purchasing the product, how often consumers see it, and whether changes in appearance or warnings are capable of changing consumer behaviour. Those questions cannot simply be answered for handmade cigars by placing them within a category that also includes materially different products and consumers.

The weakness is compounded by the evidence the IA relies upon. It includes very little evidence specifically concerning handmade cigars. The limited cigar-specific evidence it presents is

⁴ Tobacco and Related Products Regulations 2016, reg. 9; Directive 2014/40/EU, recital 26 and art. 11.

⁵ House of Lords Hansard, Tobacco and Vapes Bill, Committee, 11 November 2025, debate on amendments concerning handmade cigars and impact assessment; see in particular the contributions of the Earl of Lindsay, Lord Mendelsohn and Baroness Merron.

⁶ National Academies of Sciences, Engineering, and Medicine, *Premium Cigars: Patterns of Use, Marketing, and Health Effects* (National Academies Press, 2022), Finding 3-6; Catherine G. Corey et al., 'Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012–2013' (2014) 63 *Morbidity and Mortality Weekly Report*; Catherine G. Corey et al., 'US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013–2014' (2018) 20 *Nicotine & Tobacco Research* 1457–1466.

⁷ Consultation-stage IA, paras. 96–98 and 103, and Table 2.

principally concerned with health effects, patterns of use, or existing risk perceptions, rather than the effectiveness of the proposed packaging interventions.⁸ The IA identifies no direct cigar-specific evidence showing that standardised packaging or combined health warnings change consumer behaviour, and no direct evidence concerning their effect on handmade cigar consumers.

The final IA should assess handmade cigars as a distinct segment and explain how the relevant differences in products, consumers, purchasing channels, usage patterns, and packaging exposure affect the operation of each proposed measure. The absence of reliable handmade-cigar-specific evidence is not a limitation that can be cured simply by acknowledging uncertainty. On the evidence presented, the IA has not established that either measure will produce its intended effects for handmade cigars, or provided a sufficiently reliable evidential basis for including them within the proposed measures.

The RPC has previously treated this kind of evidential gap as capable of rendering an IA not fit for purpose. In its red-rated opinion on *Martyn's Law*, the RPC accepted the evidence concerning the general harm arising from terrorism but found that the IA had not demonstrated that the proposed requirements would reduce that risk for approximately 279,000 smaller venues. The methodological point is relevant here: evidence of a general harm does not establish that a proposed intervention will be effective for a materially distinct part of the regulated population.⁹

Unjustified reliance on cigarette and hand-rolling tobacco evidence:

The central evidential flaw in the IA is its reliance on evidence from cigarettes and hand-rolling tobacco to predict the effects of the proposals on cigars. The IA acknowledges that the evidence for the products in scope is limited and states that cigarette and hand-rolling tobacco evidence has been used as a proxy. It claims that 'any potential differences have been noted'. In reality, the major differences that determine whether the proxy provides a valid evidentiary base, including differences in consumer age and characteristics, frequency and patterns of use, purchasing behaviour, sales channels, and exposure to packaging, are not systematically examined or shown to have been incorporated into DHSC's analysis.¹⁰

The IA does not establish that the mechanisms observed for cigarettes can reasonably be transferred to handmade cigars. Cigarettes are high-frequency products sold through mass-market retail channels, with consumers carrying, handling, and viewing the same pack and its warnings multiple times per day. Handmade cigars are commonly sold through specialist channels, often from humidors and in retail environments already subject to tobacco display restrictions, purchased individually or by the box, and selected with reference to established preferences, product characteristics, and specialist advice. Where purchase by the box, they may subsequently be removed from their external packaging and stored in a humidor. These differences may materially affect the role packaging plays in product selection, the frequency with which it is seen, and the likelihood that changes to packaging or warnings will translate into behavioural change. The IA neither examines these differences nor explains why they do not affect the validity of its proxy.

⁸ Consultation-stage IA, paras. 5–12, including its citations to Mead et al. (2022), *Health Effects of Premium Cigars*, and Sharma et al. (2024), *Respiratory symptoms and outcomes among cigar smokers: findings from the Population Assessment of Tobacco and Health (PATH) study waves 2–5*.

⁹ Regulatory Policy Committee, *Martyn's Law*, RPC-HO-5254(1), 15 March 2023, pp. 2 and 6–7.

¹⁰ Consultation-stage IA, paras. 63–65.

The IA itself recognises that the effect of standardised packaging may differ across the products in scope, including cigars, but does not examine those differences or establish why evidence from cigarettes and hand-rolling tobacco can reliably be transferred to those products, including handmade cigars.

Standardised packaging

The evidence cited by the IA in support of the effectiveness of standardised packaging is drawn entirely from cigarettes, hand-rolling tobacco and heated tobacco products; none of it examines the effect of standardised packaging on cigars or cigar consumers generally, or on handmade cigars or their consumers specifically. The IA cites findings on the appeal of cigarette packs in Canada, the prominence of warnings on cigarette packs in England, and changes in cigarette-smoking prevalence following the introduction of several tobacco-control measures in the United Kingdom. These studies may be relevant to cigarettes but they do not, and cannot, demonstrate that standardising the packaging of handmade cigars will reduce their appeal, discourage their purchase, or lead consumers to stop using them.¹¹

The distinction is important because the IA moves too readily from evidence about cigarette packaging perceptions to conclusions about handmade cigar consumer behaviour. A finding that a cigarette pack is considered less attractive, or that a warning on it is more noticeable, does not establish that a handmade cigar consumer will change what they buy, reduce consumption, or stop smoking cigars. Nor is evidence that cigar smoking can cause harm evidence that standardised packaging will materially change cigar consumption. These are different propositions, requiring different evidence.

This evidential deficiency is carried directly into the IA's quantitative analysis. The IA assumes that standardised packaging will reduce cigar prevalence by 1.9% a year for two years—the same rate derived from the earlier assessment of cigarettes and hand-rolling tobacco. That figure ultimately derives from a 2013 expert-elicitation exercise undertaken expressly in the absence of direct evidence.¹² It reflects expert judgement about the expected effect of plain packaging on cigarette smoking prevalence, not an observed effect or a cigar-specific estimate. On that basis, the IA estimates that the policy will result in 24,760 fewer cigar users across an aggregated category that does not distinguish handmade from machine-made cigars. Yet it has not established that standardised packaging will reduce cigar use at all, much less the use of handmade cigars. Testing alternative rates of 1.4% and 2.4% does not resolve that deficiency. Rather, it varies the assumed size of the effect without establishing that the effect exists for cigars in the first place.¹³

The RPC has also previously made clear that the existence of sensitivity analysis is not sufficient where it does not test whether uncertainty could change the policy conclusion. In its red-rated opinion on the *Future Homes Standard*, the RPC required the IA to identify the thresholds at which uncertainties could change the ranking of options and to provide bounded estimates or scenarios showing how those uncertainties affected their relative performance. The IA's mechanical variation of the same assumed effect does not test the more fundamental uncertainty identified here:

¹¹ Consultation-stage IA, paras. 49–53 and 111–114, including para. 113 on heated tobacco products.

¹² Consultation-stage IA, para. 111 and fn 104; Rachel Peckey, David Spiegelhalter and Theresa M Marleau, 'Impact of plain packaging of tobacco products on smoking in adults and children: an elicitation of international experts' estimates' (2013) 13 *BMC Public Health* 18.

¹³ Consultation-stage IA, paras. 111–120 and 366–367.

whether the effect can reliably be transferred to cigars at all, or whether a materially lower or near-zero effect for that product category would alter the assessment.¹⁴

Combined health warnings

The same problem applies even more clearly to combined health warnings. The proposal would introduce picture warnings on individually wrapped cigars and cigarillos and on packs of larger cigars that currently require text warnings only.¹⁵ The question for the IA is therefore not whether health warnings can be useful in general. It is whether moving these particular products from text-only to combined picture and text warnings will materially change the knowledge or behaviour of handmade cigar consumers.

The IA does not answer that question. It relies principally on studies of cigarette warning labels and cigarette smokers to support claims about knowledge of risk, warning salience, relapse, and the effectiveness of picture warnings. It identifies no study showing that combined warnings change initiation, frequency of use, cessation, or other behaviour among handmade cigar consumers in particular or even among cigar smokers in general.

Taken together, these deficiencies mean that the IA has not established that evidence from cigarettes and hand-rolling tobacco provides a valid basis for predicting the effects of standardised packaging or combined health warnings on handmade cigars. It has not shown that the same behavioural mechanisms operate, that either measure will change handmade cigar use, or provided a reliable basis for estimating the scale of any effect. On the evidence presented, the proxy evidence cannot support the IA's assumptions about the effectiveness or claimed benefits of either measure for handmade cigars.

The RPC has previously treated the suitability and transferability of evidence as a red-rateable issue. In its red-rated opinion on the *Digital Markets, Competition and Consumers Bill*, it found that evidence supporting a key behavioural intervention had not been shown to be representative or suitable, questioned whether evidence from one contractual context was relevant to another, and required the department to explain the origin and applicability of its assumptions and the contribution of the individual measure. The same analytical requirement applies where cigarette and hand-rolling-tobacco evidence is used to predict the effects of different interventions on handmade cigar consumers.¹⁶

Incomplete and insufficiently balanced treatment of the evidence:

The problem is not confined to the absence of evidence directly concerning handmade cigars. The IA's treatment of the evidence it does cite is itself incomplete, insufficiently balanced, and at times misleading. It gives insufficient prominence to material qualifications, contrary findings, and evidence that weakens or contradicts the policy rationale, while failing to consider relevant real-world experience from jurisdictions where comparable requirements already apply. It also fails to distinguish consistently between evidence of health impacts, evidence about existing knowledge or perceptions, and evidence that the proposed packaging interventions will change behaviour.¹⁷

¹⁴ Regulatory Policy Committee, *Future Homes Standard impact assessment*, RPC-MHCLG-25107-IA(1), 16 February 2026, 'Justification for preferred way forward'.

¹⁵ Consultation-stage IA, para. 19; *Tobacco and vapes: packaging, appearance and display consultation*, 'Picture health warnings on the packaging of more products and devices'.

¹⁶ Regulatory Policy Committee, *Digital Markets, Competition and Consumers Bill* IA, RPC-BEIS-5224(2), 10 May 2023, pp. 3, 7–8 and 10–11.

¹⁷ Consultation-stage IA, paras. 27, 49–57 and 63.

One example concerns the IA's treatment of existing risk perceptions. Paragraph 27 cites Wackowski et al. as part of its effort to establish that "some groups underestimate the harms and addictive properties of products in scope... [emphasis added]"¹⁸, but omits the study's most relevant cigar-specific findings. Only 13.9% of respondents considered cigars less harmful than cigarettes, while 32.7% considered them more harmful. Among 18–24-year-olds, the percentage considering cigars more harmful rose to 36.8%.¹⁹ Those findings materially contradict the IA's implied application of its underestimation claim to cigars. By citing the study while omitting the findings most relevant to cigars, the IA presents a materially incomplete and misleading account of the evidence.

A similar lack of balance appears in the IA's presentation of the evidence following the introduction of standardised packaging for cigarettes and hand-rolling tobacco. Paragraph 50 highlights reductions in adult and youth smoking prevalence and a sustained trend in quit success identified in the 2022 post-implementation review. The review itself was materially more qualified about what could be attributed to standardised packaging. It emphasised that changes in relevant trends could not readily be attributed to a single intervention and that standardised packaging, the Tobacco and Related Products Regulations 2016, and other changes in the tobacco landscape operated concurrently. Its systematic review found increased thoughts of quitting but no evidence concerning cessation or relapse prevention.²⁰ Although the IA acknowledges the attribution problem later in its quantitative analysis, its initial presentation misleadingly gives prominence to the favourable trends without equivalent treatment of the limitations affecting their interpretation. Those limitations become more important still when that evidence is used to predict the effects of standardised packaging on handmade cigars.

The IA's failure to examine or report cigar-specific evidence from jurisdictions where comparable requirements already apply is also particularly striking. The IA identifies nine countries in which standardised packaging requirements apply to all tobacco products, including Australia, Canada, and New Zealand. Yet it does not assess whether the introduction of those requirements produced measurable changes in cigar prevalence, consumption, initiation, cessation, product choice, or responses to packaging. Instead, its effectiveness discussion cites a Canadian study concerning the appeal of cigarette packs and Australian evidence concerning Quitline calls.²¹ The IA neither identifies cigar-specific post-implementation evidence from these jurisdictions nor explains whether such evidence was sought, whether it exists, or why it was not considered. The same problem applies to combined health warnings: the IA refers to a substantial body of domestic and international evidence concerning picture warnings but identifies no evaluation of their effects on cigar consumers generally or handmade cigar consumers in particular.²²

Taken together, these examples reveal more than an unavoidable shortage of handmade cigar research. The IA does not provide a systematic and balanced account of the evidence relevant to the proposed interventions. It aggregates materially different products and populations, omits findings and qualifications that weaken its rationale, and does not test its assumptions against the experience of jurisdictions where comparable requirements already apply to cigars. The cited

¹⁸ Consultation-stage IA, para. 27.

¹⁹ Olivia A Wackowski and Cristine D Delnevo, 'Young Adults' Risk Perceptions of Various Tobacco Products Relative to Cigarettes: Results from the National Young Adult Health Survey' (2016) 43 *Health Education & Behavior* 328–336.

²⁰ Consultation-stage IA, paras. 50 and 112; Department of Health and Social Care, *The Standardised Packaging of Tobacco Products Regulations 2015: Post-Implementation Review* (March 2022), paras. 4.8, 5.3 and 5.9.

²¹ Consultation-stage IA, para. 52.

²² Consultation-stage IA, para. 55.

evidence may establish that tobacco products can cause harm or that packaging and warnings affect intermediate outcomes among cigarette smokers, such as warning salience, risk awareness, or perceived pack appeal. However, it does not establish that standardised packaging or combined health warnings will materially change the behaviour of cigar consumers generally or handmade cigar consumers in particular. Without a more complete and balanced assessment, the evidence presented cannot provide a reliable basis for the IA's conclusions about the effectiveness of either measure for handmade cigars.

Aggregate benefits analysis does not establish the case for handmade cigars:

The IA's foundational category error is carried directly into its benefits analysis. Because handmade cigars are not identified and assessed separately, the IA cannot isolate the benefits attributable to their inclusion in the preferred option. Because handmade cigar consumers are not disaggregated in either the baseline population or the estimated behavioural effect, the IA assesses benefits only at the level of the preferred option as a whole. It states that the preferred option will result in approximately 89,800 fewer users across all products in scope and compares that estimate with the 1,920 users it calculates would need to quit for individual health benefits to offset quantified costs.²³ That package-wide comparison cannot establish the incremental benefit attributable to including handmade cigars or whether that benefit is proportionate to the costs imposed on the segment.

The original failure to disaggregate handmade cigars is compounded by the aggregation of different interventions. The 89,800 estimate combines assumed reductions from standardised packaging across different tobacco products with estimated quits attributable to pack inserts.²⁴ The IA therefore cannot identify how much, if any, of the estimated benefit arises from handmade cigar consumers. Nor does it quantify any distinct behavioural or health benefit from extending combined picture warnings to cigar products currently subject only to text warnings.²⁵ The aggregate calculation cannot show what benefit would be lost if handmade cigars were excluded or treated differently.

The break-even calculation is also not product specific. It initially values every adult who stops using any product in scope using the estimated health gain from stopping cigarette or hand-rolling-tobacco smoking. The IA acknowledges that this may overstate the benefits of stopping other products and presents an alternative based on smokeless tobacco, while cautioning that it should not be used to estimate the benefits of stopping any individual product.²⁶ The resulting analysis cannot establish whether including handmade cigars produces benefits proportionate to the costs imposed on that segment. Taken together with the IA's failure to assess handmade cigars as a distinct category, its reliance on inapposite proxy evidence, and its incomplete treatment of the available evidence, this deficiency means the IA does not establish a sufficiently reliable case for including handmade cigars within the proposed measures. An aggregate benefits calculation

²³ Consultation-stage IA, para. 348 and Table 38.

²⁴ Consultation-stage IA, paras. 111–120 and 133–147, and Tables 5, 8 and 9.

²⁵ Consultation-stage IA, paras. 19, 53–57 and 152–153.

²⁶ Consultation-stage IA, paras. 345, 349 and 351–354, and Tables 38–39.

cannot cure the absence of evidence that either measure will materially affect handmade cigar behaviour.

SaMBA fails to assess the concentrated impact on specialist tobacconists:

The IA's foundational failure to identify handmade cigars as a distinct category carries directly into its Small and Micro Business Assessment. A SaMBA should identify whether the costs of a proposal fall disproportionately on particular small and micro businesses and assess what could be done to mitigate those effects. Here, however, the IA's use of broad business categories and sector-wide averages prevents it from determining the impact on the specialist tobacconists most exposed to the proposed measures.

The problem begins with the population used in the assessment. The IA treats approximately 1,700 businesses classified under SIC 47.26 as 'specialist tobacconists', of which 1,695 are small or micro businesses. That figure is derived from ONS/Nomis data for SIC 47.26, 'Retail sale of tobacco products in specialised stores'.²⁷ But SIC 47.26 is an industrial classification, whereas the statutory definition of a specialist tobacconist is materially narrower: it applies to premises where more than half of sales derive from cigars, snuff, pipe tobacco, and smoking accessories.²⁸ The IA does not establish how many businesses within SIC 47.26 satisfy that statutory test. Information supplied by the handmade cigar industry indicates that the number of businesses meeting the statutory definition is substantially smaller than 1,700, raising a serious question as to whether the IA has materially overstated the specialist tobacconist population.²⁹

The IA compounds that population-definition problem with an unsupported assumption about sales that materially distort the assessment. Because it lacks data on the proportion of sales attributable to businesses of different sizes, it assumes that sales of products in scope are distributed uniformly across retailers.³⁰ Information supplied by the handmade cigar industry indicates, however, that sales are heavily concentrated through specialist tobacconists, which constitute a principal retail channel for handmade cigars and, for some specialists, account for up to 70% of turnover.³¹ Treating sales as uniformly distributed therefore spreads economic activity concentrated among highly exposed specialists across a much larger retailer population. Combined with the uncertainty over the specialist population, this prevents the SaMBA from reliably assessing the severity of the proposal's impact on the businesses most dependent on handmade cigars.

The resulting averaging exercise cannot cure either defect. The IA estimates costs for small and micro retailers principally by applying their 67% share of the retailer population to aggregate costs, while also assuming common profit margins across retailer sizes. On that basis, the IA's £24.6 million estimate of lost profits across 42,139 small and micro retailers equates to an average annual profit loss of just £584 per business. It nevertheless acknowledges that specialist tobacconists may suffer higher profit losses because many of the products they sell are in scope and they have fewer opportunities to offset those losses through sales of other goods.³² It does not

²⁷ Consultation-stage IA, paras. 411 and 414; Office for National Statistics, *UK Standard Industrial Classification of Economic Activities 2007*, class 47.26.

²⁸ Department of Health and Social Care, *Tobacco and vapes: packaging, appearance and display consultation*, 'Specialist tobacconist'.

²⁹ Information supplied by representatives of the UK handmade-cigar industry.

³⁰ Consultation-stage IA, para. 417.

³¹ Information supplied by representatives of the UK handmade-cigar industry.

³² Consultation-stage IA, paras. 420–433 and Tables 54–61 (allocation of retailer costs and assumed profit margins); paras. 448–451 (potential disproportionate impacts, including higher profit losses for specialist tobacconists).

quantify that recognised disproportionate impact or account for differences in sales concentration, dependence on affected products, stockholding, margins, or capacity to absorb sustained losses.

This averaging may conceal consequences far more serious than the modest costs presented in the SaMBA. Without accepting the IA's claimed behavioural effects, any reduction in handmade cigar sales resulting from the proposal would fall disproportionately on highly dependent specialist tobacconists and, depending on its scale, could create a material risk to their commercial viability. The SaMBA neither assesses that risk nor identifies how many specialist tobacconists could be exposed to it.

Even on its own terms, the SaMBA's headline retailer cost estimate does not withstand basic arithmetic. Table 65 reports a total cost of £1,517 per small or micro retailer. Yet its five component figures total £1,421, while the stated aggregate cost of £59.9 million divided by the IA's estimate of 42,139 affected businesses also produces approximately £1,421. The IA provides no explanation for the discrepancy.³³ This unexplained internal inconsistency further undermines confidence in the transparency and reliability of the SaMBA. More fundamentally, even a mathematically correct average would not answer the relevant SaMBA question because the IA has neither established how many businesses meet the statutory definition nor accounted for the concentration of sales among those most exposed.

The assessment is also narrowly confined in its treatment of commercial impacts. It does not appear to consider significant potential downstream effects on hospitality businesses, including hotels, members' clubs, and other venues in which premium handmade cigars form part of the customer offering.

Nor does the IA adequately assess less burdensome alternatives. Within its SaMBA, the IA considers only a blanket exemption for all small and micro manufacturers or retailers and rejects that approach because small and micro businesses comprise 67% of retailers. It does not examine more targeted mitigation or scope options for the businesses most exposed, including differentiated treatment for handmade cigars, warning-only requirements, phased measures, specialist-channel arrangements, or other means of reducing concentrated impacts.³⁴ By defining the alternative so broadly, the IA avoids assessing the forms of mitigation most relevant to the businesses facing the greatest exposure.

The RPC has previously treated the failure to compare credible, less burdensome alternatives as sufficient to render an IA not fit for purpose even where the underlying problem is well evidenced. In its red-rated opinion on the *Decent Homes Standard*, the RPC found that extensive evidence of the problem did not compensate for the absence of a viable shortlist and a structured comparison demonstrating that the preferred option outperformed alternatives on cost-effectiveness, compliance, risk, and sequencing.³⁵ Here, the SaMBA's rejection of a blanket exemption for all small and micro businesses does not establish that uniform application to handmade cigars is preferable to the more targeted mitigation or scope options identified above.

The SaMBA therefore does not perform its essential distributional function. It acknowledges that specialist tobacconists may be disproportionately affected but uses assumptions and averages

³³ Consultation-stage IA, para. 416; para. 447 and Table 65.

³⁴ Consultation-stage IA, paras. 399–405 and 418 (assessment of exemptions for small and micro businesses).

³⁵ Regulatory Policy Committee, *Decent Homes Standard impact assessment*, RPC-MHCLG-26122-IA(1), 17 February 2026, 'RPC opinion' and 'Justification for preferred way forward'.

that prevent the scale of that impact from being measured. DHSC must establish how many of the businesses counted under SIC 47.26 actually satisfy the statutory specialist tobacconist definition, what proportion of handmade cigar sales is attributable to that subset, and what costs that subset bears. Until it does so, the IA cannot establish that the concentrated impacts have been properly assessed, mitigated or justified.

The RPC's red-rated opinion on the *Social Housing Bill* provides a close parallel to this distributional failure. It rejected an inadequately justified business-size proxy and an aggregate SaMBA where the affected businesses, fixed costs, transaction volumes, internal capacity, and available mitigation differed materially.³⁶ It required the department to assess the absolute and relative burdens on the distinct businesses affected rather than rely on aggregate conclusions. DHSC's broad industrial-classification proxy and uniform-sales assumption similarly prevent it from determining the actual relative burden and potential viability risk for genuine specialist tobacconists.

The IA is not fit for purpose in its treatment of handmade cigars:

The deficiencies identified in this paper are not discrete technical shortcomings capable of being cured through additional explanation. They arise from the IA's foundational analytical error in failing to identify and assess handmade cigars as a distinct product category and collectively mean that the IA does not establish a sufficiently reliable evidential or analytical basis for including them in the preferred option.

That category error affects every material stage of the analysis. The IA does not establish a reliable handmade-cigar-specific baseline or identify direct evidence that the proposed measures would change the behaviour of handmade cigar consumers. It instead transfers cigarette-derived assumptions without establishing their applicability to handmade cigars, moves from changes in noticing or perceptions to sustained behavioural effects without supporting that causal progression, and then aggregates products and interventions in a benefits analysis that cannot identify any benefit attributable specifically to handmade cigars. Its SaMBA repeats the same failure on the cost side. It does not reliably identify the specialist tobacconist population most exposed to the proposal and uses assumptions and averages that obscure the concentration and potential severity of the impacts on those businesses. Nor does it meaningfully assess less burdensome alternatives directed at this distinct category. This is particularly difficult to justify given that the need for product-specific consideration of handmade cigars had already been raised directly with DHSC during parliamentary scrutiny, and differentiated treatment of cigar categories is already embedded in the existing regulatory framework. The published precedents discussed above confirm that these are categories of analytical failure the RPC has previously treated as material and, in several cases, sufficient to render other IAs not fit for purpose.

³⁶ Regulatory Policy Committee, *Social Housing Bill* impact assessment, RPC-MHCLG-25176-IA(1), 24 July 2026, 'identification of options' and 'Small and micro business assessment and medium-sized business assessment'.

The IA therefore cannot establish that including handmade cigars would produce a material behavioural or health benefit, that any such benefit would justify the concentrated burdens imposed, or that inclusion is preferable to more targeted treatment. These are not peripheral uncertainties around an otherwise supported assessment. They concern the evidence, causal reasoning, benefits, costs, and proportionality of including handmade cigars. Taken together, the deficiencies mean that the evidence and analysis do not establish a sufficiently reliable case for applying the preferred option to handmade cigars. The IA should therefore not be regarded as fit for purpose in its treatment of that category.