

Chemnovatic's Net Population Impact Framework

Improving net population impact through risk-proportionate, implementable and enforceable nicotine regulation

Executive Summary

Chemnovatic supports an evidence-based, risk-proportionate and product-category-specific nicotine regulation framework designed to improve net population impact. In this annex, net population impact means the combined effect of regulation on youth initiation, adult switching away from combustible cigarettes, smoking-related disease and deaths, legal-market viability, traceability, illicit trade and implementation feasibility.

The proposed framework has five regulatory objectives and seven framework components. The components are not a one-to-one list: some objectives require more than one component, and some components serve more than one objective.

Regulatory objective	Framework components serving the objective	Practical role in the framework
Prevent youth initiation and protect non-users	Youth access and appeal controls; ingredient risk review and product quality standards; legal-market traceability and enforcement	Restrict underage access, youth-appealing presentation and unsafe or poorly documented products without treating adult smokers and minors as one group.
Support adult smokers in switching away from combustible cigarettes	Product-category and risk differentiation; adult smoker switching and accurate age-gated information; risk-proportionate fiscal treatment	Keep legal, adult-oriented alternatives available and understandable for smokers, while preventing youth-facing promotion and misleading claims.
Reduce smoking-related disease and deaths	Product-category and risk differentiation; adult smoker switching and accurate age-gated information; risk-proportionate fiscal treatment	Align regulatory burden with combustion risk and preserve incentives to move away from combustible cigarettes.
Maintain a legal, traceable and compliant market	Ingredient risk review and product quality standards; legal-market traceability and enforcement; implementable transition and value-chain design	Keep demand inside legal channels that regulators can supervise, while making compliance operationally feasible for legitimate companies.
Limit illicit trade and avoidable legal-market disruption	Risk-proportionate fiscal treatment; legal-market traceability and enforcement; implementable transition and value-chain design	Avoid creating price, availability or transition shocks that strengthen illegal supply, organised crime incentives or avoidable SME disruption.

Every major regulatory option should be assessed through three implementation tests: a net-population-impact test, an illicit-market and enforceability test, and an SME/value-chain implementation test. These tests are not additional objectives or components. They are the method for checking whether the framework is proportionate, enforceable and workable in practice.

This annex explains how Chemnovatic's closed-form questionnaire responses should be interpreted and why major regulatory options should be assessed against product-specific, population-level and cross-service impacts before adoption.

About Chemnovatic

Chemnovatic is a European B2B manufacturer operating across the pure nicotine and NGP value chain, including pure nicotine, nicotine salts, e-liquids and nicotine pouch mix. This position gives Chemnovatic visibility over how regulatory measures affect not only final products, but also formulation, documentation, notification, packaging, logistics, taxation, SMEs and cross-border supply.

1. Chemnovatic's recommended framework: risk-proportionate, product-category-specific nicotine regulation

Chemnovatic's position is that nicotine regulation should be evaluated by its net population impact, not by a mechanical distinction between nicotine and no nicotine. This annex does not defend every product, every flavour, every presentation or every business practice. It defends evidence-based differentiation: protect minors and non-users, preserve effective legal alternatives for adult smokers, keep demand in legal and traceable channels, and design rules that compliant operators can actually implement.

Nicotine should be regulated according to its relevant chemical, pharmacological and toxicological characteristics, rather than its production route alone. Where nicotine from different production routes has equivalent identity, composition, purity and quality, origin alone should not create a separate risk category. Nicotine analogues or other substances with materially different pharmacological or toxicological properties should be assessed separately on the basis of evidence and, where relevant, workable analytical methods.

The framework below translates the five regulatory objectives into practical components. It should be read as one system rather than as separate, standalone recommendations.

Framework component	Regulatory objective(s) served	Practical regulatory design
Product-category and risk differentiation	Support adult switching; reduce smoking-related disease and deaths	Differentiate combustible cigarettes, heated tobacco, e-cigarettes, nicotine pouches and medicinal nicotine by combustion, delivery route, tobacco content, evidence maturity, user group and enforcement profile. For nicotine itself, production route should not be used as a proxy for risk where chemical identity, purity and quality are equivalent; substances with materially different pharmacological or toxicological properties should be assessed separately.
Youth access and appeal controls	Prevent youth initiation and protect non-users	Use age verification, underage-sales enforcement, restrictions on youth-appealing descriptors, youth-facing communication and digital promotion.
Adult smoker switching and accurate age-gated information	Support adult smokers in switching; reduce smoking-related disease and deaths	Allow adult smokers to receive accurate, non-misleading, age-gated information about regulated alternatives, while prohibiting youth-facing promotion and health claims that are not substantiated.
Ingredient risk review and product quality standards	Protect non-users; maintain a compliant market	Focus on toxicological review, targeted restrictions on named substances where supported by evidence, product standards, nicotine delivery consistency, impurities, batch consistency, documentation and EU-CEG-compatible data. Ingredient controls should avoid exhaustive positive lists, broad functional prohibitions or de facto formulation pre-authorisation unless supported by a clear and proportionate safety justification.
Risk-proportionate fiscal treatment	Support switching; reduce smoking-related disease; limit illicit trade	Preserve fiscal differentiation from combustible cigarettes where justified by risk and evidence. This does not mean absence of taxation; it means avoiding tax design that unintentionally preserves cigarettes as the economically dominant nicotine product.
Legal-market traceability and enforcement	Maintain a legal, traceable and compliant market; limit illicit trade	Target illegal operators, product authenticity risks, online and cross-border non-compliance, release-to-market documentation and demonstrated traceability gaps. Traceability requirements should be proportionate to the product and operator concerned and should not automatically extend unit-level traceability designed for finished tobacco products to upstream B2B ingredients, formulations or mixtures.
Implementable transition and value-chain design	Maintain legal-market viability; limit avoidable disruption	Use realistic transition periods for reformulation, testing, packaging, notification/re-notification, stock management, supplier documentation and supply-chain adjustments.

2. Evidence basis for the framework

The table below explains why Chemnovatic supports risk-proportionate, product-category-specific nicotine regulation rather than uniform treatment of all nicotine products. It connects each framework component with evidence, with the limits of that evidence, and with the resulting regulatory implication. This avoids two errors: treating all nicotine products as equivalent, and treating every harm-reduction argument as a reason for deregulation.

Framework component	Evidence-based conclusion	What this does not prove	Regulatory implication
Product-category and risk differentiation	Combustion is central to smoking-related disease. EU and international evidence also shows that non-combustible products are not risk-free and differ in evidence maturity [1-6, 17].	It does not prove that nicotine is harmless or that all NGP categories have the same risk profile.	Rules should distinguish combustion risk, delivery route, tobacco content, product category and evidence maturity. For nicotine, regulatory treatment should be based on relevant chemical, pharmacological and toxicological characteristics rather than on production route alone, including whether nicotine is tobacco-derived or synthetic. Nicotine analogues or other nicotine-like substances with materially different properties should be assessed separately using evidence-based criteria and, where necessary, workable analytical methods.
Youth access and appeal controls	EU/JRC, SCHEER, Eurobarometer, CDC and other sources identify youth use, flavours, digital marketing and nicotine exposure as relevant concerns [2-5, 15, 16, 20].	Youth risk does not prove that legal adult-oriented alternatives should be removed.	Youth protection should directly target access, appeal, marketing and enforcement rather than rely only on broad category bans.
Adult smoker switching and accurate age-gated information	Cochrane and NHS evidence supports the role of nicotine e-cigarettes for smoking cessation, while EU/JRC and SCHEER stress caution and the need for long-term evidence [2, 5, 7, 8].	This does not justify use by minors, never-smokers or unlimited promotion.	Adult smokers should retain access to regulated alternatives and accurate age-gated information, with youth-facing promotion prohibited.
Ingredient risk review and product quality standards	The TPD already uses safety, quality, labelling and notification requirements for e-cigarettes; EU-CEG captures ingredients, emissions and toxicological data [9, 10].	This does not prove that every ingredient or presentation is acceptable.	Regulation should use toxicological review, product standards, batch consistency, documentation duties and, where evidence identifies a specific risk, targeted restrictions on named substances. EU-CEG and other available data should be used to identify and prioritise such risks. Controls should not default to exhaustive positive ingredient lists, broad functional prohibitions or formulation-level pre-authorisation without a demonstrated and proportionate safety justification.
Risk-proportionate fiscal treatment	EU tobacco taxation rules set harmonised minimum structures for manufactured tobacco and the Commission has proposed revising the framework in light of market developments [13].	Equal taxation of all nicotine products has not been shown to reduce net harm or prevent illegal supply.	Fiscal design should preserve incentives away from combustible cigarettes while maintaining youth safeguards and enforcement.
Legal-market traceability and enforcement	EU traceability systems and the 2026 illicit-trade analysis connect tobacco regulation with legal-market protection, state budgets and enforcement [11, 12, 18].	Prohibition or severe restriction does not eliminate demand by itself.	Major restrictions should be preceded by an illicit-market and enforceability assessment, including online and cross-border channels. Traceability and enforcement measures should address demonstrated gaps and be proportionate to the product and operator concerned, focusing on illegal supply, product authenticity and release-to-market documentation. Unit-level traceability designed for finished tobacco products should not be extended by default to upstream B2B ingredients, formulations or mixtures.
Implementable transition and value-chain design	Better Regulation requires assessment of feasibility, proportionality and burden; EU-CEG, TPD, traceability and tax systems show how compliance obligations interact operationally [9-14].	Implementation concerns do not mean regulation should be avoided.	Rules should include realistic transition periods and assess reformulation, testing, notification, packaging, stock losses, SME burden and supply-chain documentation.

3. Policy impact matrix: comparison of possible regulatory approaches and Chemnovatic's recommended framework

Chemnovatic's recommended framework is risk-proportionate, product-category-specific nicotine regulation. It is designed to improve the net population impact of nicotine regulation by preventing youth initiation, supporting adult smokers in switching away from combustible cigarettes, reducing smoking-related disease and deaths, maintaining a legal, traceable and compliant market, and limiting illicit trade and avoidable legal-market disruption.

Other approaches are also possible, including prohibition, undifferentiated treatment of all nicotine products, non-proportionate taxation or broad flavour bans. For a balanced impact assessment, these options should be placed side by side and tested against the same net population impact criteria. The matrix below is qualitative and directional; it is not a quantified model.

Approach	Youth initiation	Adult smoker switching	Smoking-related disease/deaths	Illicit market / organised crime	SME/legal-market impact	Overall assessment	Refs
A. Chemnovatic recommended framework: risk-proportionate, product-category-specific nicotine regulation (with strong youth protection and preserved adult switching pathways)	Down through age enforcement and youth-appeal controls	Up if legal alternatives and adult information remain available	Down if switching away from cigarettes increases	Down/neutral if legal supply remains viable and traceable	More workable if transition, notification and value-chain impacts are considered	Preferred balance: targeted control, adult harm reduction and enforceability	[1, 2, 3, 4, 6, 10, 11]
B. Ban or near-ban on all nicotine products	Down for legal youth access, but illegal access risk remains	Down legal alternatives; smokers may remain with cigarettes or illegal products	Uncertain / potentially worse if smoking persists	Up/high if demand remains; organised crime incentives increase	High disruption for legal operators and SMEs	May look protective in isolation but is not the evidence-based middle ground	[3, 8, 9, 10]
C. Treat all nicotine products like cigarettes	Possible reduction in legal attractiveness	Down, because lower-risk alternatives become less available or less attractive	Uncertain / potentially worse if switching falls	Up if legal products become less viable	High fixed costs and product withdrawals likely	Over-inclusive: ignores product-category and risk differences	[1, 3, 5, 8, 9]
D. Non-proportionate taxation of non-combustible products	Uncertain; higher prices may reduce uptake but can create illegal demand	Down if adult alternatives become less attractive than cigarettes	Uncertain / potentially worse if smokers do not switch	Up if legal/illegal price gap widens	Higher market-access burden for compliant operators	Weakens price signal away from cigarettes and can strengthen illicit supply	[6, 8, 9, 10]
E. Risk-proportionate fiscal differentiation as part of a broader framework	Requires youth price safeguards	Up if price signal supports movement away from cigarettes	Down if switching increases and smoking falls	Down/neutral if legal products remain competitive	More predictable if fiscal definitions are harmonised	Appropriate if paired with youth protection and enforcement; not absence of taxation	[1, 2, 3, 6, 8, 9, 10]
F. Blanket flavour bans	Possible reduction in youth appeal	Down if adult alternatives lose acceptability	Uncertain / potentially worse if adult switching falls	Up risk of DIY, illicit imports or informal supply	Reformulation, re-notification, packaging waste and stock losses	Requires market-specific impact assessment. Where specific ingredient-related risks are identified, targeted restrictions on named substances based on evidence of harm under realistic conditions of use should be considered before broader flavour or functional prohibitions.	[1, 4, 6, 8, 10, 12]
G. Targeted youth restrictions + strong enforcement	Down if age controls and youth-appeal limits are enforced	Neutral / positive if adult access is preserved	Positive if adult switching remains available	Down if illegal operators are targeted effectively	More implementable than broad category bans	Core part of the recommended framework	[4, 5, 6, 7, 8, 10]

4. Product-category scope and regulatory differentiation

Product-category differentiation is one of the foundations of Chemnovatic's recommended framework. Risk-proportionate regulation requires the Commission to distinguish products by characteristics that matter for harm, use patterns, evidence maturity and enforcement. The table below does not claim that any non-combustible product is risk-free. It shows why mechanically applying cigarette-style regulation to all nicotine products would ignore material differences.

Category	Key characteristics	Evidence maturity	Core regulatory implication
Cigarettes	Combustion, inhalation and tobacco content.	Very high evidence base on mortality, morbidity and EU health costs [1, 17].	Highest-risk category; strongest restrictions, taxation and enforcement.
Heated tobacco products	Heated tobacco aerosol; no conventional cigarette combustion; inhalation and tobacco content remain relevant.	Developing and product-specific; EU/JRC evidence supports caution [2, 3].	Separate assessment from cigarettes and e-cigarettes; regulate based on emissions, use patterns, youth appeal and comparative risk.
E-cigarettes / vaping products	No tobacco in liquid and no combustion, but inhalation and nicotine exposure may occur.	Strongest NGP evidence for adult cessation and relative-risk discussion, but long-term monitoring remains necessary [2, 5-9].	Adult switching potential + strict youth protection + quality, ingredient, labelling and notification controls.
Nicotine pouches	Usually tobacco-free; no combustion and no inhalation, but nicotine exposure and youth appeal risks remain.	Less mature long-term evidence; category-specific EU evidence is still developing [2, 3].	Distinct category; strong youth protection, labelling, traceability, product standards and category-specific evidence collection.
NRT / medicinal nicotine	No combustion and usually no inhalation; medicinal or cessation context.	Regulated medicinal context.	Maintain access for cessation; illustrates that nicotine risk depends on delivery, user group, intent and controls.

5. Cross-service implications for the impact assessment

The revision should not be assessed only as a public-health file. The same measures may require assessment by services responsible for taxation, customs, anti-fraud enforcement, SMEs, internal market, consumer protection, digital enforcement, trade, environmental effects and competitiveness. For this reason, the impact assessment should be cross-service in substance, not only in formal consultation.

For Chemnovatic, this is not abstract. The company operates across nicotine, nicotine raw materials, nicotine salts, e-liquids and formulations for nicotine pouch products. This position in the value chain makes visible how one regulatory measure can trigger multiple operational consequences at the same time: formulation, toxicology, packaging, notification, documentation, taxation, release to market, logistics and customer access.

Traceability, documentation and enforcement requirements should be proportionate to the product's role in the value chain and to the demonstrated enforcement need. Requirements designed for finished consumer products should not automatically be extended to B2B ingredients, formulations or mixtures. Any additional upstream obligations should be evidence-based, necessary and operationally workable across the supply chain.

Impact area	Why it matters for this file
Public health	Youth initiation, adult smoking prevalence, cessation, relapse to smoking, dual use and net population impact.
Taxation, customs and anti-fraud enforcement	Excise design, price differentials, legal/illegal price gaps, release-to-market documentation, cross-border leakage and illicit trade incentives.
Internal market, SMEs and competitiveness	Fixed compliance costs, harmonised definitions, fragmentation, product withdrawals, investment decisions and market concentration effects.
Consumer protection and digital enforcement	Age verification, online sales, cross-border platforms, misleading claims, product authenticity and information available to adult smokers.
Environment and packaging	Reformulation, repackaging, stock write-offs, packaging waste, recyclability and interaction with sustainability obligations.
Value-chain implementation	Raw-material sourcing, supplier documentation, purity and impurity profiles, SDS, CLP/REACH interfaces, testing, notification/re-notification and logistics.

6. References

Chemnovatic has relied primarily on EU and institutional evidence sources, including European Commission evaluation documents, JRC evidence reports, SCHEER, EU-CEG, EU tobacco traceability and taxation materials, OHID/KCL, Cochrane, NHS, WHO FCTC, National Academies and CDC/NYTS. Where evidence is jurisdiction-specific, especially from the United Kingdom or the United States, Chemnovatic treats it as relevant evidence but recommends EU-specific and Member-State-specific data collection before adopting EU-wide measures.

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