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Part 5

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

(Text with EEA relevance)

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A.4 ASSESSMENT CRITERIA & COMPARING THE OPTIONS

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A.4.1. ASSESSMENT CRITERIA OF IMPACTS

ASSESSMENT CRITERIA	IMPACTS
ECONOMIC IMPACTS	
<i>Functioning of the internal market</i>	<ul style="list-style-type: none"> -Facilitate cross border trade by removing national discrepancies for product specific measures -Create/maintain a level playing field for economic stakeholders (including SMEs), in particular for imported and domestic products -Allow the adaptation of the level of harmonisation in light of market, scientific and international developments. -Remove unjustified differential treatment of products
<i>Impact on economic players (farmers, manufacturers, wholesalers, retailers, others)</i>	<ul style="list-style-type: none"> -Cost/benefits for the industry concerned when envisaged measure is implemented (one off/ fixed costs, running/variable costs, comparison with status quo) -Cost/benefits for the upstream suppliers/downstream distributors -Redistribution effects (input/output model)¹ -Indirect impacts associated with expected change in consumption -Innovation and research
<i>Impact on Government</i>	<ul style="list-style-type: none"> -Costs/benefits for the public authorities when envisaged measure is implemented: administrative burden -Indirect impacts associated with the expected change in consumption (macroeconomic environment): public health (as monetised in line with IA guidelines), health care costs, productivity/absenteeism, taxes (even though no macroeconomic impact) -Illicit trade
<i>Impact on consumers</i>	<ul style="list-style-type: none"> -Consumer choice, price, quality -Consumer protection
<i>Third countries and international relations</i>	<ul style="list-style-type: none"> -Import, export -International agreements (WTO, including TRIPs and TBT) -WHO Framework Convention on Tobacco Control (FCTC)

¹ Whilst money not spent on tobacco will be spent on other goods and services, the "redistribution effects" based on the input/output model will not be used in the comparison tables, as it would mean not show the expected impact on the tobacco industry and would always be neutral or positive (for details see explanations below).

SOCIAL IMPACTS	
<i>Employment and labour markets</i>	<ul style="list-style-type: none"> -Employment, including upstream/downstream and specific regions -Redistribution effects (input/output model) - Impact on SMEs
<i>Equality of treatment and opportunities</i>	<ul style="list-style-type: none"> -Young people -Vulnerable groups -Equality
HEALTH IMPACTS	
<i>Awareness and appeal</i>	
<i>Prevalence, smoking cessation and initiation</i>	
<i>Morbidity and mortality</i>	
ENVIRONMENTAL IMPACTS	
<i>Waste, water, soil</i>	

A.4.2. COMPARING THE OPTIONS

In order to evaluate the relative effectiveness and efficiency of the options identified in the impact assessment, consideration has to be given to their positive and negative impacts and how well each option will meet the objective identified in section 3.

Policy option 0, status quo, has been taken as a baseline and therefore the potential positive and negative impacts associated with the other options will be measured against the status quo.

To help comparisons between options the impacts have been rated: +++: fully achieves the objectives; ++: mostly achieves the objectives; +: partly achieves the objectives 0: no impact on the achievement of the objectives; -: partly impedes the achievement of objectives; - -: mostly impedes the achievement of objectives; ---: fully impedes the achievement of the objective.

Two **important explanations** are warranted: (1) For the purpose of the scoring exercise, the impacts on economic players and on employment have been limited to the **tobacco sector**, although it is expected that money not spent on tobacco will be spent on other products and services and will benefit the economy and employment in these other sectors. This is described in more details in Annex 5, which suggests that – from a macro-economic

perspective – measures impacting strongly on the tobacco industry are positive for the economy as a whole.

(2) When comparing the status quo (national discrepancies) with a situation in which industry has to adapt its production lines to one EU standard (e.g. on labelling and content/ingredients) it is generally accepted that **cost savings** are achieved for the "one off costs" (familiarisation etc.). Also economies of scale are possible if industry has to comply with one EU standard. For the running/variable costs the impact will also depend on the envisaged measure. However, these (positive) direct impacts could be outweighed by "**indirect impacts**" linked to the decrease in tobacco consumption (for details see Annex 5), which explains in the table below why the impact on the tobacco industry could be negative.

A.4.2.1. STP and extension of the product scope

A.4.2.1.1. Smokeless tobacco products (STP)

A.4.2.1.1.1. Comparison table

Impacts	Specific criteria	Option 0: No Change	Option 1: Lift the ban on oral tobacco and subject all STP to general product standards	Option 2: Lift the ban on oral tobacco and subject all STP to stricter labelling and ingredients regulation	Option 3: Maintain the ban on oral tobacco, subject all novel tobacco products to a notification obligation and all STP placed on the market to stricter labelling and ingredients regulation	Option 4: Maintain the ban on oral tobacco and subject all STP to the same treatment	Option 5: Remove the current circumvention potential of STP
Economic	<i>Internal market</i>	0	+	++	++	+++	+
	<i>Economic players</i>	0	++	+	-	--	---
	<i>Governmental</i>	0	0	0	0	0	0
	<i>Consumers</i>	0	+	+	++	+	0
	<i>International</i>	0	0	+	0	+	0
Social	<i>Employment</i>	0	++	+	-	--	---
	<i>Equality</i>	0	--	-	++	++	+
Health	<i>Awareness/Appeal</i>	0	--	-	++	++	++
	<i>Prevalence</i>	0	--	-	+	++	++
	<i>Morbidity</i>	0	-	-	+	+	+
Envi	<i>Waste, water, soil</i>	0	0	0	0	0	0

A.4.2.1.1.2. Reference

Detailed explanations can be found in section 5.2.1. of the main report.

A.4.2.1.2. Nicotine containing products (NCP)

A.4.2.1.2.1. Comparison Table

Impacts	Specific criteria	Option 0: No Change	Option 1: Subject all NCP to labelling and ingredients requirements under TPD	Option 2: Establish a new authorisation scheme for NCP	Option 3: Subject NCP over a certain nicotine threshold to the medicinal products' legislation and the remaining NCP to labelling requirements	Option 4: Subject all NCP to the medicinal products' legislation
Economic	<i>Internal market</i>	0	+	+	++	+
	<i>Economic players</i>	0	-	-	-	--
	<i>Governmental</i>	0	+	-	+	+
	<i>Consumers</i>	0	+	++	+	+
	<i>International</i>	0	0	0	0	0
Social	<i>Employment</i>	0	-	0	0	0
	<i>Equality</i>	0	+	-	++	++
Health	<i>Awareness/Appeal</i>	0	+	-	+	+
	<i>Prevalence</i>	0	0	0	+	+
	<i>Morbidity</i>	0	+	++	+++	+++
Envi	<i>Waste, water, soil</i>	0	0	0	0	0

A.4.2.1.2.2. Reference

Detailed explanations can be found in section 5.2.2. of the main report.

A.4.2.1.3. Herbal products for smoking

A.4.2.1.3.1. Comparison table

Impacts	Specific criteria	Option 0: No Change	Option 1: Subject all herbal products for smoking to labelling requirements under TPD	Option 2: Phase out marketing of herbal products for smoking
Economic	<i>Internal market</i>	0	+	-
	<i>Economic players</i>	0	-	--
	<i>Governmental</i>	0	0	0
	<i>Consumers</i>	0	+	-
	<i>International</i>	0	0	0
Social	<i>Employment</i>	0	-	--
	<i>Equality</i>	0	++	+++
Health	<i>Awareness/Appeal</i>	0	++	n.a.
	<i>Prevalence</i>	0	++	+++
	<i>Morbidity</i>	0	++	+++
Envi	<i>Waste, water, soil</i>	0	0	0

A.4.2.1.3.2. Reference

Detailed explanations can be found in section 5.2.3. of the main report.

A.4.2.2. Packaging and labelling

A.4.2.2.1. Comparison table

Impacts	Specific criteria	Option 0: No Change	Option 1: Mandatory enlarged picture warnings	Option 2: Option 1 plus harmonise certain aspects of pack and FMC appearance and prohibit promotional and misleading elements	Option 3: Option 2 plus full plain packaging
Economic	<i>Internal market</i>	0	+	++	++
	<i>Economic players</i>	0	-	-	--
	<i>Governmental</i>	0	0	+	+
	<i>Consumers</i>	0	+	++	+
	<i>International</i>	0	+	++	+
Social	<i>Employment</i>	0	-	-	--
	<i>Equality</i>	0	+	+++	++
Health	<i>Awareness/Appeal</i>	0	+	++	+++
	<i>Prevalence</i>	0	+	++	+++
	<i>Morbidity</i>	0	+	++	+++
Envi	<i>Waste, water, soil</i>	0	0	0	0

A.4.2.2.2. Reference

Detailed explanations can be found in section 5.3. of the main report.

A.4.2.3. Reporting and regulation of ingredients

A.4.2.3.1. Comparison table

Impacts	Specific criteria	Option 0: No change	Option 1: Common reporting format on a voluntary basis. Prohibit toxic, addictive and attractive additives in tobacco products.	Option 2: Mandatory reporting in harmonised format. Prohibit products with characterising flavours.	Option 3: Mandatory reporting in harmonised format. Prohibit all additives not essential for manufacturing.
Economic	<i>Internal market</i>	0	--	++	+++
	<i>Economic players</i>	0	+	0	---
	<i>Governmental</i>	0	+	+	+
	<i>Consumers</i>	0	0	0	--
	<i>International</i>	0	0	0	--
Social	<i>Employment</i>	0	0	0	-
	<i>Equality</i>	0	0	+	+
Health	<i>Awareness/Appeal</i>	0	-	+	+
	<i>Prevalence</i>	0	0	+	++
	<i>Morbidity</i>	0	0	+	++
Envi	<i>Waste, water, soil</i>	0	0	0	0

A.4.2.3.2. Reference

Detailed explanations can be found in section 5.4. of the main report.

A.4.2.4. Cross-border distance sales of tobacco

A.4.2.4.1.1. Comparison table

Impacts	Specific criteria	Option 0: No change	Option 1: Minimum harmonisation requiring notification and age verification system	Option 2: Prohibit cross border distance sale of tobacco products
Economic	<i>Internal market</i>	0	++	+
	<i>Economic players</i>	0	++	+
	<i>Governmental</i>	0	+	++
	<i>Consumers</i>	0	+++	+
	<i>International</i>	0	+	++
Social	<i>Employment</i>	0	++	+
	<i>Equality</i>	0	+	+
Health	<i>Awareness/Appeal</i>	0	+	++
	<i>Prevalence</i>	0	+	+
	<i>Morbidity</i>	0	+	+
Envi	<i>Waste, water, soil</i>	0	0	0

A.4.2.4.1.2. Reference

Detailed explanations can be found in section 5.5. of the main report.

A.4.2.5. Traceability and security features

A.4.2.5.1. Comparison table

Impacts	Specific criteria	Option 0: No change	Option 1: EU tracking and tracing system	Option 2: Tracking and tracing system, complemented by security features
Economic	<i>Internal market</i>	0	++	+++
	<i>Economic players</i>	0	++	++
	<i>Governmental</i>	0	+++	+++
	<i>Consumers</i>	0	++	+++
	<i>International</i>	0	+++	+++
Social	<i>Employment</i>	0	+	++
	<i>Equality</i>	0	+	++
Health	<i>Awareness/Appeal</i>	0	++	+++
	<i>Prevalence</i>	0	++	+++
	<i>Morbidity</i>	0	++	+++
Envi	<i>Waste, water, soil</i>	0	0	0

A.4.2.5.2. Reference

Detailed explanations can be found in section 5.6. of the main report.