

Clause on selected impacts

1. Basic information	
Title of the document	
Draft Act on new psychoactive substances and on amendments to certain acts	
Submitter (and co-submitter)	
Ministry of Health of the Slovak Republic	
Nature of the submitted document	☐ Document of a non-legislative nature
	☒ Document of a legislative nature
	☐ Transposition/implementation of EU law
<i>In the case of transposition/implementation, please provide a list of transposed/implemented legislation:</i>	
Start and end dates of the preliminary consultation procedure	16.04.2026 – 24.04.2026
Expected date of submission for the consultation procedure	April 2026
Expected start and end dates of final assessment**	
Expected date of submission to a session of the Government of the Slovak Republic*	August 2026

2. Definition of the issue
The draft Act on new psychoactive substances and on amendments to certain acts (hereinafter the ‘draft Act’) addresses pressing issues associated with the regulation of new psychoactive substances that are appearing on the market with increasing frequency and pose a risk to public health. At present, these substances are added to Annex 1 to Act No 139/1998 on narcotic substances, psychotropic substances and preparations, as amended (hereinafter ‘Act No 139/1998’), on a case-by-case basis for each substance, making the legislative process complex and time-consuming. The draft Act will enable these substances to be classified as prohibited substances on the basis of the ‘generic model’, i.e. according to whether they fall within the defined groups of substances listed in Annex 1 to the draft Act, thereby streamlining the process and strengthening public health protection.
3. Objectives and outcome
The main objective of the draft Act is to ensure more effective protection of public health and safety by a) introducing a generic model that will enable groups of new psychoactive substances to be classified as prohibited substances more quickly and systematically; b) prohibiting the production of these substances and laying down clear rules for record-keeping and monitoring their distribution; c) enhancing transparency and preventing the illegal production and dissemination of substances without restricting legitimate research.

The adoption of the draft Act will result in a clear and effective regulatory framework, in contrast to the current situation, in which the legislative process for classifying substances is protracted and does not adequately protect public health.

4. Stakeholders

The Police Force, the Financial Administration of the Slovak Republic, the Slovak Trade Inspection, consumers, illicit manufacturers, carriers and distributors of these substances.

5. Alternative solutions

Several alternative solutions were considered in the preparation of the draft Act.

The 'zero option' – retaining the legal status quo without adopting new legislation. This option was assessed as insufficient since the status quo does not provide sufficiently effective tools to respond flexibly to developments in the market for new psychoactive substances and to the rapid changes in their chemical structures.

Retaining the current system of individual classification of substances in Annex 1 to Act No 139/1998 whilst streamlining the process – consideration was given to retaining the existing mechanism for the individual classification of substances with a view to speeding up legislative or administrative processes. This option was assessed as insufficient, as the system would continue to be unable to respond adequately to the rapid emergence of new chemical modifications of substances. At the same time, new psychoactive substances do not constitute narcotic drugs or psychotropic substances under the legal framework of Act No 139/1998, and their regulation under that regime would therefore be neither systematic nor appropriate.

Amending Act No 139/1998 without adopting the draft Act – the possibility of amending the current legislation without creating a separate regulatory framework was considered. This option was not selected, as it would not allow the new generic regulatory model to be introduced comprehensively and would not provide a sufficiently distinct and effective mechanism for regulating new psychoactive substances.

Narrower definition of the regulated groups of substances – consideration was given to limiting regulation to selected groups of new psychoactive substances only. This option was assessed as less effective as it would leave room for the emergence and distribution of substances with new chemical structures falling outside the defined groups.

Following an assessment of the above alternatives, the draft Act introducing a generic regulatory model based on groups of chemical structures was identified as the most appropriate solution, as it will enable more effective, systematic and preventive regulation of new psychoactive substances.

6. Implementing legislation

Is implementing legislation expected to be adopted/amended? ☐ Yes ☒ No

If so, please specify which areas will be governed by this legislation or which implementing legislation will be affected:

7. Transposition/implementation of EU law

Please specify whether the submitted draft legislation involves gold-plating according to the correlation table or whether gold-plating occurs in the context of implementation of EU law.

☐ Yes ☒ No

8. Expediency review

Expediency will be reviewed by the Ministry of Health of the Slovak Republic within two years of the date on which the draft Act enters into force, on the basis of an assessment of the number of regulated new psychoactive substances, the effectiveness of the regulatory mechanism, experience gained in practice and the impacts on public health protection, as well as an assessment of the need to broaden the range of competent authorities and other public authorities involved, in particular market surveillance authorities, in order to ensure the effective application of the Act.

* to be completed only if the document is not included in the Work Plan of the Government of the Slovak Republic or in the Plan

of Legislative Tasks of the Government of the Slovak Republic.

** to be completed only if the final assessment of selected impacts has been carried out in accordance with point 9.1 of the Uniform Methodology.

*** the assessment concerns changes to Pillars I and II of the universal pension system with an identified impact of 0.1 % of GDP (inclusive) in the long term.

9. Selected impacts of the document

Impacts on the general government budget	☐ Positive	☐ None	☒ Negative
of which impacts covered in the budget, in case of identified negative impact	☒ Yes	☐ No	☐ Partial
of which impacts on the budgets of municipalities and higher territorial units	☐ Positive	☒ None	☐ Negative
of which impacts covered in the budget, in case of identified negative impact	☐ Yes	☐ No	☐ Partial
Impact on the long-term sustainability of public finances for selected measures ***	☐ Yes		☐ No
Impacts on the public expenditure limit	☐ Positive	☒ None	☐ Negative
Impacts on the business environment	☐ Positive	☒ None	☐ Negative
of which impacts on SMEs	☐ Positive	☐ None	☐ Negative
The bureaucracy and cost reduction mechanism is being applied:	☐ Yes		☐ No
Social impacts	☒ Positive	☐ None	☐ Negative
Environmental impacts	☐ Positive	☒ None	☐ Negative
The document is assessed under Act No 24/2006 on environmental impact assessment and on amendments to certain acts, as amended	☐ Yes		☒ No

Impacts related to information society	☐ Positive	☒ None	☐ Negative
Impacts on public administration services for the public, of which	☒		
 impacts of public administration services on the public	☐ Positive	☐ None	☐ Negative
 impacts on service processes in public administration	☐ Positive	☒ None	☐ Negative
Impacts on marriage, parenthood and the family	☒ Positive	☐ None	☐ Negative

10. Notes

Entities currently manufacturing or distributing new psychoactive substances, including through vending machines and over the Internet, may be affected by the draft Act. As these are undesirable antisocial activities posing a high risk to public health, the draft Act does not affect the legitimate business environment.

The draft Act has no direct positive impact on the environment. The introduction of a more effective regulatory mechanism for new psychoactive substances will curb their illegal production and distribution, thereby reducing the environmental risks associated with the operation of illegal laboratories, particularly in relation to the improper handling of chemicals and the generation of hazardous waste.

The impact cannot be quantified; it is an indirect positive impact resulting from the regulatory nature of the draft Act, and therefore no separate impact assessment has been prepared.

11. Contact details of the author

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12. Sources

Draft legislation of the Federal Ministry of Health – Third Regulation amending the Annex to the Act on New Psychoactive Substances (Germany);

- Decisions adopted at meetings of the Commission on Narcotic Drugs of the United Nations Office on Drugs and Crime (UNODC);
- Report on the state and development of the drug scene in the Slovak Republic for 2022;
- Report on the state and development of the drug scene in the Slovak Republic for 2021, etc.

13. Opinion of the Commission on the Assessment of Selected Impacts from preliminary consultation procedure No 240/2024 (if carried out pursuant to point 8.1 of the Uniform Methodology)

☐ **Agrees**

☐ **Agrees with a proposal for revision**

☒ **Disagrees**

Please provide the comments from the Commission's opinion in Part II, together with your evaluation:

Regarding the clause on selected impacts

The Commission requests that point 5. Alternative solutions and point 8. Expediency review of the clause on selected impacts be completed.

Grounds: The Commission requests that point 5 of the clause on selected impacts be completed. The Commission does not consider the statement that there 'are no' alternative solutions to be sufficient or in accordance with the Uniform Methodology for the Assessment of Selected Impacts. In the case of a draft Act that changes the regulatory model for new psychoactive substances itself from the individual classification of specific substances to a generic model based on groups of chemical structures, it should have been indicated, at least briefly, which alternatives had been considered and why they had not been selected. Relevant alternatives could have included, for example, retaining the current system of individual classification of substances in the annex to Act No 139/1998 whilst streamlining the process; partially amending the existing legislation without adopting a separate Act; or defining the regulated groups of substances more narrowly. It would also be advisable to describe the 'zero option', i.e. maintaining the status quo.

The expediency review is worded in overly general terms, as it merely states that it will take place on an ongoing basis after the Act enters into force, without specifying a particular deadline, the method of evaluation or a clearer link to measurable indicators. The Commission does not consider such wording sufficient from the perspective of the methodology, under which the expediency review must be designed so as to permit an objective assessment of whether the legislation has achieved the objectives pursued.

Evaluation: The comment has been accepted by adding relevant alternatives, including the zero option, and by specifying the expediency review in greater detail, including the deadline, the method of evaluation and measurable indicators. Points 5 and 8 of the clause on selected impacts have been completed.

Regarding impacts on the general government budget

Approval of the document in question is possible only on condition that all negative impacts are kept within the approved limits of the budget chapter of the Ministry of Health (including the employment limit) for the relevant budgetary years, without placing any additional demands on the general government budget or the overall public expenditure limit. In this regard, the Commission requests that the analysis of impacts on the general government budget be amended so that it does not indicate an impact not covered in the budget and that the clause on selected impacts indicate a negative impact on the general government budget that is covered in the budget.

In the analysis of impacts on the general government budget, the insurance contributions have been calculated incorrectly in Tables 4/B and 5 (35 % instead of 35.95 %). The Commission requests that this be corrected throughout the impact analysis.

Evaluation: The comment was accepted by amending the clause on selected impacts and the analysis of impacts on the general government budget, including the removal of the impact not covered in the budget. The calculations have also been corrected.

Regarding social impacts

The Commission recommends that the social impacts in point 9 of the clause on selected impacts (Selected impacts of the document) be reassessed. If the submitter indicated that there were no social impacts because it considered them marginal, it should state in point 10 of the clause (Notes) why they are negligible.

Grounds: The draft Act envisages simplifying the process of classifying new psychoactive substances as prohibited substances, which would reduce the production, distribution and consumption of drugs in Slovakia. The submitter expects that this will improve the protection of public health and the safety of the population. This could have social impacts, specifically a positive impact on access to resources,

rights, goods and services.

Evaluation: Following reassessment, the Ministry of Health of the Slovak Republic prepared a social impact analysis.

Regarding impacts on marriage, parenthood and the family

From the perspective of the analysis of impacts on marriage, parenthood and the family, the document has a predominantly positive societal impact on the family and parenthood. The aim of the draft is to make the environment in which children grow up safer.

As part of the legislative process, the Commission recommends that the analysis of selected impacts elaborate on the explicit impact of eliminating the availability of new psychotropic substances on the protection of the health of children and young people in the family environment. Specifically, this concerns preventing substance addiction from taking hold within families and the related causal relationships within families. The clear objective of this document is to protect families from breakdown and to safeguard the family environment through law-enforcement measures against the spread of new drugs. Quantification should correlate with the number of families affected and the rate of successful detection of illicit handling (trafficking/possession) of illicit psychotropic substances by natural persons.

Evaluation: The comments were accepted by adding an explanation of the positive societal, social and family impacts of the draft Act, particularly in relation to the protection of public health, children, young people and the family environment. The Ministry of Health of the Slovak Republic has drawn up an analysis of impacts on marriage, parenthood and the family.

14. Opinion of the Commission on the Assessment of Selected Impacts from Final Assessment No (if carried out pursuant to point 9.1 of the Uniform Methodology)

☐ Agrees ☐ Agrees with a proposal for revision ☐ Disagrees

Please provide the comments from the Commission's opinion in Part II, together with your evaluation:

Analysis of impacts on the general government budget, employment in public administration, and financing of the draft

2.1 Summary of impacts on the general government budget in the draft

Table 1/A

Impacts on the general government budget	Impact on the general government budget (in EUR)			
	2026	2027	2028	2029
Total general government revenue	0	0	0	0
of which: separately for each public administration entity	0	0	0	0
<i>of which:</i>				
- <i>impact on the State budget</i>	0	0	0	0
Budget funds	0	0	0	0
EU funding	0	0	0	0
- <i>impact on municipalities</i>	0	0	0	0
- <i>impact on higher territorial units</i>	0	0	0	0
- <i>impact on other public administration entities</i>	0	0	0	0
Total general government expenditure	0	58 730	58 730	58 730
of which: separately for each public administration entity/programme	0	0	0	0
<i>of which:</i>				
- <i>impact on the State budget</i>	0	58 730	58 730	58 730
Budget funds	0	58 730	58 730	58 730
EU funding	0	0	0	0
co-financing	0	0	0	0
- <i>impact on municipalities</i>	0	0	0	0
of which the impact of new tasks within the meaning of paragraph (2), Article 6 of Constitutional Act No 493/2011 on budgetary responsibility	0	0	0	0
- <i>impact on higher territorial units</i>	0	0	0	0
of which the impact of new tasks within the meaning of paragraph (2), Article 6 of Constitutional Act No 493/2011 on budgetary responsibility	0	0	0	0
- impact on other public administration entities – savings in health insurance companies' expenditure on medicinal products	0	0	0	0
- - impact on other public administration entities an increase in expenditure on new medicinal products and medicinal products reimbursed subject to individual approval	0	0	0	0
Impact on the number of employees	0	2	2	2
- <i>impact on the State budget</i>	0	2	2	2
- <i>impact on municipalities</i>	0	0	0	0
- <i>impact on higher territorial units</i>	0	0	0	0
- <i>impact on other public administration entities</i>	0	0	0	0
Impact on wage expenditure	0	36 000	36 000	36 000
- <i>impact on the State budget</i>	0	36 000	36 000	36 000
- <i>impact on municipalities</i>	0	0	0	0

- <i>impact on higher territorial units</i>	0	0	0	0
- <i>impact on other public administration entities</i>	0	0	0	0
Financing secured in the budget	0	58 730	58 730	58 730
of which: separately for each public administration entity/programme	0	0	0	0
Other than budgetary funds	0	0	0	0
Impact/savings not covered in the budget	0	0	0	0

The Ministry of Health of the Slovak Republic undertakes to monitor, on a regular basis, the budgetary impacts of the new legislation and its effects on the implementation of the currently applicable programme decree of the Ministry of Health of the Slovak Republic on the allocation of public health insurance expenditure by individual types of healthcare provided for in § 15(8)(b), (d), (e), (f), (h) and (i) of Act No 581/2004 on health insurance companies, supervision of healthcare and on amendments to certain acts, as amended, and to present an analysis of the impacts of the new categorisation process at meetings of the Council for Healthcare Budgeting.

Table 1/B

	2026	2027	2028	2029
Impact on the total general government expenditure limit (under ESA 2010 methodology)	0			
of which: separately for each public administration entity/programme	0			
of which:				
impact on the public expenditure limit of the state budget	0			
impact on the public expenditure limit of other public administration entities	0	0	0	0
impact on the public expenditure limit of other components of the general government budget				

2.1.1. Financing of the draft – Proposal to address a loss of revenue or increased expenditure pursuant to § 33(1) of Act No 523/2004 on budgetary rules in public administration:

Funding for the draft will be provided within the approved expenditure limits of the budget chapter of the Ministry of Health of the Slovak Republic for the relevant budgetary years, including the limit on the number of employees, without any additional demands on the general government budget and without affecting the overall public expenditure limit.

2.2. Description and characteristics of the draft

2.2.1. Description of the draft:

The draft Act governs the conditions for the handling of new psychoactive substances, in particular their seizure, record-keeping, expert assessment and disposal, and lays down the scope of competence of public authorities in this field. The draft also governs procedures for

granting authorisations for research, teaching and expert activities, as well as control and sanction mechanisms relating to the handling of new psychoactive substances.

2.2.2. Characteristics of the draft:

☐	change in rate
☐	change in entitlement
☒	new service or regulation (or abolition thereof)
☐	combined draft
☐	other

2.2.3. Anticipated developments in the volume of activities:

Provide a clear description; if necessary use the table below. Also provide estimates of tax bases and/or fees if the changes apply to them.

Table 2

Volume of activities	Estimated volumes			
	y	y + 1	y + 2	y + 3
ABC indicator				
KLM indicator				
XYZ indicator				

2.2.4. Calculations of impacts on public finances

Indicate the most important calculations that were used to determine revenue and expenditure impacts and the underlying assumptions. The submitter should clearly distinguish between the supporting data from the individual budget chapters and organisations so that the basis used for the calculations is clearly apparent.

1. Introduction

The present draft Act has a negative impact on general government expenditure that is covered in the budget, arising from the need for the Ministry of Health of the Slovak Republic to perform new tasks relating to the regulation, record-keeping, authorisation procedures and administrative proceedings concerning new psychoactive substances. The impact on the general government budget will arise from 2027, given that the draft Act is to enter into force on 1 January 2027. This expenditure will be financed within the approved limits of the budget chapter of the Ministry of Health of the Slovak Republic for the relevant budgetary years, including the employment limits, without any additional demands on the general government budget and without affecting the overall public expenditure limit.

2. Description of legislative changes

2.1 Introduction of new legislation

The draft Act introduces a comprehensive legal framework for the handling of new psychoactive substances, including their seizure, record-keeping, expert assessment and disposal.

2.2 Implementation of authorisation and control mechanisms

The draft Act governs the procedures for granting, amending and revoking authorisations for the handling of new psychoactive substances for research purposes and lays down the record-keeping obligations of authorisation holders, checks on compliance with statutory obligations and sanction mechanisms in the event of breaches.

2.3 Impact on the activities of the Ministry of Health

The Ministry of Health of the Slovak Republic will be responsible for carrying out these activities, which will require additional staffing capacity.

3. Methodology for calculating the budgetary impact

3.1 Number of employees

The budgetary impact was determined on the basis of the need to create two posts at the Ministry of Health of the Slovak Republic:

- One lawyer, grade 9 (specialist work, administrative proceedings)
- One clerk, grade 7 (record-keeping, administration)

3.2 Wage expenditure

The calculation was based on the following average monthly wages:

- lawyer: EUR 1 800;
- clerk: EUR 1 200.

The total annual wage expenditure amounts to EUR 36 000.

3.3 Insurance premiums and contributions

The employer's contributions were calculated at approximately 35.95 % of wage expenditure, amounting to EUR 12 942 per year.

3.4 Goods and services

Expenditure on the material and technical resources required for the posts, in particular work equipment, IT support and operating costs, was estimated at approximately 20 % of personnel expenditure, amounting to EUR 9 788 per year.

4. Results of the calculation of the budgetary impact

Total annual expenditure is as follows:

- wages: EUR 36 000
- insurance premiums: EUR 12 942
- goods and services: EUR 9 788

total: EUR 58 730 per year.

The impact remains stable throughout all the years under review and no year-on-year change is expected.

Basis: the submitter's internal calculations based on projected wage expenditure and staffing requirements.

Impacts and conclusions

The draft Act has a negative impact on the general government budget that is covered in the budget, in the form of increased expenditure in the budget chapter of the Ministry of Health of the Slovak Republic arising from the performance of new regulatory, record-keeping and control activities relating to new psychoactive substances.

The proposed expenditure is proportionate to the scope of the new responsibilities and necessary to ensure the proper implementation of the Act, particularly as regards the protection of public health and the prevention of risks associated with the emergence of new psychoactive substances.

The impact on the general government budget constitutes stable and predictable expenditure within the approved limits of the budget chapter of the Ministry of Health of the Slovak Republic.

Funding for the draft will be secured within the approved limits of the budget chapter of the Ministry of Health of the Slovak Republic for the relevant budgetary years, including the employment limits, without any additional demands on the general government budget and without affecting the overall public expenditure limit.

Table 3

Revenue (in EUR)	Impact on the general government budget				note
	y	y + 1	y + 2	y + 3	
Tax revenue (100)¹					
Non-tax revenue (200)¹					
Grants and transfers (300)¹					
Revenue from transactions in financial assets and financial liabilities (400)					
Loans, credits and repayable financial assistance received (500)					
Total impact on general government revenue	0	0	0	0	

1 – itemise revenue according to applicable economic classification

Note:

If the impact concerns several public administration entities, a separate table must be completed for each entity.

Expenditure (in EUR)	Impact on the general government budget				note
	2026	2027	2028	2029	
Current expenditure (600)	0	58 730	58 730	58 730	Expenditure comprises wage expenditure, insurance premiums and contributions, as well as the related operating costs required for two posts.
Wages, salaries, emoluments and other forms of personnel compensation (610)	0	36 000	36 000	36 000	
Insurance premiums and contributions (620)	0	12 942	12 942	12 942	
Goods and services (630) ²	0	9 788	9 788	9 788	
Current transfers (640) ²	0	0	0	0	
Payment of interest and other payments related to a loan, credit, repayable financial assistance and financial leasing (650) ²	0	0	0	0	
Capital expenditures (700)	0	0	0	0	
Acquisition of capital assets (710) ²	0	0	0	0	
Capital transfers (720) ²	0	0	0	0	
Expenditure on transactions in financial assets and financial liabilities (800)	0	0	0	0	
Total impact on general government expenditure	0	58 730	58 730	58 730	

2 – itemise expenditure according to applicable economic classification

Note:

If the impact concerns several public administration entities, a separate table must be completed for each entity.

Table

4/B

Impacts (under ESA 2010 methodology)	Impact on the public expenditure limit of the public administration entity				note
	2026	2027	2028	2029	
Capital revenue (230)					
Current expenditure (600)	0	58 730	58 730	58 730	Expenditure comprises wage expenditure, insurance premiums and contributions, as well as the related operating costs required for two posts.
Wages, salaries, emoluments and other forms of personnel compensation (610)	0	36 000	36 000	36 000	
Insurance premiums and contributions (620)	0	12 942	12 942	12 942	
Goods and services (630) ²	0	9 788	9 788	9 788	
Current transfers (640) ²	0	0	0	0	
Payment of interest and other payments related to a loan, credit, repayable financial assistance and financial leasing (650) ²	0	0	0	0	
Capital expenditures (700)	0	0	0	0	
Acquisition of capital assets (710) ²					
Capital transfers (720) ²					
Total impact on the public expenditure limit of the public administration entity	0	58 730	58 730	58 730	

2 – itemise expenditure according to applicable economic classification

Note:

If the impact concerns several public administration entities, a separate table must be completed for each entity.

Table 5

Employment	Impact on the general government budget				note
	2026	2027	2028	2029	
Total number of employees		2	2	2	
of which impact on the State budget		2	2	2	
Average wage expenditure (in EUR)		1 500	1 500	1 500	
of which impact on the State budget		1 500	1 500	1 500	
Total personnel expenditure (in EUR)	0	48 942	48 942	48 942	
Wages, salaries, emoluments and other forms of personnel compensation (610)		36 000	36 000	36 000	
of which impact on the State budget		36 000	36 000	36 000	
Insurance premiums and contributions (620)		12 942	12 942	12 942	
of which impact on the State budget		12 942	12 942	12 942	

Note:

If the impact concerns several public administration entities, a separate table must be completed for each entity. Where different groups of employees are concerned, the numbers, wages and insurance contributions must be specified separately according to the method of remuneration (e.g. police officers, customs officers, etc.).

The average wage cost is calculated as the wage cost per employee per calendar month of the current year.

Categories 610 and 620 are carried over from this annex into the corresponding categories of the

‘expenditure’ annex.

2.2.5. Calculation of impacts on the long-term sustainability of public finances

Please indicate the model used to determine the impacts on revenue and expenditures in the long term, as well as the assumptions on which you relied and which were included in the model. Describe the model used together with any modifications made in the calculation.

Table 6

Long-term sustainability	Impact on public finances					Note
	d	d + 10	d + 20	d + 30	d + 40	
Impact on expenditure in percentage points of GDP						
Impact on revenue in percentage points of GDP						
Impact on the balance in percentage points of GDP						

Note:

The letter ‘d’ indicates the first year of the next decade.

The table must be completed separately for each measure. Where several measures are introduced, a table showing the cumulative effect of introducing all the measures simultaneously must also be completed.

Analysis of impacts on marriage, parenthood and the family Impacts on the family environment, cohesion among family members, the upbringing of children, parents' rights in relation to their children, the fundamental principles of the Family Act, entering into marriage and the disposable income of households with several children
8.1 Identify, describe and quantify the impact on the family environment and specify the positive/negative impacts on the family environment.
<i>8.1.1 Will the present draft result in a change in the family environment? If so, to what extent? Where possible, please provide quantification; otherwise, explain why quantification is not available.</i>
The draft Act will bring about a positive change in the family environment, namely a shift from a vulnerable or potentially unstable family environment towards one that is more stable, safer and more functional. The introduction of the generic model for regulating new psychoactive substances will make it possible to restrict their availability more quickly, thereby reducing the risk of their entering the family environment, particularly as regards children and young people. The proposed legislation has the potential to reduce the incidence of substance dependence among family members, limit secondary social consequences such as indebtedness, crime or job loss, and thereby help protect the health of children and young people. At the same time, it may help maintain the proper functioning of families, reduce conflicts between family members and prevent family breakdown caused by the use of psychoactive substances. Direct quantification of the impact on the family environment is not possible since this is an indirect, long-term preventive effect that depends on several factors.
<i>8.1.2 Could the present draft disrupt a healthy family environment?</i>
The present draft Act will not disrupt a functional family environment, as its objective is, on the contrary, to restrict the availability of new psychoactive substances and thereby reduce risk factors affecting families. The proposed measures are preventive and protective in nature and help strengthen the stability and safety of the family environment.
<i>8.1.3 Does the present draft have an impact on population growth? If so, what is the impact in terms of the population replacement level?</i>
The present draft Act has no direct impact on population growth or on achieving the population replacement level, as it does not regulate economic or social factors that directly influence decisions regarding the number of children. Indirectly, however, it may contribute to a more stable and safer family environment, which is a favourable factor in decisions to start or expand a family, without the negative impacts associated with addiction.
<i>8.1.4 Does the present draft have an impact on removing barriers that prevent working parents from having their desired number of children?</i>
The present draft Act has no direct impact on removing the barriers that prevent working parents from having their desired number of children, as it does not regulate working conditions, flexible working arrangements or the availability of services for families. Indirectly, however, it may contribute to a more stable and safer family environment, which may have a positive impact on parents' decisions about how many children to have.
<i>8.1.5 Does the present draft have an impact on the amount of time or opportunities available to parents or children to participate in family life?</i>
The present draft Act has no direct impact on the amount of time or opportunities available to parents or children to participate in family life, as it does not regulate working time or introduce measures to support parents in spending time together with their children. Indirectly, however, it may help improve the quality and effective use of time within the family, as a reduction in the incidence of addiction leads to less disruption of family life and creates more scope for family relationships to function properly.
<i>8.1.6 Does the present draft have an impact on substance-related or behavioural addictions entering families?</i>
The present draft Act has a significant positive impact on limiting the entry of both substance-related and behavioural addictions into families, as it introduces a more effective mechanism for regulating new psychoactive substances through a generic model for classifying them as prohibited substances. This approach makes it possible to respond more quickly to new forms of these substances, thereby reducing their

availability on the market, which is one of the main risk factors for the development of addiction identified in professional publications, particularly among children and young people as the most vulnerable group. Reducing the availability of these substances leads to a decline in the incidence of substance-related addictions, which often trigger or accompany other forms of risky behaviour. This also indirectly limits the development of behavioural addictions (e.g. pathological gambling or addiction to digital technologies), as it reduces the overall level of risky behaviour and social disorganisation in the individual and family environment.

At the same time, limiting these risk factors has significant secondary impacts on the family environment, particularly in the form of reducing conflicts between family members, strengthening parenting skills, reducing the economic burden on households and preventing family breakdown. The draft Act thus systematically helps protect families against the entry of addictions and strengthens their stability and proper functioning.

8.2 Identify, describe and quantify the impacts on cohesion among family members.

8.2.1 Does the present draft have an impact on cohesion among family members? If so, what impact? Where possible, please provide quantification; otherwise, explain why quantification is not available.

The present draft Act has a positive impact on cohesion among family members, as restricting the availability of new psychoactive substances helps reduce the incidence of addiction, which is a significant risk factor that undermines family relationships. A reduction in addictive behaviour leads to fewer conflicts, improved communication between family members and more stable performance of parental and family roles. Direct quantification of the impact on cohesion among family members is not possible, as this is an indirect and qualitative social phenomenon.

8.2.2 Does the present draft have an impact on strengthening ties between family members?

The present draft Act has an indirect positive impact on strengthening ties between family members, as reducing the incidence of addiction helps restore trust, responsibility and effective communication among family members. At the same time, more stable parental behaviour creates more favourable conditions for establishing and maintaining bonds between parents and children, particularly in early childhood, and supports proper care for children and the performance of parental roles.

8.2.3 Does the present draft have an impact on rebuilding or preserving families?

The present draft Act has an indirect positive impact on rebuilding and preserving families, as restricting the availability of psychoactive substances reduces one of the key factors destabilising family life. Although the draft Act does not introduce direct intervention mechanisms to support families in crisis, its preventive nature creates more favourable conditions for stabilising family relationships and restoring them where they have been disrupted by addiction.

8.2.4 Does the present draft have an impact on the emergence or persistence of conflicts between family members?

The present draft Act has a positive impact on reducing both the emergence and persistence of conflicts between family members, as restricting the availability of psychoactive substances reduces behaviour associated with impulsivity, aggression and social disorganisation. At the same time, the draft Act does not create economic or social pressures that could lead to conflict or to family members living separately, thereby contributing to a stable and predictable family environment.

8.2.5 Does the present draft have an impact on family breakdown?

The present draft Act has an indirect positive impact on reducing family breakdown, as it reduces the incidence of addiction, a significant long-term factor destabilising family relationships. The draft Act does not create economic or other incentives that would lead to family breakdown and thereby helps maintain the proper functioning and stability of families.

8.2.6 Does the present draft have an impact on the provision of assistance to a family member who is dependent on such assistance?

The draft Act has no direct impact on the availability or scope of assistance provided to a family member who is dependent on such assistance, as it does not regulate the social services system or the provision of

assistance. Indirectly, however, it may help reduce the number of persons dependent on assistance as a result of addiction, thereby reducing the burden on both families and the social assistance system.

8.3 Identify and describe impacts on the upbringing of children.

8.3.1 Does the present draft have an impact on the upbringing of children? If so, what impact?

The present draft Act has a positive impact on the proper upbringing of children, as restricting the availability of new psychoactive substances helps protect children from risky behaviour and negative socio-pathological phenomena. It thereby promotes a safe environment for the upbringing of children not only in the family but also in schools and extracurricular facilities, and contributes to their healthy psychological and social development.

8.3.2 Does the present draft have an impact on the upbringing of children in families?

The present draft Act has a positive impact on raising children within families, as reducing the incidence of addiction among both parents and children promotes a stable family background and the responsible performance of parental duties.

8.3.3 Does the present draft have an impact on preparing children for marriage and parenthood?

The present draft Act has an indirect positive impact on preparing children for marriage and parenthood, as it promotes a stable and functional family environment as the basic unit of society. By eliminating the negative phenomena associated with addictions, it helps create patterns of behaviour based on responsibility, stability and care for the family, thereby strengthening appreciation of the value of marriage and parenthood.

8.4 Identify and describe the impacts on parents' rights in relation to their children.

8.4.1 Does the present draft have an impact on parents' rights or responsibilities towards their children? If so, what impact?

The present draft Act has an indirect positive impact on the exercise of parents' rights and responsibilities towards their children, as restricting the availability of psychoactive substances helps reduce the incidence of addiction, which may adversely affect parents' ability to properly provide for a minor child's upbringing, health, nutrition and all-round development. This improves the conditions for the responsible exercise of parental rights and performance of parental duties, including caring for and protecting the child, in the child's best interests.

8.5 Identify and describe the impacts on the fundamental principles of the Family Act.

8.5.1 Does the present draft have an impact on the protected interests set out in the fundamental principles of the Family Act? If so, what impact?

The present draft Act is in line with the fundamental principles of the Family Act and has a positive impact on them. It contributes to the protection of the family as the fundamental unit of society (Article 2) and promotes the stability of the family environment, which is essential for the proper upbringing of children (Articles 1 and 3).

By restricting the availability of psychoactive substances, it also strengthens parents' ability to provide a safe and peaceful environment for their child (Article 4) and upholds the principle of the best interests of the minor child, particularly with regard to the child's safety, stability and healthy development (Article 5).

8.6 Identify and describe impacts on entering into marriage.

8.6.1 Does the present draft have an impact on entering into marriage? If so, what impact?

The present draft Act has no direct impact on entering into marriage, nor does it create any factors that would discourage people from entering into marriage or directly encourage them to do so. Indirectly, however, it may contribute to creating a more stable societal and family environment that promotes the values of lasting partnerships and starting a family.

<i>8.6.2 Does the present draft have an impact on the preferred timing of marriage?</i>
The present draft Act has no impact on the preferred timing of marriage, as it creates no incentive either to postpone marriage or to marry earlier and does not regulate factors that directly influence individuals' decisions on the timing of their marriage.
<i>8.6.3 Does the present draft have an impact on awareness of the nature of marriage, the obligations between spouses and starting a family?</i>
The present draft Act has no direct impact on awareness of the nature of marriage and the obligations between spouses. Indirectly, however, it may help reinforce the view that a stable family environment is essential for starting a family and raising children properly.
<i>8.6.4 Does the present draft have an impact on preventing the breakdown of marriages?</i>
The present draft Act has an indirect positive impact on preventing the breakdown of marriages, as restricting the availability of psychoactive substances reduces the incidence of addiction, which is a significant factor in the disruption of partner relationships. Furthermore, the draft Act does not introduce any administrative or other measures that would facilitate the breakdown of marriages, or any preventive or remedial programmes for families in crisis, while its preventive nature contributes to marital stability and the maintenance of functional family relationships.
8.7 Identify, describe and quantify impacts on the disposable income of households with several children.
<i>8.7.1 Does the present draft have an impact on the disposable income of households with several children? If so, please specify this impact, taking into account the number of children in the family, their specific needs in view of their age and health status and, where applicable, other circumstances. Where possible, please provide quantification; otherwise, explain why quantification is not available.</i>
The present draft Act has no direct impact on the disposable income of households with several children, as it does not introduce any financial measures or impose any direct costs on households. Indirectly, however, it may have a positive impact, particularly by reducing expenditure associated with the consequences of psychoactive substance use (e.g. healthcare, addiction treatment, loss of income due to incapacity for work or social problems within the household). This effect may be particularly significant for families with several children, single-parent households and families at risk of poverty or social exclusion, for which the negative consequences of addiction have a more pronounced impact on the household budget. The draft Act may indirectly help stabilise the financial situation of families and move them further away from the at-risk-of-poverty threshold. Direct quantification of the impact is not possible, as this is an indirect, long-term effect that depends on several factors. The impact may be monitored on an indicative basis using secondary indicators such as household healthcare costs, the prevalence of addiction or the overall socio-economic situation of the families concerned.

Analysis of social impacts Impacts on household finances, access to resources, rights, goods and services, social inclusion, equal opportunities and equality between women and men, and impacts on employment (If an impact has not been identified in any of the social impact areas assessed (points 4.1 to 4.4), please indicate 'No impact' in the appropriate line of the analysis.)		
4.1 Identify, describe and quantify the impact on household finances and specify the groups of households that will be affected positively/negatively.		
<i>Will the draft cause household income or expenditure to increase or decrease?</i> <i>Which groups of households/population are affected and how?</i> <i>Are the groups at risk of poverty or social exclusion among the potentially affected groups?</i> (Where a larger number of measures are assessed, add further sections to the table before point 4.2, as appropriate – 4.1.1 Positive impact/4.1.2 Negative impact).		
a)	4.1.1 Positive impact	
b)	Describe the measure and its impact on household finances, indicating whether this is an increase in income or a decrease in expenditure:	The measure does not have a direct financial impact on household income. An indirect positive impact can be expected in the long term in the form of a reduction in household expenditure associated with the health and social consequences of the use of new psychoactive substances, in particular expenditure on healthcare, addiction treatment, repeated hospitalisations, as well as loss of income due to incapacity for work or social exclusion.
c)	Specify the affected groups:	Affected group no 2
	Affected group no 1 Residents of the Slovak Republic.	Affected group no 3
d)	Quantify the increase in income or decrease in expenditure for each affected group of households/group of individuals and the number of people/households affected by the present draft.	
e)	- average increase in income/decrease in expenditure in the group in EUR and/or %/period: - size of the group (number of persons):	Affected group no 2
	Affected group no 1	Affected group no 3
f)	Reason why quantification is not available:	Quantification of the positive social impacts is not possible because these are indirect and long-term effects of a preventive nature that depend on a number of variables, in particular the developments on the drug scene, user behaviour and the effectiveness of law-enforcement and preventive measures. The draft Act does not introduce measurable financial transfers or obligations that would enable direct quantification of the impacts on household finances.
g)	4.1.1.1 Of which positive impact on groups at risk of poverty or social exclusion (In the event of significant impacts on the income or expenditure of households at risk of poverty, identify and quantify the positive impact on poverty among the population (e.g. a reduction in the at-risk-of-poverty rate, average increase in income/decrease in expenditure in the group))	
h)	Describe the measure and its impact on household finances, indicating whether this is an increase in income or a decrease in expenditure:	The draft Act also has an indirect positive social impact on population groups at risk of poverty or social exclusion. This particularly concerns persons on low incomes, minors, the long-term unemployed, persons with disabilities and persons living in a socially disadvantaged environment, who are at increased risk of the health and social consequences of using new psychoactive substances.

		Reducing the availability of new psychoactive substances and ensuring a swifter response from the State to their emergence may help limit the development of addictions, health complications and secondary social problems, which have a significant negative impact on the finances of these households. The measure may thus indirectly contribute to reducing the financial burden associated with healthcare, social services and loss of income.
	Specify the affected groups:	Affected group no 2
i)	Affected group no 1 Residents of the Slovak Republic.	Affected group no 3
j)	Quantify the increase in income or decrease in expenditure for each affected group of households/group of individuals and the number of people/households affected by the present draft.	
k)	- average increase in income/decrease in expenditure in the group in EUR and/or %/period: - size of the group (number of persons):	Affected group no 2
	Affected group no 1	Affected group no 3
l)	Reason why quantification is not available:	Not possible due to the indirect, preventive and long-term nature of the identified impacts.
a)	4.1.2 Negative impact	
b)	Describe the measure and its impact on household finances, indicating whether it is a decrease in income or an increase in expenditure:	
c)	Specify the affected groups:	Affected group no 2
	Affected group no 1 Residents of the Slovak Republic	Affected group no 3
d)	Quantify the decrease in income or increase in expenditure for each affected group of households/group of individuals and the number of people/households affected by the present draft.	
e)	- average decrease in income/increase in expenditure in EUR and/or in %/period: - size of the group (number of persons):	Affected group no 2
	Affected group no 1	Affected group no 3
f)	Reason why quantification is not available:	No negative social impacts of the draft Act were identified, as the measures have no direct impact on household income or expenditure.
g)	4.1.2.1 Of which negative impact on groups at risk of poverty or social exclusion (In the event of significant impacts on the income or expenditure of households at risk of poverty, identify and quantify the negative impact on poverty among the population (e.g. an increase in the at-risk-of-poverty rate, average decrease in income/increase in expenditure in the group))	
h)	Describe the measure and its impact on household finances, indicating whether it is a decrease in income or an increase in expenditure:	
i)	Specify the affected groups:	Affected group no 2
	Affected group no 1	Affected group no 3
j)	Quantify the decrease in income or increase in expenditure for each affected group of households/group of individuals and the number of people/households affected by the present draft.	
k)	- average decrease in income/increase in expenditure in EUR and/or in %/period:	Affected group no 2

	- size of the group (number of persons):	
	Affected group no 1	Affected group no 3
l)	Reason why quantification is not available:	No negative social impacts of the draft Act were identified, as the measures have no direct impact on household income or expenditure.

4.2 Identify, describe and quantify impacts on access to resources, rights, goods and services for individual affected population groups and the impact on social inclusion.

Does the draft have an impact on access to resources, rights, goods and services?

Describe the evaluated measure, specify the affected population groups and the nature of the change in accessibility with regard to financial and geographical accessibility, quality, organisation, etc. Indicate the size of each affected group.

a)	This concerns, in particular, access to: - social protection, socio-legal protection, social services (including childcare services and services for the elderly and people with disabilities); - quality jobs, protection of employees' health, dignity and safety at work, and existing employment rights; - assistance with the payment of disability-related expenses; - employment, the labour market (e.g. facilitation of the reconciliation of family and professional responsibilities, employment services), training, vocational education and preparation for the labour market; - healthcare, including affordable medical aids for people with disabilities; - formal and non-formal education and lifelong learning; - housing and related basic municipal services; - transport; - other services, in particular services of general interest, and goods; - justice, legal protection and legal services; - information; - other rights (e.g. political).	The draft Act has no negative impact on the population's access to resources, rights, goods and services. On the contrary, the measure has an indirect positive impact on the protection of public health and the safety of the population by enabling faster regulation and restriction of the availability of new psychoactive substances, which pose a significant health and social risk. The draft Act contributes to better protection of the health of the population and to stronger social inclusion, particularly among groups that are at increased risk of the negative consequences of using new psychoactive substances. The positive impact is particularly evident in a) health protection and addiction prevention; b) reduced health and social risks; c) improved safety and protection of personal dignity. The measure has no impact on the financial, geographical or organisational accessibility of public services, but indirectly improves the quality of public health protection.
b)	<i>Does the draft have a significant impact on any vulnerable population group or group at risk of poverty or social exclusion?</i> <i>Please specify the affected groups at risk of poverty and social exclusion and describe the impact on them. Is this impact greater than its impact on other groups or entities? Indicate the size of each affected group.</i>	
c)	- low-income households (e.g. those living solely on social benefits, with income below the at-risk-of-poverty threshold or below the subsistence minimum, or belonging to the 25 % of households with the lowest income); - the unemployed, in particular the long-term unemployed, the young unemployed and unemployed persons over 50 years of age; - children (0–17); - young people (18–25 years of age); - the elderly, e.g. persons over 65 years of age or pensioners; - people with disabilities; - marginalised Roma communities; - households with three or more children; - single-parent households with children (incomplete families made up mainly of single mothers with children); - third-country nationals, persons granted asylum and asylum seekers; - other vulnerable groups, such as homeless people and people leaving children's homes or other institutional facilities.	The draft Act has no negative impact on the population's access to resources, rights, goods and services. On the contrary, the measure has an indirect positive impact on public health protection and the social inclusion of vulnerable population groups, which are at increased risk of the negative consequences of using new psychoactive substances. Affected groups and their size: a) Young people (15–24 years of age): The 15–24 age group represents a significant proportion of the population of the Slovak Republic. According to demographic statistics, the 15–19 age group comprises approximately 262 174 people and the 20–24 age group approximately 286 207 people (a total of approximately 548 381 people). Given a total population of around 5.4 million, this is a demographically significant group that is also more likely to experiment with psychoactive substances (as indicated, for example, by other studies of drug trends in this group). Impact: the draft Act improves health protection and awareness among young people, which may reduce the risk of using new psychoactive substances and the associated

		consequences (e.g. health and social consequences). b) People with drug addiction or problematic drug use: estimates based on research and monitoring reports (e.g. EUDA/NMCD) briefly indicate that there may be thousands of people in the population affected by risky drug use (e.g. problematic users of opiates and stimulants). c) Persons at risk of poverty or social exclusion: The draft Act contributes to preventing health problems and promotes social inclusion, thereby mitigating the risk of further deterioration in the situation of persons at risk of poverty or social exclusion. According to data from the Statistical Office of the Slovak Republic, more than 980 000 people (approximately 18 % of the population) were at risk of poverty or social exclusion in 2024, highlighting the need for legislative measures to protect the most vulnerable population groups. The draft Act is primarily aimed at groups at higher risk of the negative effects associated with the use of new psychoactive substances (young people, people with addiction and socially vulnerable persons), and its effect on these groups is therefore more pronounced than on the general population, which is not directly at risk from the use of new psychoactive substances. The draft Act contributes to the protection of public health and the social inclusion of vulnerable groups, primarily by strengthening prevention, supporting treatment and reducing the risks associated with new psychoactive substances.
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4.3 Identify and describe the impact on equal opportunities.		
Identify, describe and quantify the impact on equality between women and men.		
a)	4.3.1 Does the draft comply with the obligation to treat groups or individuals equally regardless of sex, race, ethnicity, religion or belief, disability, age, sexual orientation or other status? Could it lead to indirect discrimination against certain groups of the population? If so, which groups are affected in this way and how?	
b)	Not applicable.	
c)	4.3.2 Can the draft increase inequalities between women and men? Does the draft promote equal opportunities? Does the draft have a different impact on women and men? Describe the impacts.	
d)	Describe the risks of the draft that may lead to widening inequalities:	Not applicable.
e)	Describe the positive impacts of the draft on achieving equality between women and men and equal opportunities for women and men, or any differing impacts on women and men:	Not applicable.
f)	Does the draft have significant impacts on any vulnerable population group? If so, which ones? In what way? Vulnerable population groups include in particular women at risk of multiple discrimination, pregnant women, elderly women, women belonging to marginalised population groups, migrant women, women and girls with disabilities, victims of violence, etc.	Not applicable.
g)	When identifying impacts on equality between women and men, account should be taken of existing differences between women and men that are relevant to the policy concerned. Promoting equality between women and men consists not only in removing restrictions and barriers to full participation in the economic, political and social life of society and in family life, but also in promoting equality between them. In which areas relating to the promotion of equality between women and men does the draft remove barriers and/or promote equality between women and men? Areas relating to the promotion of equality between women and men include, but are not limited to: - promotion of freedom of choice of profession and economic activity; - promotion of equal economic independence; - reconciliation of professional, private and family life; - promotion of equal opportunities for participation in decision-making; - combating domestic violence, violence against women and human trafficking; - promotion of recognition of personal care for a child as equivalent to economic activity and promotion of invisible domestic work as such; - respect for personal preferences when choosing a profession and reconciling work and family life.	Not applicable.

4.4 Identify, describe and quantify the impacts on employment and the labour market.
*In the case of a positive answer, attach a **justification** in accordance with the Methodological Procedure for Social Impact Analysis.*

a)	Does the draft facilitate the creation of new jobs? If so, how? If possible, provide quantification.	
b)	Identify the sectors and industries of the economy and the regions concerned, the groups of employees affected, the types of jobs/employment arrangements involved, etc.	Not applicable.
c)	Will the draft cause loss of jobs? If so, how and which jobs? If possible, provide quantification.	
d)	Identify the sectors and industries of the economy and the regions concerned, the types of jobs/employment arrangements involved, etc. Identify the possible consequences, the groups of employees that will be more affected and the extent of the impact.	Not applicable.
e)	Does the draft affect demand for labour? If so, how?	
f)	Demand for labour depends, on the one hand, on the production of goods and services in the economy and, on the other hand, on the cost of labour.	Not applicable.
g)	Does the draft have an impact on the functioning of the labour market? If so, what impact?	
h)	This concerns macroeconomic impacts, such as labour market participation, long-term unemployment and regional differences in employment rates. Labour supply can be affected by different variables, e.g. wage levels and institutional settings (e.g. reconciliation of work and private life or facilitation of different forms of mobility).	Not applicable.
i)	Does the draft have specific negative consequences for certain occupational groups, groups of employees or self-employed persons? If so, what are they and which groups do they affect?	
j)	The draft may, for example, adversely affect workers in certain occupations by favouring specific activities or technologies.	Not applicable.
k)	Does the draft affect specific age groups of employees? If so, which ones? In what way?	
l)	Identify whether the draft may affect the decisions of employees or employers and whether it may constitute a reason for delayed entry into the labour market or early exit from the labour market by individuals.	Not applicable.