

LEGAL AND TOXICOLOGICAL CONSIDERATIONS IN DRIVING UNDER THE INFLUENCE: A CALL FOR PREDICTABLE AND EVIDENCE-BASED LEGISLATION

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CONTEXT

Following an extended period (2014–2025) marked by a fluctuating and inconsistent doctrinal and judicial approach regarding the legal treatment of driving under the influence of psychoactive substances, particularly in the interpretation and application of the relevant provisions of the Romanian Criminal Code, the High Court of Cassation and Justice (HCCJ) definitively settled the existing jurisprudential divergences in January 2025. The Court held that, for criminal liability to arise, it is necessary to establish both the presence of the psychoactive substance in the biological samples and its inherent potential to impair the offender’s ability to drive: “it must be established both that the psychoactive substance is present in the biological samples, and that said substance has the potential to affect the perpetrator’s driving capacity.”

Merely two days later, a group of senators initiated a legislative proposal to amend the fundamental criminal legislation by introducing a policy of absolute zero tolerance. The proposed amendment seeks to criminalize the mere detection of any psychoactive substance, irrespective of any potentially exonerating circumstances, thereby eliminating the requirement for an individualized assessment of each case, the necessity of demonstrating actual impairment, or the obligation to conduct quantitative toxicological analyses.

In a modern society, public health is a critical priority, and governments implement health policies aimed at protecting the population from major risks. However, these measures can sometimes conflict with individual rights, generating intense debates regarding the limits the state can impose in the name of the common good. On the other hand, individual rights are

safeguarded by constitutions and international treaties. Critics of state intervention argue that the imposition of mandatory health measures can lead to abuse and the unjust restriction of freedoms.

To reconcile these two perspectives, it is essential that policies respect proportionality, transparency, and fundamental rights. The state must justify any restrictive measures and provide alternatives that are as minimally invasive as possible. Additionally, it is important that decisions are based on scientific evidence.

The conflict between health policies and individual rights does not have an absolute solution; rather, it requires a careful balance between protecting public health and respecting personal freedoms. While the state may sometimes need to intervene, such measures must be proportional, justified, and based on social dialogue. Only in this way can we build a healthy yet democratic society.

Road Safety and Psychoactive Substance Use: Finding a Balance

Road safety is an essential priority for any society, and the use of psychoactive substances by drivers represents a major risk for road participants. In this context, many states apply a zero-tolerance policy (further elaborated below, distinguishing between mathematical and biological zero) towards driving under the influence of drugs. However, this approach can conflict with fundamental rights, particularly the protection against abusive incrimination.

I will analyze the benefits and risks of this policy, as well as potential solutions to find a balance between safety and justice.

There are three main models used internationally to manage driving under the influence:

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(1) identification of the state or effects of intoxication; (2) the “*per se*” approach, which involves pre-established laboratory limits (zero tolerance) or legally set threshold values; and (3) a hybrid system, in two stages, which punishes driving beyond certain limits more lightly (e.g., as an administrative offense) and more severely (e.g., as a criminal offense) when identifying the state of intoxication. Furthermore, the presence of prescribed medications used appropriately is not penalized.

1. Model of Identifying the State or Effects of Intoxication

Known as “impairment” in European literature and “effect-based” in trans-Atlantic literature, this model is the subject of the current provisions under the criminal code and reinforced by the Decision of the High Court of Cassation and Justice. It involves proving by criminal investigation bodies that the driver was under the influence of psychoactive substances in terms of “adverse impairment of driving abilities.”

Although this model is used in most of the United States and in 11 European Union member states, it is considered to have low efficiency due to difficulties in training police forces, issues with standardizing motor tests, the subjectivity of on-site personnel, and the diversity of traffic cases and incidents. Nevertheless, like the following two models, this model seeks to limit the possibility of sanctioning drivers when we cannot be certain they were under the influence of psychoactive substances based solely on on-site symptoms, but also from subsequent examinations and analyses.

2. “Per Se” Model with Pre-Established Limits

A significant number of states around the world have transitioned in recent decades to the “*per se*” approach, which involves establishing various limits for substances in the order of nanograms per milliliter of blood (or equivalent in serum or plasma analysis). Identifying psychoactive substances above these limits automatically incriminates the driver (except in cases where a hybrid model, analyzed later in this report, applies), while the presence of substances below these limits automatically presumes that the driver was not under the influence of the psychoactive substances tested for. This approach also includes the “zero tolerance” subcategory, which imposes the use of minimum laboratory limits, as well as the separate legal limits imposed by law. Eight European countries and 16 U.S. states adopt such limits.

2A. Zero Tolerance

Contrary to popular belief, a ‘zero tolerance’

approach does not mean that any particle or substance residue identified through analyses automatically presumes the driver to be under the influence. On the contrary, all countries that declare a zero-tolerance policy use different laboratory limits. Given the extremely high sensitivity of modern laboratory equipment, which can detect the presence of even minute traces of substances (e.g., 0.001 ng/ml – detection limit, with quantification limits around 0.01 ng/ml), Forensic Medicine and/or Toxicology Councils may standardize minimum reporting values based on internal conventions.

We know with certainty that, regardless of the individual characteristics of the driver, the presence of substances in blood below these toxicologically relevant thresholds is incapable of impairing driving abilities, as these are, in essence, merely infinitesimal analytical limits.

Such thresholds strictly avoid the incrimination of illicit substances or medications consumed days or even weeks prior, for which only minimal residues or inactive metabolites may be detectable.

The main issue with this approach, however, is that a significant portion of the academic and scientific communities, alongside a number of states, believe that even these 1-2 ng/ml thresholds place too many individuals—whose physical and/or mental capacities are unaffected by the substances (or traces thereof) in their bodies—at risk of being wrongfully incriminated.

2B. Legally Established Thresholds

Considering the extremely low laboratory levels practiced in countries that implement the so-called “zero tolerance” approach, an increasing number of countries impose, by law, significantly higher legal thresholds for the presence of substances. These decisions are made to avoid the incrimination of drivers who show higher quantities of residues or substances in their blood but are presumed, based on scientific literature, to be at minimal risk of being under the influence. Furthermore, recognizing the need for certain psychoactive substances as psychiatric treatments, countries such as the United Kingdom and Germany allow driving with therapeutic concentrations (considering that such treatments can significantly reduce the risks that drivers—such as those with ADHD—are exposed to while driving).

Additionally, therapeutic limits are established for a wide range of other medications, such as nasal decongestants, flu treatments, sleep aids, anxiety medications, and panic attack treatments.

However, in relation to most “classic” illicit

substances beyond medications, 20 jurisdictions worldwide, including 8 European Union countries (Belgium, Czech Republic, Denmark, France, Ireland, Luxembourg, the Netherlands, and recently, Germany), have introduced, by law, legally established cut-off values (higher than laboratory limits) for most illicit substances.

3. Hybrid Two-Tier Model

Given the variety of policy conventions in different countries regarding legally established thresholds (other than laboratory technical limits), particularly for THC, but also applicable to a wide range of classic substances and especially for managing new psychoactive substances, a significant number of states choose to implement hybrid or two-tier models. These systems combine 1. the identification of signs of intoxication and 2. one of the “*per se*” model variants—zero tolerance (laboratory quantification and reporting limits) and/or legally established limits.

Alongside Norway, which recently transitioned to a hybrid model, 9 other European countries (Slovakia, Latvia, Iceland, Finland, Germany, Belgium, Denmark, France, the Netherlands) use this model in various forms, such as adopting either higher legal limits or lower technical laboratory limits, along with clinical examination, to more accurately determine whether the driver is under the influence or poses a real risk in traffic.

At the same time, different sanctioning mechanisms can be implemented: for example, administrative fines if the substance levels exceed laboratory or legal limits, but clinical examination and contextual interpretation show that the driver would not be considered impaired. On the other hand, if laboratory limits are exceeded along with clinical findings that suggest the driver was impaired, harsher penalties—such as criminal charges—apply. There may also be differences between prescription medications (with relevant therapeutic doses) and illicit substances in terms of sanctions, applying administrative penalties for exceeding the limits of the former along with proof of influence, and criminal penalties for meeting the conditions of the latter.

While this model is the most complex of all, requiring the combination of both previous models, it is considered the most protective and is also recommended by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) for implementation in the case of most psychoactive substances.

CONCLUSION

There is no perfect law! Any of the previous models, when applied rigidly, has gaps and strengths compared to others. For example:

It is impossible to establish an absolute equivalence between a substance concentration value and the degree of impairment (although we can certainly negate the existence of impairment in cases where concentrations fall below a minimum threshold).

Legal thresholds are the result of a conventional choice between clinical effects and the concentration at which a substance’s prevalence/incidence is significant, along with the status of the substance’s regulation, the state’s objectives, and the medical/population context, among other factors.

Laboratory thresholds prevent the wrongful incrimination of drivers in situations where, medically and biologically, it is impossible to generate the abstract risk that the law punishes (the crime of abstract danger ceases once the effect ceases); however, it may still incriminate drivers who do not exhibit effects at these low concentrations.

The current adoption of legislation in this direction cannot ignore the international humanitarian context, trends in prevention and treatment policies, societal pressure (as seen in the public reaction to the provisions of OUG 84/2024), or the reality of increasing consumption despite the existence of the harshest anti-drug legislation in Europe.

Returning to the legislative proposal for incrimination *per se*, based solely on the presence of the substance in the body: Theoretical Arguments in Favor of Zero Tolerance: Advocates publicly for increased road safety; deterrent effect; ease of law enforcement. Counterarguments stem from the risks of abusive incrimination – it can lead to abuses or unfair criminalizations (e.g., detecting traces of substances consumed long ago – some drugs, such as cannabis, can be detected in the body days or even weeks after consumption, even though the person tested is no longer impaired/ lack of a clear correlation between concentration and actual impairment / violation of the presumption of innocence – if a person consumes drugs outside of driving activities and is later tested positive, the punishment could be considered disproportionate – more situations below).

Therefore, it is crucial to have accurate tests, additional evaluations, and flexible legislation that only penalizes drivers who are truly impaired. This is the only way to maintain a balance between citizen protection

and the respect of fundamental rights.

A legislative project in such a complex, socially sensitive, and medically controversial area, with historical and comparative examples that are not unified in terms of clearly and indisputably outlining a direction, must start from the premise of attempting to adequately address the most common potential situations that practice daily presents before the judicial bodies.

Health / Medical Policies aim at the general good but without affecting even a single patient! For example, the risk of therapeutic abandonment can prove, in certain cases, much more serious than the presumed/ hypothetical benefit – often minimal or absent – from the perspective of influencing the patient's ability to drive (patients who follow their treatments may abandon therapy, which restores neuro-cognitive and motor abilities needed for driving, due to fear of legal repercussions generated by the *per se* incrimination).

Fundamental legal principles also include protection from abusive criminalization and punishment, beyond scientific and biological truths, by deviating from the presumption of innocence (in the absence of effect, the presence of a substance in the body is completely harmless – the presence of mercury in the body at low concentrations, for example, is almost detectable in all people in modern society).

The purpose of *per se* incrimination, and the absolutization of the zero-tolerance policy to a mathematical zero for detectable concentrations (ignoring the extraordinary detection capacity of modern devices, with detection and quantification limits of an order of magnitude 10-100 times lower than the smallest concentration with potential effect), has never been effective in the history of other countries (tightening legislation, without the parallel implementation of many other, more complex and multilayered measures, has not led to the discouragement of the phenomenon), but will generate disproportionately large effects. I only mention the risk of incriminating an extraordinarily large number of drivers, who are aprioristically transformed into offenders, whose judicial situation ends – according to the project – with a criminal conviction (I will not detail the socio-economic impact of the increasing penitentiary population, loss of socio-professional impact, and educational costs invested in them, etc.).

In general, the effects occur at nanogram/ml levels – one-billionth of a gram; modern devices in toxicology laboratories can detect thousands of substances with no potential biological effect, reflecting what is called the toxicological “background noise” (resulting from the introduction of substances into the

body in non-voluntary contexts, such as contamination, residues, accidental exposure, or exposure long ago, etc.).

Zero tolerance, applied in this way, contradicts the laws of biology (where the quantity of a substance dictates its effect, not merely its presence – Paracelsus: any substance can be a poison, it depends only on the amount), invoking the unpredictability of individual reactions (Gilbert 1996 – the difference in response between individuals is due to their own reactivity), represents a biased selection of circumstances in which individual reactivity becomes a distinct factor to analyze: this may only have an impact at values above a certain concentration, below which it has not been shown to have any effect – the biological threshold limit (the duration of effect is much shorter than its persistence in blood).

This form of *per se* incrimination provides no concrete benchmark for the judiciary to individualize punishment, analyze or prove circumstantial elements, or any potentially relevant factors that are impossible to address or suggest under the current proposal. It is not possible to conduct a judicial inquiry by trivializing the toxicokinetics and pharmacodynamics of each substance, aspects that are dismissed and entirely obscured by the provisions of the current draft.

Per se incrimination deviates from the fundamental principles of biology, pharmacology, and toxicology. Punishment *per se*, based on qualitative analysis, becomes a true witch hunt by aprioristically translating harmless findings (the possible detection of very low values, ignoring that these are always asymptomatic) into indisputable potential harm, using the narrative that it is impossible to establish a correlation between a certain concentration of a substance in the body and the effect exerted, ignoring the fact that the potential effect – regardless of reactivity, individual, or substance – has the potential to materialize only and only if there is a concentration above a minimum threshold.

A legislative project must take into account the appropriate resolution of any of the concrete situations that may occur daily:

1. Traffic testing by police currently only applies to 8 types of substances – which risks, if not already present, drivers attempting to evade detection by switching to other types of substances not detectable by screening devices; therefore, a complex evaluation of such drivers beyond testing limits becomes absolutely necessary – sobriety tests and/or qualitative tests.

2. Consumption of illegal substances – to

determine the time of consumption, quantity, effects, etc.

3. Patients undergoing treatment who follow the rules and prescription – including the avoidance period for driving after the last administration – but the detection time is much longer than the duration of clinical effects; without scientific analysis, including complex analyses of the primary substance, metabolites, and their reports, it is impossible to assess whether the patient followed the treatment or was within the clinical effect period, etc.

4. Patients who follow prescriptions from their home countries – these make drivers (more) capable (e.g., hypnotics given to long-distance drivers who are given a prescription in their home countries stating that they can drive safely after 24 hours).

5. Over-the-counter medications – simple ones, with detection far beyond the time of administration, even more than 48 hours after the effects of the substance have ceased.

6. Presence of psychoactive substances originating from food.

7. Consumption long before the moment of interest – well beyond the duration of manifestation – which can leave residues in blood for 1-8 weeks, depending on anthropometric data, frequency of consumption, different elimination circumstances, etc.

8. Abuse of prescription drugs – abuse of one's own prescription.

9. Need to establish the legal/illegal origin of the substance – these may be identical for the laboratory device, and only a complex analysis of the sample searching for the presence of congeners/substance additives, impurities, etc., will allow proper identification.

10. Consumption of substances not identifiable by current technology and medical knowledge – new psychoactive substances.

11. Identification of inactive metabolites as an expression of concentration in the brain – sometimes the only measure for determining the potential of manifest clinical symptoms (given the instability of the active substance).

12. Metabolites must be summed with the parent substance to truly describe the potential for influence – excluding complex toxicological analysis will result in an incomplete representation of the facts.

13. An analysis based solely on the presence of psychoactive substances in the blood will not allow an analysis of withdrawal status or post-consumption exhaustion (compulsive binge consumption over a short

time period) – only complex blood/urine tests can offer retrospective assessments.

14. Criteria for non-accountability *per se* – habitual, accidental exposure – only complex blood/urine tests can offer retrospective assessments.

15. Co-ingestion of multiple substances – accountability *per se* for the accumulation of substances, but not applicable if all substances reflect very old consumption, or, conversely, incriminate by association.

Judges do not have the ability, based solely on the case file evidence that does not include a complete toxicological evaluation and the interpretation of its significance, to prove the existence of the offense and to establish accountability—responsibility—guilt.

The law must fulfill the requirement of the concept of predictability (predictability) — the requirements of clarity, precision, and predictability — as the European Court of Human Rights emphasized, “a norm can only be considered as ‘law’ if it is stated with sufficient precision to allow the individual to regulate their conduct (even medical personnel cannot anticipate/foresee the duration of residue/elimination of a substance from the body!!)” — ambiguity of uncertain legal situations.

The duration of residue in the body/elimination goes well beyond the knowledge of an average educated person, and even many doctors. The half-life times and plasma clearance do not belong to the average medical knowledge level, and the detection levels of laboratory equipment place detection after many more half-life cycles than what seems predictable — for example, for codeine, from a small therapeutic concentration of 50 ng/ml, with a half-life time of 4-6 hours and a detection threshold of 0.02 ng/ml (quantification limit — therefore the certain detection limit), detection of the active substance can extend for 36-48 hours after the cessation of the clinical effect.

The ideal legislation is the one that involves incrimination based on a quantitative toxicological analysis with values exceeding toxicological relevance limits and the evaluation of the impact on the ability to drive.

This approach also provides the imperative evidence necessary for the individualization of punishment/circumstances, which is needed by the judiciary (also regarding the broad range of potential applicable punishments), as well as the law's predictability through the possibility of implementing educational/informational measures for the driver population, by translating to the clinical effect intervals (which correlate with concentrations above toxicological

relevance levels) and to medication leaflets.

The limits of toxicological relevance belong to evidence-based medicine, based on the results of thousands of studies and meta-analyses, drug market studies, and reference toxicological bibliographies, not arbitrarily or randomly chosen, but in accordance with and analogy to toxicological knowledge. Without appealing to toxicological relevance limits, incrimination occurs even in cases of detecting residues, accidental contamination, environmental exposure, old consumption from weeks/days ago, food consumption, etc. Moreover, it completely amputates the driver's ability to regulate their conduct (even medical personnel cannot anticipate/foresee the duration of residue/elimination of a substance from the body) — it does not ensure in any way the concept of predictability of the law (the duration of residue in the body/elimination exceeds the knowledge level of an average educated person and even of many doctors). The half-life times and plasma clearance do not belong to the average medical knowledge level, and the detection level of laboratory equipment places detection after many more half-life cycles than seems predictable.

Laboratory limits prevent close-incriminating situations (where, medically and biologically, generating the abstract risk that the law penalizes is impossible - the crime of abstract danger ceases once the effect ceases); but it will incriminate drivers who show no effects at these low concentrations.

A balanced hybrid system would allow for appropriate evaluation for the use of medicinal substances or those in combination, at the lower threshold of toxicological relevance, following a forensic medical evaluation. This is not based solely on clinical examination at the time of the offense — it integrates many other criminalistic, testimonial, medical history, investigation, toxicological criteria and is always reported to the reference literature used worldwide.

Thus, as a professional with a humanitarian background,

- I appreciate that the *per se* incrimination of the presence of any quantity (even traces) of psychoactive substance in the blood is abusive.

- I appreciate that the *per se* incrimination based solely on the detection of psychoactive substances is limiting — with respect to the possibility of individualizing punishment and identifying exonerating situations in the absence of the instrument for case-by-case evaluation, which is only possible through comprehensive toxicological testing and the complex interpretation of all pharmacological-toxicological and

clinical factors involved.

- I appreciate that legislation must lack unpredictability, without referring to an implicit need for information, which is presumed to be known/cognizable, exceeding the knowledge and education level of an average person.

I appreciate that appealing to toxicological relevance thresholds (minimum effect thresholds, lower limit of effect, minimum effective concentration, etc.), which are well-known in the reference literature, with absolute sustainability in evidence-based medicine, belonging exclusively to biology and not to the legislator, is the most balanced form of predictability that this type of legislation can take (the information can be associated with the contents of drug leaflets or common information about the duration of clinical effects).

Pairing these thresholds with the possibility of individual analysis, for those who exceed these values in toxicological testing, through technical-scientific/forensic medical expertise, will provide the judge with the scientific tool for individualization and circumstantiation, and for creating the argumentation to support accountability and guilt.

References

1. CRIMINAL CODE of July 17, 2009 (LAW No. 286/2009) ISSUED BY: The Parliament of Romania Published in the Official Gazette No. 510 of July 24, 2009. <https://legislatie.just.ro/public/detaliidocument/109855>
2. HIGH COURT OF CASSATION AND JUSTICE – Panel for the Clarification of Points of Law Decision No. 25/2025 – Case No. 640/1/2024 Delivered in public session on January 27, 2025 Published in the Official Gazette, Part I No. 70 of January 28, 2025 <https://www.iccj.ro/2025/01/29/decizia-nr-25-din-27-ianuarie-2025-2/>
3. European Monitoring Centre for Drugs and Drug Addiction, Driving Under the Influence of Drugs, Alcohol and Medicines in Europe – Findings from the DRUID Project, 2012. https://www.euda.europa.eu/publications/thematic-papers/druid_en
4. Superior Council of Forensic Medicine, Position Paper, 2024 <https://csml.ro/punctul-de-vedere-al-csml-privind-evaluarea-sofatului-sub-influenta-substantelor-psihoactive/>
5. European Union Agency for Drugs, Legal Approaches to Drugs and Driving, 2022. https://www.euda.europa.eu/publications/topic-overviews/legal-approaches-to-drugs-and-driving/html_en
6. Favretto D, Visentin S, Stocchero G, Vogliardi S, Sneghi R, Montisci M. Driving under the influence of drugs: Prevalence in road traffic accidents in Italy and considerations on *per se* limits legislation. *Traffic Inj Prev.* 2018;19(8):786-793.
7. Zaha V, Gorun G. Driving Under the Influence of Psychoactive Substances in Romania – Analysis and Recommendations on Alignment with International Control Models. <https://analiza-influenta.declie.ro/>
8. Romanian Association of Psychiatry and Psychotherapy (ARPP), Position Paper – The Drug Issue, August 2024. <https://drive.google.com/file/d/1C7KYv3q2rKA1QtmiLCNaesGJIrLq4n3C/view?usp=sharing>