

**Release's Response to the Department for Transport Consultation –
'Regulations to specify the drugs and corresponding limits for the new
offence of driving with a specified controlled drug in the body above the
specified limit'**

Release is the national centre of expertise on drugs and drugs law – providing free and confidential specialist advice to the public and professionals. Release also campaigns for changes to UK drug policy to bring about a fairer and more compassionate legal framework to manage drug use in our society.

Release welcomes the opportunity to respond to this Consultation process. Whilst we agree that ensuring road safety is important, from the proposals made in the consultation document¹ it would appear that promotion of the Government's overall drug strategy is taking priority over road safety issues. This is a continuation of the use of the criminal law to deter drug use despite evidence that this approach does not in fact work.² It is also particularly concerning to note that the Department's preferred option is contrary to the advice and evidence provided by their own expert panel in their report 'Driving Under the Influence of Drugs'.³

Changing drug-driving legislation from an impairment model to a 'specified-limit' model in line with drink-driving will create a legal shortcut, whereby the police need only prove evidential specimens, and not further proof of impaired driving. This could lead to the penalisation of drivers who are not impaired and pose no risk to themselves or others on the road. Release envisages a number of legal and technical issues that may arise in relation to proceedings brought against an individual in relation to the new offence under Section 5A of the Road Traffic Act 1988.

Legal issues

Prescription medication

The offence does not target standard medication but controlled drugs. Some controlled drugs have medicinal purposes and are widely prescribed, for example pain analgesics. There is no qualified evidence that those who take prescribed controlled drugs are necessarily impaired from driving, and medication may improve driving facilities impaired by the condition itself.

¹ Department for Transport - 'Regulations to specify the drugs and corresponding limits for the new offence of driving with a specified controlled drug in the body above the specified limit – A Consultation Document', July 2013

² Rosmarin, A & Eastwood, N, 2012, 'A Quiet Revolution – Drug Decriminalisation Policies in Practice Across the Globe', Release, United Kingdom

³ <https://www.gov.uk/government/publications/driving-under-the-influence-of-drugs--2>

Whilst there will be a specific medical defence available when a person takes the drugs in accordance with medical advice, drug testing equipment will not be able to distinguish between legally prescribed and illegal substances. Additionally, the simple fact that a person has taken unprescribed medication is not evidence in itself that they are more likely to be under the influence of a substance than someone who had legally been prescribed exactly the same drug.

The heavy onus on the prescribed-drug driver to defend himself may rely on subjective evidence of his medicine taking behaviour including accordance with small-print medical instructions. Providing such a defence as the only way to challenge a positive test may cause unnecessary disruption, invasive testing and bureaucratic burden on those who are prescribed controlled drugs and who pose no risk to other road users. The likelihood of being granted legal aid as a defendant in these sort of proceedings is minimal if viewed in the same way as drink driving cases which are not publicly funded save for exceptional circumstances. Indeed the Department “assumes that 4% of drug drive cases are eligible for legal aid”⁴ leaving the majority of defendants either representing themselves or having to pay for a lawyer on a private basis. There is a fallacy to the assertion that savings will be achieved in this way, as in reality there will be an increase in people representing themselves which has a knock on effect in terms of delays and extended proceedings.

Furthermore, studies that focus on drug-driving include in that definition, illegal substances; psychotropic medications and some over the counter medications (for example antihistamines, cough and cold remedies)⁵. However, the proposals only apply to controlled substances as defined in section 2 of the Misuse of Drugs Act 1971.

Legal limit to drive

If a specified limit approach is to be adopted difficulties in estimating consumption, as with alcohol, remain. Whilst there maybe little sympathy for the recreational drug-driver unable to estimate purity of street drugs prior to driving, those who are prescribed controlled substances will face difficulties in knowing whether they are indeed ‘above the limit’ given the complex variation in pharmacology between each substance and indeed the physiology of each individual.

Net widening and disproportionality

There is potential for net widening in terms of drivers being randomly stopped to undertake roadside tests for the presence of drugs. Although the proposals state that “an officer may only administer a preliminary drug test if the officer suspects that a driver has a drug in his body or is under the influence of some drug, if the driver has committed a moving traffic offence, or of the driver has been involved in a road traffic accident”⁶, there is potential for abuse of power in the

⁴ Department for Transport - ‘Regulations to specify the drugs and corresponding limits for the new offence of driving with a specified controlled drug in the body above the specified limit – A Consultation Document’, July 2013, at Annex D, Table 7

⁵ Transport Research Centre, 2010, ‘Drugs and Driving: Detection and Deterrence’, Organisation for Economic Co-Operation and Development (<http://www.internationaltransportforum.org/jtrc/safety/drugs/DrugsSummary.pdf>)

⁶ Department for Transport - ‘Regulations to specify the drugs and corresponding limits for the new offence of driving with a specified controlled drug in the body above the specified limit – A Consultation Document’, July 2013, at Para. 12.3

reasons given for suspecting that someone is under the influence of a drug. This can be compared to the use of reasonable suspicion stop and searches in England and Wales under section 1 of the Police and Criminal Evidence Act 1984, where the arrest rate is only 9%.⁷ This falls to just 7% for drugs offences.⁸ Once the test is administered it will then be for the individual to challenge the legality of that at a later stage, again without recourse to public funding.

In 2009/10 police carried out 223,423 breathalyser tests for alcohol – only 3% were positive, failed or refused⁹, this level of success is deeply worrying considering the fact that someone is being detained by the police to carry out this test. Interestingly, in the same year only 489 field impairment tests were carried out but with an 18% success rate. There is a significant risk that this new offence will cause hundreds of thousands of citizens to be subjected to roadside drug tests with little positive impact.

A further concern is that young, black men will be targeted by the police in relation to this new power. In relation to the policing of drug offences this group is 6.3 times more likely¹⁰ to be stopped and searched for a drugs offence than their white counterparts despite the fact that drug use is lower amongst the black community. This statistic demonstrates the inaccuracy of this power which is clearly being used speculatively in the hope of discovering something that will permit further detention. There is no reason to suppose that the powers to drug test drivers would not be used in the same way as the current stop and search provisions. The introduction of this offence in the way proposed could be used as a new investigatory power to stop and search individuals.

Criminalising consumption

There is currently no offence under the Misuse of Drugs Act 1971 of having a controlled drug in your body. Section 5A in effect creates a strict liability offence of having a specific-limit (potentially set a zero) of a controlled substance in your body when driving or being in control of a motor-vehicle.

In this context, a focus on controlled drugs rather than any substance which may affect impairment is therefore not without note. This highlights the difficulties of scheduling drugs in Britain, including the current problems faced by Government in relation to controlling novel psychoactive substances known often as ‘legal highs.’

Lack of Evidence

In the case of drink-driving, decades of research have clearly proven the link between alcohol consumption and impaired driving, and therefore a specified-limit short-cut to prove impairment case-by-case is evidenced. In comparison, there is a lack of data on drug-driving. There are logistical

⁷ <http://www.homeoffice.gov.uk/publications/science-research-statistics/research-statistics/police-research/police-powers-procedures-201011/stops-searches-1011>

⁸ Eastwood, N, Shiner, M & Bear, D, 2013, ‘The Numbers in Black and White: Ethnic Disparities in the Policing and Prosecution of Drug Offences in England and Wales, Release, United Kingdom

⁹ <http://www.concateno.com/about-us/news/16030/>

¹⁰ Eastwood, N, Shiner, M & Bear, D, 2013, ‘The Numbers in Black and White: Ethnic Disparities in the Policing and Prosecution of Drug Offences in England and Wales, Release, United Kingdom

and methodological difficulties in collating any reliable and accurate data of the use of drugs in drivers and the exact scale of the problem in Britain remains undetermined. Additionally, the Government have declined to participate in international research into drug-driving and roadside devices.¹¹

Impairment offence versus specified limits offence

Throughout the European Union there are substantial differences in drug driving provisions, testing procedures, and sample analysis. Legislation falls broadly into two groups, an impairment model (as is the current system in the UK) or a specified-limits model. Specified limits can be set at zero resulting in a 'zero tolerance' policy. The majority of countries now follow a specified-limit model for drink driving, however, limits are not standardised and there is variation even across Europe, for example, Poland (20mg per 100ml blood), Switzerland (50mg) and UK (80mg.)

Great degrees of varying levels of specified limits and evidential standards for both drugs and alcohol highlight the lack of science or evidence based foundation to legislation. Furthermore, according to a report of the Organisation for Economic Co-Operation and Development ('OECD') in 2010, 'the impact of controls on drug-driving has yet to be demonstrated.' The same report argues that adapting specified limits laws to the drug-driving situation has proven difficult: 'whereas research over the past fifty years has clearly established the link between alcohol impairment and crash risk, similar evidence is not available for every potentially impairing substance'.

The UK is not the only country with an impairment based model, other major developed countries including Canada, United States, and New Zealand all follow the same approach. Many argue that one reason for this is the weaknesses associated with the current screening devices. Unsurprisingly, since the introduction of specified limits offences in Australia there has been a significant decline in prosecutions under the old impairment offence.

Technical issues

Individual Variables Involved in Drug Testing

Pharmacokinetics, defined as 'what the body does to the drug', is essentially metabolic processes and breakdown of drugs in the body. These metabolic products are the substances tested for. As can be expected, there are a great number of factors involved that lead to variations from person to person, hence the complexity of forensic drug testing. Factors that influence testing can be summarised as follows, and are applicable to every individual:

- **Metabolism of individual** - Generally speaking metabolic processes/reactions break down everything that enters the body. This can occur at a faster or slower rate depending age, body mass, exercise, genetic make-up, and even gender.

¹¹ The Rosita Projects; The ERMSA project DRUID (Driving Under the Influence of Drugs, Alcohol and Medicines); Transport Research Centre, 'Drugs and Driving: Detection and Deterrence', Organisation for Economic Co-Operation and Development

- **Type of drug** - Some drugs are broken down faster by the body, whilst some remain in the system for longer.
- **Purity of drug** - Generally speaking, the more pure a drug is the more detectable in the system it is. This is mainly because less pure drugs contain higher levels of cutting agents and not the drug itself.
- **Frequency/pattern of use** - the more a drug is taken, either in frequency or actual consumption; the more likely it is to be detected. This can be related to the section below on specific variables: tolerance.
- **Diet** - There is evidence to suggest certain foods can affect detectability of drugs, or alter metabolism which has its own effects (see above).

Specific Variables:

False Positives and Passive Consumption

Another issue that arises through the Helpline at Release and our Expert Witness work is that of unintended positives in forensic testing, which are not caused by technical issues. Most cases we deal with are in relation to urine and hair testing, but the principle is also relevant for oral fluid testing.

A positive reading can also be produced in passive consumption. We have had a number of cases where passive consumption and ingestion of substances similar to illicit drugs (such as poppy seeds showing up as opiates) led to a positive reading. In terms of passive consumption, leading Toxicologists Baselt and Cravey¹² state that passive inhalation of cannabis smoke has resulted in a plasma THC level of 1-7µg/L. This potentially means that an individual who has been exposed to passive cannabis smoke, could potentially be 3 times over the cut off level of 2µg/L for THC. Release is again concerned that not only will this lead to unnecessary disruption and invasive testing but also a bureaucratic burden on those who have not intentionally consumed a drug, whether licit or illicit.

The issue of passive consumption or environmental contamination, particularly with cannabis, is from our perspective of significant relevance to the proposed legislative changes. While much of the existing evidence suggests that the situational exposure to cannabis smoke that triggers a drug positive requires a setting with little ventilation, a very condensed space and a lot of smoke, the tightening (lowering) of limits increases the risk of passive consumption. It is a reality that congregating at clubs and parties where cannabis proliferates affects many people in their social lives, simply, as was said at an employment tribunal that Release attended last year, 'to walk out and leave' is not a culturally congruent response.

¹² Baselt RC & Cravey RH (1995). Disposition of Toxic Drugs and Chemicals in Man. Fourth Edition, Chemical Toxicology Institute.

Tolerance

Tolerance is also relevant to certain drugs and with the issue of impairment.¹³ Drugs such as opiates, benzodiazepines, and cannabis (others including alcohol are also in this list) are more prone to producing tolerant effects than other drugs. This means that, people who take these drugs frequently, over a long period of time, no longer have the same effects, and would probably not be considered 'impaired'. Release believes this would particularly impact on people who are on prescription medication, including pain killing medication such as codeine or anxiolytics such as Diazepam (Valium), and opiate substitution medication such as methadone. Those who have a high tolerance to a particular drug, and have a high pharmaceutical/forensic level of a drug in their system but are not in any way mentally or physically impaired to drive will be singled out. We believe the proposed changes would not be able to tackle this problem and that the current system also prevents this potentially damaging situation from occurring.

Sativex, Prescribed Medication and Internet Medication

We are also concerned that while the 'Sativex' issue is addressed in the consultation document, a 'safe level' (non-impaired) of THC/CBD cannot be estimated. To suggest that it is sufficient to observe the advice of a clinician or pharmacist, partly misses the huge range of tolerance variations seen, for example in the section above (range of drug types). Our Head of Drugs Services works in a General Practice setting where diazepam is prescribed in ranges from 2mg-60 mgs per day. The bearing of population-variable doses on the ability of the individual to drive is extremely complex, and while the packaging of this medication may advise against driving (or operating heavy machinery), it would be our experience that many doctors allocating 10 minute slots to patients with a range of serious psychological problems, rarely have the opportunity to discuss driving. Yet the guidance implies that this would be an acceptable defence. Similarly, just in terms of road safety, a person buying valium on-line and self-medicating with 15 mgs per day is just as likely to be, without further consideration of the variables, as much as a potential threat as a person prescribed 15 mgs per day. The opioid analgesic family poses another dilemma, but where patients are habituated, it is almost a certainty that a therapeutic dose (which again covers a massive range) would be preferable to any abstinence until a level homeostatic situation had been achieved.

Saliva/Oral Fluid as a Preferred Specimen on the Roadside

It is well-recognised that blood is considered to offer a better indication of acute impairment. However, it has a great disadvantage in that it is an invasive and too complicated to use on the roadside.¹⁴ Other specimens such as sweat are also not favoured as testing sweat may identify the person as a user but would not accurately be able to detect recent or actual drug use.¹⁵ Release

¹³ Drummer OH (2006). Drug Testing in Oral Fluid. *Clinical Biochemistry Review* 27:147-159 Review of developments (over last 10 years) on application of testing for drugs in oral fluid.

¹⁴ Drummer OH (2006). Drug Testing in Oral Fluid. *Clinical Biochemistry Review* 27:147-159 Review of developments (over last 10 years) on application of testing for drugs in oral fluid.

¹⁵ Skopp G & Potsch (1999). Perspiration versus saliva – basic aspects concerning their use in roadside drug testing. *International Journal of Legal Medicine* 112: 213-221.

understands that saliva is the primary specimen to be analysed on the roadside under these provisions however it is not without its problems.

As far as drug testing goes, saliva and oral fluid both refer to fluid found in the mouth. Technically saliva is the secreted liquid from the salivary glands and oral fluid is composed of saliva and other components found in the mouth. Although oral fluid should not be seen as a substitute for other specimens it has an advantage in that it can be attained non-invasively.¹⁶ Salivary concentration is greatly affected by various factors, including pH levels (how acidic or basic it is) of the saliva and chemical properties of the drug itself. Acidic drugs (such as diazepam) favour blood, so concentrations in oral fluid are less, whereas basic drugs (such as opiates and cocaine) have higher oral fluid concentrations than blood. Oral fluid predominantly contains the parent drug and until now, no suitable confirmatory tests have been commercially available.¹⁷ Furthermore, the pH of oral fluid and therefore concentration of the drug is altered by agents such as citric acid sweets, chewing gum, or other agents. These products have been shown to lower concentration of codeine by 2 to 6 fold; methamphetamine 2 to 4 fold; and around 5 fold for cocaine.¹⁸ We accept this could be due to the lack of good quality technology (discussed further in the paper), but as of yet, saliva/oral fluid is still not a specimen that best reveals drug levels in the system.

Oral Fluid Testing Devices

There are a number of studies that have tested devices for use on the roadside in various countries and/or States; each comes to differing conclusions regarding the effectiveness of the specific devices and so highlighting the complexities involved in using this equipment.

The main terminology used in these studies refers to:

Sensitivity: the percentage figure used to outline the performance of the testing kit and the relative detectability of the kit or device. This is calculated by comparing positive readings of the device on the roadside to a suitable laboratory equivalent.

Specificity: a percentage figure of negative results using the kit or device compared to the total number of negative specimen in the laboratory.

The comparison method in both cases is usually a confirmatory test in the laboratory on either blood or urine specimen.

- **EU: ROSITA I STUDY 2001**

The Rosita 1 Study was one of the first major reviews of drug driving with emphasis on the equipment used. The Study evaluated the effectiveness of oral fluid drug detection technologies for

¹⁶Drummer OH (2006). Drug Testing in Oral Fluid. Clinical Biochemistry Review 27:147-159 Review of developments (over last 10 years) on application of testing for drugs in oral fluid.

¹⁷ Samyn N, Verstraete A, van Haeren & Kintz P (1999). Analysis of drugs of abuse in saliva. Forensic Science Review 11: 1-19.

¹⁸ Drummer OH (2006). Drug Testing in Oral Fluid. Clinical Biochemistry Review 27:147-159 Review of developments (over last 10 years) on application of testing for drugs in oral fluid.

potential use in law enforcement¹⁹. The main device used across the study was the Drugwipe® device. Results from roadside sample tests were compared to lab-based results.

In terms of sensitivities for amphetamine, cocaine, opiates and cannabinoids the oral device used fell below 50% (range of 7.7-42.9%). However, in relation to specificities for the same drugs the device operated more effectively with results around 97-99%. This means the device was unable to accurately detect drugs in general, but that when it did it was able to identify what that drug was. Therefore, 'Drugwipe® failed to meet the criteria for acceptable device performance, required performance sensitivities **and** specificities 90% or over.'²⁰

- **ROSITA II (2006): EU and USA**

The sensitivities and specificities for all 9 devices tested in this second study ranged as follows:

- Amphetamine and methamphetamine: sensitivity 40-83%, specificity 80-100%
- Benzodiazepine: sensitivity 33-69%, specificity 85-94%
- Cannabis: sensitivity 0-74%, specificity 70-100% (this clearly shows the problems in identifying cannabis though oral detection)
- Cocaine: sensitivity 0-97%, specificity 91-100%
- Opiates: sensitivity 51-100%, specificity 86-100%

The recommended minimum requirement as defined in Rosita 1 is 90% for sensitivity and 95% for specificity. In relation to amphetamines, benzodiazepines and cannabis none of the devices met minimum standards.

No device was considered to be reliable enough to recommend for use on the roadside to screen drivers.

Summary of Device Efficacy

Table 1 below summarises the devices that were tested in the studies cited above. Release cannot guarantee which of these devices will be tested and/or used in the UK and clearly new devices are produced regularly in this field. However, it shows that no one device is suitable for use for all drugs and in all conditions. This also demonstrates the importance of evaluating the effectiveness of each device, the manner the sample is taken, the method that results are reported, whilst taking into consideration the accuracy, efficiency and practicability of deploying these devices on the roadside. The efficacy of the device can also be affected by weather conditions and limited training of law enforcement to use the equipment.

¹⁹ ROSITA I Roadside Testing Assessment (2001). Alain Verstraete, Ghent University. EU Project

²⁰ Crouch D, Walsh JM, Cangianelli L & Quintela O (2008). Laboratory Evaluation and Field Application of Roadside Oral Fluid Collectors and Drug Testing Devices. Therapeutic Drug Monitoring 30: 188-195

Testing Device	Technique and Practicability	Drugs accurate for	Drugs not accurate for	Disadvantages	Tested in
DrugWipe® Securetec	quick wiping of the tongue collecting saliva	Benzodiazepines Amphetamines	Cannabis	Readout and weather problems	Belgium, Finland, Norway, Utah, Washington
Draeger Drug Test®/Orasure Uplink (Withdrawn from market after study)	Easy sample collection.	N/A	Cannabis Amphetamines Cocaine	Machine needed to read results, not portable. Complicated to use	Belgium, Germany, Norway, Spain, US, Norway
Oralstat™	Sponges on sticks	N/A	Cannabis	Time consuming, difficult to collect samples	Germany
Oratect	Small and portable	N/A	Cannabis Cocaine	Too many invalid results Difficult to collect samples, Time consuming	Germany, Florida
RapiScan (Cozart)	Direct procedure	N/A	Cannabis Amphetamines	Difficult to use	Wisconsin
Oraline (Sun Biomedical)	Simple to use	N/A	Cannabis Cocaine	Large sample needed, time consuming. Not suitable for use	Norway
Oralab (Varian)	Simple. Automatically splits specimen	Cannabis	Amphetamines	High rate of invalid tests. Weather problems	Spain, Wisconsin
SalivaScreen (Ultimed)	Pipette style method	N/A	Cannabis	More invalid than valid tests. Smearing. Not enough saliva	Washington

Table1: results of device testing studies, ROSITA II²¹ and DRUID²²

NB: Where N/A is shown under the section 'Drugs accurate for' this denotes that the device did not reach the minimum criteria for both sensitivity and specificity.

²¹ ROSITA 2 Project. Roadside Testing Assessment (2006). Alain Verstraete & Elke Raes, Ghent University. EU Project

²² DRUID: Driving under the Influence of Drugs, Alcohol and Medicines. Analytical evaluation of oral fluid screening devices and preceding selection procedures (2010). Integrated project of Belgium, Finland, Denmark, and The Netherlands.

Disadvantages/Limitations of Roadside Testing

1. *Variable results due to differences in the collection protocol*

Some devices consist of a pad attached to a stick which is placed into the mouth (e.g. Intercept™) where the saliva is absorbed and then transported to the laboratory. The problem with this is that it is not known exactly how much oral fluid is actually collected, so there is a potential for erroneous results, most likely false negatives based on insufficient sample volume. Cut-off concentrations based on such a device are not relevant or applicable to other types of collectors (as highlighted in 'specified limits section').

2. *Adequate specimen volume*

With possible low levels of specimen available due to the nature of oral fluid, problems can arise when the issue of re-testing (in the event of test failure) and splitting samples (when a laboratory sample is also required for confirmation).

3. *Oral Fluid is not the most reliable specimen*

Concentrations in oral fluid are much lower than other specimens such as urine. Also, concentrations are affected by pH and can be altered by synthetic agents that have been shown to alter drug concentrations (see section on saliva as preferred specimen). However, oral fluid seems to be better than sweat to be used on the roadside.

4. *Cannabis and Benzodiazepines: slow metabolisers*

Oral fluid is not an accurate specimen for cannabis and benzodiazepine metabolites. They are very slowly metabolised out of the body. This must be considered by device testers.

5. *Recovery of drugs from collectors varies greatly*

This refers mainly to the differences of sample collection of each device for specific drugs. The following examples of each device can be given for this point:

- a. Salivette has poor recovery for THC but good for codeine
- b. Cozart has good delivery for THC and methamphetamine
- c. Quantisal has contradictory evidence, in some studies it showed good recovery for THC but another study found it had lower recoveries for THC²³

6. *Limited to few drugs*

If devices only test for very few drugs, such is the preferred method in Australia, then how will impairment and recent drug use be detected for other drugs? What about the issue of Novel Psychoactive Substances? There are a very limited number of tests that can detect these drugs, even in laboratory conditions.

²³ Samyn N, Verstraete A, van Haeren & Kintz P (1999). Analysis of drugs of abuse in saliva. Forensic Science Review 11: 1-19

7. Chosen minimum adequate % for specificity and sensitivity when testing these devices

Most studies have shown that there needs to be at least 90% accuracy for each of these factors. Also, specificity must always be analysed by laboratory testing versus field testing. Release emphasises that the results and the process should be transparent.

8. Minimum detectable concentration

If specified limits will be implemented, where would the evidence base for this derive from? Will SAMHSA, the Australian government, or US States be referred to? As these all have differing concentrations, Release finds this a problematic issue.

9. Unintended positives

At Release, we have been involved in a few cases that relate to false positives from drug testing that have arisen from factors other than consumption of illicit drugs.

10. Environmental issues

One of the biggest problems that the studies highlighted was the issue of weather conditions. Evidence has shown that weather can impact on the results, or law enforcement officials being unable to conduct tests. This was particularly relevant to countries with colder climates such as Norway where it is often snowing or temperatures are found below zero.

11. Technical problems related to the use of devices

Most studies have shown that law enforcement officials conducting the tests, found certain devices too complicated, too time consuming or too impractical to use on the roadside.

Conclusion

It is the view of this organisation that the exercise is flawed for the reasons outlined in this response. We consider that the apparatus to the best of our knowledge is currently not available. The cost of implementing these proposals, through the science, the training, the transporting and maintenance of the equipment to a satisfactory level will be prohibitive.