NEW ZEALAND POLICE
Ngā Pirihimana o Aotearoa

NATIONAL ROAD POLICING CENTRE

To: Superintendent Steve Greally, Director: National Road Policing Centre

From: Impaired Driving Programme, National Road Policing Centre

Oral Fluid Testing – Outcomes of Procurement

Date: 31 October 2022

Executive Summary

1. The Land Transport (Drug Driving) Amendment Act 2022 (the Act) introduces the use of a random roadside Oral Fluid Test (OFT) regime to detect and deter drug driving as part of a significantly enhanced impaired driving programme. The regime sets out that two consecutive positive roadside tests for the same qualifying drug establishes an infringement offence.

2. Commercially available OFT devices are designed as screening tests that lack accuracy resulting in false positive and false negative results. The basis of the device technology is such that the individual channels are cross-reactive which lacks the specificity to know for which qualifying drug a positive result has been returned.

3. If random roadside OFT testing is unable to be rolled out as envisaged by the Act and the underlying policy outcomes it seeks to achieve, there is a risk that the policy intent is undermined, and public trust and confidence in Police to deliver road safety outcomes is impacted.

4. It is recommended that Police raise these concerns with the Ministry of Transport and Waka Kotahi to review the options identified. Working collaboratively with our agency partners to further explore and develop joint advice on potential responses that support the road safety outcomes the introduction of OFTs is intended to deliver.

Recommendations

It is recommended that Superintendent Steve Greally;

:a)	**Note** the contents of this memorandum.	Noted
b)	**Note** the findings from the procurement process are consistent with the concerns raised by the Independent Expert Panel and in line with the advice previously provided during the drafting process	Noted
c)	**Approve** the sharing this report with NZP governance bodies with a view to engaging with agency partners and sharing this report with Minister of Police.	Approve / Not Approve

_____

Superintendent Steve Greally

Director: National Road Policing Centre

Date: 1/11/2022

Land Transport (Drug Driving) Amendment Act 2022: Oral Fluid Testing Device Procurement Outcome

Purpose

1. Having conducted a procurement process to source an Oral Fluid Testing (OFT) device, based on the currently available technology, New Zealand Police (NZP) has not been able to identify a device that meets the policy intent and requirements of the Land Transport (Drug Driving) Amendment Act 2022 (the Act).

2. This memorandum is provided to the Impaired Driving Governance Board (IDGB) with a summary of the outcome of the procurement process that establishes this statement based upon how NZP can operationalise the Act.

3. Outlined are options identified, that include delaying implementation of the roadside device and amendment of the Act, for discussion with our agency partners, Ministry of Transport and Waka Kotahi, to ensure that the NZP could operationalise the Act, meeting ultimately its policy intent and requirements.

Policy Intent and Requirements

4. Though the Act is broader than OFT devices, this memorandum focuses specifically on the constraints that currently prevent introduction of a roadside saliva based device .

Policy Intent of the Act

5. The main beneficiary of the random drug driving testing is the New Zealand public. The Act is expected to deliver a reduction in deaths and serious injuries from crashes involving impairing drugs. The Ministry's cost-benefit analysis (CBA) predicts harm savings from the preferred option in the range of $239M to $778M over ten years (37 to 123 lives).[1]

6. Data from the NZ Transport Agency's (NZTA's) Crash Analysis System (CAS) shows that in 2020, 115 people were killed and 214 people were seriously injured in crashes where illegal drugs were a factor[2].

7. The policy intent of roadside drug testing is to reduce death and injury on New Zealand roads. The Land Transport (Drug Driving) Amendment Bill (the Act) is designed to allow the effective implementation of OFT with the policy intent that:

    - NZP to influence the public to reduce drug driving through deterrence
    - NZP supports the Government priorities though undertaking OFT at the roadside

Requirements of the Act

8. Police may stop any driver of a motor vehicle and administer an OFT at the roadside without good cause to suspect a driver has consumed drugs. This ability to test drivers anywhere and anytime is consistent with the existing approach to drink driving enforcement.

9. Detect those drugs which are the most prevalent legal and illegal drugs used by drivers: THC (the psychoactive ingredient in cannabis), methamphetamine, benzodiazepines (sedatives), MDMA (ecstasy), opioids, and cocaine.

[1] Ministry of Transport - Impact Statement: Enhanced drug driver Testing

[2] Based on data for all crashes reported by Police to Waka Kotahi for 2020 as recorded in the Crash Analysis System as of 19 July 2021

10. A driver who receives a negative result for a qualifying drug on a first or second OFT will usually be free to go. Drivers who receive two consecutive positive OFTs[3] will be subject to an infringement offence notice.

11. Section 77A provides that two positive OFT results is evidence of an offence leading to the issue of an infringement notice:

> *"For the purposes of proceedings for an infringement offence against section 57A(3), 57B(3), 57C(3), or 57C(4), it is to be presumed in the absence of proof to the contrary that a person's oral fluid contains a qualifying drug if the results of the first oral fluid test and second oral fluid test undergone by the person indicate use of the drug."*

12. A driver who refuses or disputes the OFT result can elect to undertake an evidential blood test.

13. A medical defence is available for drivers who can demonstrate that they have taken prescription drugs in accordance with their current prescription and followed any instructions from either their health practitioner or the manufacturer.

14. Any OFT device to be used must first have been approved by the Minister of Police. The Minister must:

    - consult with the Minister of Transport and Research, Science and Innovation Minister,
    - consider the accuracy of the device,
    - be satisfied that the device will only return a positive result if it detects the presence of a qualifying drug at a level that indicates recent use,
    - take into consideration any relevant New Zealand or joint Australian and New Zealand Standards for the device (Standard)[4].

15. The Gazette Notice for the device, must for each qualifying drug tested for, identify the in-built concentration level at which the device returns a positive result.

Constraints to implementation of roadside testing

16. During the drafting of the Act a number of points about device technology were raised which could constrain NZP on how they can operationalise the Act.

Independent Expert Panel & Joint Ministers Briefing

17. The Independent Expert Panel (IEP)[5] advised:

    - These devices are not confirmatory devices. They do not prove the use of a drug. False positives and false negatives are possible.
    - Commercially available oral fluid testing devices lack specificity which may lead to false negative or false positive test results.
    - Few of the channels on these devices react to a single drug. This is known as cross reactivity because, due to similarities between the chemical structures of some drugs, the device cannot distinguish between them.

[3] The need for two consecutive positive test is to reduce the risk of device inaccuracies, and though it does, it does not remove it

[4] AS/NZS 4760:2019 Australian/New Zealand Standard - Procedure for Specimen Collection and the Detection and Quantification of Drugs in Oral Fluid

[5] Independent Expert Panel on Drug Driving. *Recommending statutory limits for drug concentrations relating to impaired driving* (April 2021).

- The Panel recommends laboratory confirmation of blood concentrations following a positive oral fluid screen. The Panel specifically states, 'There should be no requirement to follow strictly the detection limits in the Standard for devices used by NZ Police because confirmatory analyses will be carried out on blood samples'.
- With THC, presence in oral fluid can, for a chronic user, be present for long periods of time, sometimes up to 30 hours .

Manufacturer's responses and other jurisdictions

18. In responses to the Request for Proposal (RFP), vendors advised;

> "*The Drug Test provides only a preliminary screening result (initial testing). In case of presumptive positive results, a more specific alternative methodology must be used in a laboratory in order to obtain a confirmed analytical result (confirmatory testing).*"
>
> "*is a preliminary onsite screening test*"
>
> "*is a qualitative test only*"

19. All other jurisdictions that use an OFT device use it as a screening tool to initially detect presence of a drug or family of drugs, and then require a confirmatory laboratory test to establish presence and concentration level if required.

What the procurement process has shown

20. In late 2020, NZ Police issued a Request for Information (RFI) to the market outlining an opportunity to provide information about oral fluid testing devices.
21. On 23 March 2022 a RFP was released to market through the Government Electronic Tender Service (GETS).
22. Ten responses were received. All respondents were asked to provide as part of their submission independent results for their products, as tested against the Standard. On initial review, two were disregarded as the device didn't physically exist.
23. The procurement evaluation process was broken down into the eight stages which are documented in Appendix 1.
24. Based on the known implementation constraints previously identified, two key areas were considered and due-diligence steps built into the process to mitigate:

    a) Poor device accuracy

    b) Cross-reactivity of drugs and impact on the identification of a specific qualifying drug

Device Accuracy (Specificity)

25. Device accuracy was determined by engaging an independent expert to;

    a) Undertake independent laboratory evaluation of devices with the provision of certificates of compliance where appropriate, providing the results of the evaluation and an expert opinion on how these correlate to meeting the required performance criteria as specified in AS/NZ 4760:2019 Standard : Appendix C - Verification of performance of devices used for the collection, on-site testing, transport and storage of oral fluid specimens

    b) Provide a qualified expert opinion, not a legal opinion, on how the results and device would be deemed as meeting the evidential test under the New Zealand Solicitor General's Prosecution Guidelines.

26. The Independent Expert Report is provided in Appendix 2

27. The verification criteria within the Standard allows for a 10% error rate. s9(2)(h) [redacted]

28. Three devices were shortlisted, when tested for accuracy against the Standard, none of the devices met the verification criteria.

29. Following engagement with the vendors of the short-listed devices to establish the reason for failure, two of these were re-tested and once again neither achieved the verification criteria.

30. The outstanding five devices which passed the initial review, were sent for verification testing. Of these Device A met both the verification criteria and concentration levels as defined in the Standard, Device B met the verification criteria but not the concentration levels. The findings of the two devices were:

s9(2)(b)(ii) [redacted]

31. Concerns for operationalisation due to results of independent device accuracy testing:

    - It is a requirement that a device does not returns false positive results of a qualifying drug, although Device A meets the criteria it returned false negative results despite high concentration levels of THC in the test solution.
    - Devices are designed for the purpose of a preliminary screen for presence; they are known to provide false positive results.
    - The Standard sets out that following an initial or presumption screen using an immunoassay test, an 'unconfirmed' (positive) result must be confirmed by a technique utilising mass-spectrometry. This ensures the specific identity of compound is determined and the chances of a 'false positive' is negligible.

32. Other jurisdictions overcome these concerns around accuracy with the use confirmatory mass-spectrometry testing which is not currently available at the roadside.

33. s9(2)(g)(i) [redacted]

34. Some of these concerns were considered during the drafting process with inclusions of ss64(6) and 77A in the Act. It should be noted that those provisions appear to have been drafted to mirror similar provisions that are in place for alcohol.

35. Section 71D of the Act provides the right for a person to elect a blood test after two positive OFT results. This was also included in the Act with the knowledge of the potential accuracy issue for OFT devices.

36. Although the decision was made with the knowledge of a potential device accuracy issue, the full context of that decision was not fully known. It has now been established that the recommended process for analysing a blood sample (along with medical expenses) is approximately $1,800.

37. This means, for a driver to potentially prove their innocence, they will need to balance their decision to elect a blood sample on the risk of a criminal conviction, mandatory disqualification and large financial penalty.

38. If those are considered by the courts to be an influencing factor on a driver's decision to elect a blood sample, it further highlights the focus for challenges on the accuracy of the device results.

Identification of the qualifying drug

39. The policy intent of the Act is for NZP to test drivers for the presence of qualifying drugs most prevalent in New Zealand crash data.

    - NZP undertook retrospective blood analysis of dataset of 2021 specimens collected from hospitalised crash-involved drivers. The most prevalent drugs were;

        i. THC (34%),

        ii. Stimulants (21%, though no individual stimulant was over 1%),

        iii. Methamphetamine (16%)

        iv. MDMA at 4%

        v. Cocaine was recorded at less than 1% of the sample.

40. The procurement process asked vendors to provide devices that deliver at least one of the drugs identified as most prevalent; in the majority all provided devices that measured all of these.

41. As noted earlier the Expert Panel identified that few of the channels on these devices react to a single drug. This is known as cross reactivity because, due to similarities between the chemical structures of the drugs, the device cannot distinguish between them.

42. Each qualifying drug is required to be individually identified as:

    - Part of device gazetting,
    - Upon the outcome of a positive roadside test, and
    - In charging documentation.

43. Only drugs which the device has been specifically approved for and can uniquely identify can be tested for. Due to cross reactivity in the devices, NZP will be limited to testing for THC and cocaine only, as:

    - Methamphetamine has cross reactivity with MDMA
    - 6MAM, a metabolite of Morphine, is the qualifying drug most devices use for detecting Opiates. 6MAM has a cross reactivity with a number of qualifying drugs that includes morphine and codeine.

- Benzodiazepines are a class of drug rather than a specific qualifying drug. As noted in the IEP report, devices lack specificity and will detect more than one drug in this class.
- In addition, if testing for Amphetamine, this has cross reactivity with MDA

44. Medicinal cannabis is now available by prescription (as of August 2022 there are 18 products available on the market). Seven of the 18 are dried cannabis flower products with a level of THC between 1-25%.

45. It is likely that with the availability of prescriptions for medicinal cannabis from sources such as online prescribers, there will be a significant number of medical prescription defences.

Summary of the constraints on operationalisation

46. The key constraints for the operationalisation are;

- The form of the Bill constrains the options for NZP to recommend an appropriate drug testing device on the basis of:
    i. The lack of the ability of a device to test for the most prevalent qualifying drug, and
    ii. Devices are not sufficiently accurate and, even if approved and gazetted, are likely to be subject to legal challenge, and
    iii. The ability to meet the relevant considerations of the Standard
- There are likely resourcing implications for multiple workgroups as a result of this Bill. For some, such as PPS and NRPC, there is no funding arrangement in place for the resourcing implications.
- The potential impacts of the indicated increase in testing from 33,000 to 66,000 tests would likely mean staff time would be redirected from alcohol testing (or other RIDS activity), given there is no indicated addition in staff resourcing. This currently represents an opportunity cost.

47. Operationalising a device that is subject to scrutiny in respect of accuracy and it not being used as designed could lead to significant impact on public trust and confidence in NZP's road safety initiative.

48. Testing for only THC and cocaine fails to meet the policy intent of testing for the most prevalent drugs used by New Zealand drivers as:

- Not testing for methamphetamine, seen in 16% of crash statistics data, or prescription drugs, seen sin 21% of crash statistics data, greatly reduces policy intent of targeting the most prevalent impairing drugs.
- To be seen as not being an effective deterrence to reducing drug driving.
- Once drivers are aware that only THC and cocaine are tested for, they may transfer to drugs not tested for which will further reduce general deterrence capability.
- The availability of a medical defence for lawfully prescribed medicinal cannabis negatively impacts the roadside testing.

49. Not being able to test specifically for methamphetamine could be seen by the public as a significant failure of the policy intent of the legislation

50. New Zealand Police do not believe that there is a device currently available that meets the policy intent and requirements adequately, that will not impact on trust and confidence and legal challenge.

Identified Options

51. A number of options have been identified for consideration and discussion for mitigation of the constrains identified. It is proposed that these options are discussed with executive and external stakeholders to determine an agreed approach which will then be communicated to the Minister of Police and Minister of Transport.

52. It is key to note that early engagement with all stakeholders should be undertaken to ensure agreement and alignment of approach.

53. The identified options are listed below, a fuller definition of each can be found within Appendix 1:

    a) Implement all areas of the Act (i.e. infringement notices and blood testing taken as a result of outcome from Compulsory Impairment Testing and/or vehicle crashes), proceeding with the current OFT technology testing at the roadside only for cocaine and THC.

    b) Implement the other areas of the Act other than OFT and wait for OFT technology to catch up to implement roadside testing.

    c) Implement all areas of the Act, proceeding with the current OFT technology testing at the roadside only for cocaine and THC and all positive OFT results being sent a lab for confirmatory testing of the oral saliva

    d) Amend the Act to align with current device technology to enable the testing for all intended drugs/classes and that all positive OFT results are sent a laboratory for confirmatory testing.

Appendix 1 – OFT Device procurement process

- STAGE 1-2: EVALUATION OF NON-PRICE CRITERIA & SHORTLISTING
    - Responses were evaluated against a Qualitative Criteria to reach a moderated result for each response. This is a non-weighted criterion, using a narrative approach to assess and distinguish the relative merits of each response.
    - At the conclusion of the non-price and price evaluation stages, responses were ranked based on their suitability to meet requirements in a manner most suited to the NZ Police environment
    - Six devices were longlisted for operational trials.
- STAGE 3: TRIALS & ASSESSMENT
    - As part of the Request for Proposal response, responders were asked to submit device samples that could be trialled if shortlisted.
    - The trial and assessment took place over a two-day period in a controlled environment through a range of scenarios involving volunteers being tested
    - Evaluating officers evaluated the devices and assessed them individually against the operability requirements
    - Following the testing, as a team, participants meet to discuss and reach a moderated score.
    - Three devices where shortlisted
- STAGE 4-6: CONFORMING TENDERS, PRICE EVAULATION, RANKING
    - Following the trial, follow-up questions were asked to all three responders to address points raised from the evaluation team where information was missing, or clarification was needed.
    - Reponses were then reviewed where it was concluded all three tenders conformed
    - Based on this, the TET decided to proceed with evaluating the price of all three
    - Following price evaluation, there were large price disparities between the three. A single preferred device could not be chosen due to consensus that referee check and scientific evidence should be collected before reaching a decision
- STAGE 7: REFEREE CHECKS
    - References were requested, via email, from all referees provided by the three responders, with responses received on each device.
- STAGE 8: FINAL RANKING & DUE DILIGENCE
    - Based on the references received, previous outcomes, and further research, the TET were unable to choose a single preferred device. This is because of the conflicting pros and cons of each that prevents one device clearly standing out over the others.

- Overall, the TET agreed that all three devices meet the core requirements outlined in the RFP.

- The three shortlisted devices were laboratory tested by an external provider (Racing Analytical Services Ltd), with the process overseen and results reviewed by an independent scientific expert s9(2)(a) (Med) from Independent Forensic Consulting. The testing was to identify compliance with the AS/NZ standards and validate the manufacturer claims.

- Once the outcome of the independent expert review is completed, a preferred device recommendation would be submitted.

- It should also be noted that testing has taken place on six drugs with the final decision on what drugs the device will test for at the roadside are to be decided

Appendix 2 – Independent Expert Report (Draft)

IFC Expert Report_220227_DRA

Appendix 3 – Implementation Options

#	Description of option	Benefit / Dis-Benefit	Impact on implementation	Risk
1	Implement the other requirements of the Act (infringement notices and blood testing) but not the roadside OFT. **This option fails to meet both the requirements and policy intent of the Act**	**Benefit** • Removes possibility of false-positive results from oral fluid testing devices **Dis-benefit** • Unlikely to changes drug use patterns • Police can better influence the public to reduce drug driving • Police are unable to support the Government priorities though undertaking OFT at the roadside • Regulatory failure	**Time:** • All other requirements of the Act will be implemented as of March 2023. **Quality** • Reduced quality of implementation by not undertaking roadside testing **Cost** • Initial reduction in costs as not undertaking OFT's	Medium
2	Proceed with testing at the roadside with a device testing for only for cocaine and THC. **This option fails to meet both the requirements and policy intent of the Act**	**Benefit** • Police can better influence the public to reduce drug driving • Police are able to support the Government priorities though undertaking OFT at the roadside **Dis-benefit** • Regulatory failure • False-positive results from oral fluid testing devices • Changes drug use patterns to drugs which are not tested by the OFT	**Time:** • All other requirements of the Act will be implemented as of March 2023. • Challenge to implement roadside OFT as need to ensure Community Consultation of the deployment strategy has been fairly delivered. • Legal challenge of the device likely to delay the next phase of implementation **Quality** • Reduced quality of implementation by only testing for cocaine and THC **Cost**	High

#	Description of option	Benefit / Dis-Benefit	Impact on implementation	Risk
			• No additional costs	
3	Proceed with testing at the roadside with a device testing for only for cocaine and THC and send all positive roadside saliva samples to a lab for confirmatory testing **This option fails to meet both the requirements and policy intent of the Act** **NOTE :** This option would require a change to the Act as there is currently no provision for NZP to retain the sample for this purpose.	**Benefit** • Police can better influence the public to reduce drug driving • Police are able to support the Government priorities though undertaking OFT at the roadside • Less chance of regulatory failure • Removes possibility of false-positive results from oral fluid testing devices **Dis-benefit** • Changes drug use patterns to drugs which are not tested by the OFT (Ability to testing for the full range of drugs, but as this is a confirmatory test this could be seen as unfair outcome)	**Time:** • All other requirements of the Act will be implemented as of March 2023. • Implement roadside OFT not achievable as device for capture of the saliva and logistic for to ensure chain of custody need to be established. • Procure laboratory testing of oral saliva • Challenge to implement roadside OFT as need to ensure Community Consultation of the deployment strategy has been fairly delivered. **Quality** • Reduced quality of implementation by only testing for cocaine and THC **Cost** • Additional cost of laboratory saliva testing • Cost of specific device to collect saliva sample • Potential cost saving on blood test fees	Medium
4	Amendments to the Act to align with current device technology to support all qualifying drugs and carrying out a confirmatory test to remove the risk of device inaccuracy **This option meets both the requirements and policy intent of the Act**	**Benefit** • Police can better influence the public to reduce drug driving • Police are able to support the Government priorities though undertaking OFT at the roadside • Less chance of regulatory failure • Removes possibility of false-positive results from oral fluid testing devices **Dis-benefit**	**Full impact will need to be determined once any revised legislation is known** **Time:** • All other requirements of the Act will be implemented as of March 2023. **Quality** • Reduced quality of implementation by not undertaking roadside testing **Cost**	Low

#	Description of option	Benefit / Dis-Benefit	Impact on implementation	Risk
	NOTE : It is not known of any alternative technology that will be available within the next two to three years.	• Changes drug use patterns (if lab testing was for the full range of drugs, not just those testing via the OFT then this would be mitigated)	• Initial reduction in costs as not undertaking OFT's • Future costs likely to significantly increase	