Title: **Control of a 3rd generation of synthetic cannabinoids** **IA No:** HO0245 **Lead department or agency:** HOME OFFICE **Other departments or agencies:** DEPARTMENT OF HEALTH, DEPARTMENT FOR BUSINESS INNOVATION AND SKILLS	**Impact Assessment (IA)** **Date:** 19/7/2016 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries**: James Mclellan 0207 035 1885 james.mclellan@homeoffice.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: N/A

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
NK	NK	NK	No	NA

What is the problem under consideration? Why is government intervention necessary?

The ACMD has made recommendations to control the 'third generation' synthetic cannabinoids. Given the harms associated with these substances the ACMD has concluded that they should be placed under the Misuse of Drugs Act 1971.

In line with recommendations from the Advisory Council on the Misuse of Drugs, the Government has already controlled two generations of synthetic cannabinoids.

The first report in 2009 described the associated physical and social harms and proposed generics legislation to control these substances. The current controls on synthetic cannabinoids came into force following the ACMD's second report in 2012. However, following further advice from the ACMD of 27 November 2014 and addendums to this advice, most recently on 14 January 2016, it is evident that there is a 'third generation' of these materials which are available on the market and fall outside the scope of these controls.

Government intervention is necessary to prevent harm being caused by these substances by restricting their supply using the strict regime provided by control under the Misuse of Drugs Act 1971. Given the reported risks that these substances pose to public health, the ACMD has advised that the 1971 Act remains the preferred option for control. Control under the 1971 Act provides more effective restrictions than the alternative option of control under the Psychoactive Substances Act 2016. The ACMD has based the assessment for stricter controls on the evidence that currently exists on these substances and the need for law enforcement to take specific action on these substances to restrict their availability.

What are the policy objectives and the intended effects?

The policy objective is to reduce the risk of harms from the misuse of these substances in the UK.

The intended effects are to limit access to the identified compounds, to signal to the public the potential danger from these substances and to enable the police and other authorities to take action against the sale or distribution of these substances.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

'Third Generation' Synthetic Cannabinoids

Option 1 - Do nothing and allow these compounds to be controlled under the Psychoactive Substances Act 2016.

Option 2 – Control, designation and scheduling of the generic definition of synthetic cannabinoids under the Misuse of Drugs Act 1971 and its subordinate legislation.

Option 2 is the preferred option on the basis of the current evidence and the ACMD's assessment of evidence on the harms and misuse associated with these compounds. The Misuse of Drugs Act 1971 provides a higher level of control with a possession offence, more strictly defined supply and distribution offences and wider powers for enforcement than the Psychoactive Substances Act 2016.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Within 12 months.

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs

Signed by the responsible Minister: Sarah Newton Date: 19 July 2016

Summary: Analysis & Evidence

Policy Option 2

Description: Control, desgination and scheduling of 3rd generation synthetic cannabinoids under the Misuse of Drugs Act 1971..

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate:** NK

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate	NK		NK	**NK**

Description and scale of key monetised costs by 'main affected groups'

It is not possible to monetise the costs of this option in light of the current available data.

Other key non-monetised costs by 'main affected groups'

Businesses – following consultation with BIS, the MHRA and the chemical and pharmaceutical industry, these compounds and related substances have been identified as having no legitimate industrial or medicinal use. There should be no further cost to business by controlling these compounds under the Misuse of Drugs Act 1971, as under option 1 their supply would be restricted under the Psychoactive Substances Act..

The **Public sector** may face some costs from enforcement responses, though it is expected that these will be subsumed into the enforcement and regulatory response to similar drugs permanently controlled under the Misuse of Drugs Act 1971

For synthetic cannabinoids, as the supply of these substances would be restricted anyway under option 1, the personal cost of option 2 is likely to be negligible.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate	NK		NK	**NK**

Description and scale of key monetised benefits by 'main affected groups'

It is not possible to monetise the benefits of this option in light of the current available data.

Other key non-monetised benefits by 'main affected groups'

Public Sector: If the 'third generation' synthetic cannabinoids were to be controlled under the Psychoactive Substances Act 2016 this would result in lower maximum penalities for supply, production and importation/exportation and a different regime for control, involving different offences. Listing them of the face of the Misuse of Drugs Act 1971 provides law enforcement with a consistent regime to control these substances in line with other synthetic cannabinoids that have been previously controlled with similar harms. Under the proposed option, enforcement costs would likely be lower, given the burden of proof is less for offences under the Misuse of Drugs Act 1971 which don't include the forensic requirement to prove that a substance is 'capable of producing a psychoactive effect' and that it is being sold for human consumption.

Personal: It is possible that **personal** benefits arise from the deterrence effect of a clear message sent out that these substances have had an initial harms assessment and found to pose a risk to public health and safety.

Society: Given the lower enforcement costs and the message sent out by Misuse of Drugs Act control, it provides a stronger, more targeted tool to address the societal harms of these substances.

Key assumptions/sensitivities/risks **Discount rate**

To the best of our knowledge, these substances do not have any legitimate industrial or medicinal uses. It is possible that the substances in question are currently being used by UK research bodies, creating the possibility that research will be hampered by the proposed controls. However, most research organisations will already have current licences which will permit access to these drugs for research purposes.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs:	**Benefits:**	**Net:** 0	No	NA

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

1.1. This Impact Assessment considers the proposal to add a revised generic description of synthetic cannabinoids to the Misuse of Drugs Act 1971 (1971 Act) as class B drugs.

Synthetic Cannabinoids (taken from ACMD report: 'Third Generation Synthetic Cannabinoids', 2014)

1.2. Synthetic cannabinoids are an increasingly diverse class of chemical compounds which produce psychoactive effects similar to those produced by *Cannabis*.

1.3. Synthetic cannabinoids which affect the CB_1 cannabinoid receptors in the brain can produce psychoactive effects similar to those produced by cannabis. Following the identification of such materials in smoking products, the UK enacted two rounds of controls under the Misuse of Drugs Act 1971.

1.4. The first, coming into force at the end of 2009, was based around materials then known to be available as novel psychoactive substances (NPS) and included a number of named compounds together with generic controls covering groups of materials related to those known to be in circulation in order to try to avoid simple 'designer' variants being brought to the market (ACMD Report on the Major Cannabinoid Agonists, August 2009).

1.5. The second round drafted in 2012 and coming into effect in early 2013, expanded control to include a broader range of 'second generation' materials, which had appeared between 2009 and 2012. However, it was accepted that the controls might have to be revisited if further materials were commercialised as NPS (ACMD Further Consideration of Synthetic Cannabinoids, October 2012).

1.6. Since the second round of controls came into effect (February 2013), a 'third generation' of synthetic cannabinoids, outside the scope of the 2012 controls, has indeed entered the NPS market and become widely available, including materials intended for use in electronic cigarettes, so that a further review of controls is required.

1.7. The ACMD advises that the reported effects of the new materials are similar to those caused by cannabinoids that have already been controlled under class B of the Misuse of Drugs Act and there are suggestions that some of the new substances may be more potent than those which they have replaced. Drugs Early Warning System reports include a number of cases of users being

overwhelmed by the effects of smoking materials believed to contain the new cannabinoids, resulting in collapse and hospitalisation.

1.8. At the time of their current report (published 2014), the ACMD reported widespread availability on internet sites and in high street headshops, as well as a trend in use within e-cigarettes. More recently the 2015-2016 Forensic Early Warning System Prison Collection noted that 99% of NPS it encountered in prisons were synthetic cannabinoids. In a similar headshop collection in 2015-2016, it noted that 66% of samples collected from headshops were synthetic cannabinoids. However it is important to note that, as the Psychoactive Substances Act has only recently commenced, it is unclear what impact option 1 will have had on the prevalence on these substances more recently.

1.9. As such the ACMD recommends inserting a new generic definition into the 1971 Act to control a wider range of synthetic cannabinoids as class B drugs.

Wider uses

1.10. The ACMD identified a number of cannabinoids covered by the generic definition which have legitimate medicinal uses. These have been excluded by name from the proposed controls.

1.11. Following consultation with the Department for Business Innovation and Skills (BIS), the Medicines and Healthcare products Regulatory Agency (MHRA) and the chemical and pharmaceutical industry, the compounds covered by the generic definition (and not explicitly excluded) have been identified as having no legitimate industrial or medicinal use. The MHRA also confirmed that there are no marketing authorisations for medicines containing these compounds.

A.2 Groups Affected

1.12. The proposal to control these compounds may affect groups making legitimate use of any of these substances, such as organisations which use and produce chemical standards for research and forensic purposes.

1.13. There will be minimal impact on the illicit market in drugs ('head shops' and internet suppliers) as they currently would not be able to sell, produce or import/export these substances to be consumed for psychoactive effect under the controls of the Psychoactive Substances Act 2016. The stricter regime of control under the Misuse of Drugs Act 1971 is likely to make it even more difficult for them to operate and as such will be of benefit.

A.3 Consultation

Within Government

1.14. The Home Office and the ACMD consulted with the MHRA, BIS and the chemical/pharmaceutical industry in deciding its preferred options when the ACMD original produced its advice for these substances.

Public Consultation

1.15. The Government has considered the recommendations of the Advisory Council on the Misuse of Drugs.

B. Rationale

2.1. The misuse of drugs imposes a cost on society in excess of the individual costs to users. A 2013 Home Office study estimated that the total social and economic costs of illicit drugs in 2010/11 was £10.7bn, which included £5.8bn in drug-related crime costs and around £2bn in criminal justice system and health service costs. In addition, users are not always aware of the costs associated with particular drugs due to the novelty of the substances. As the ACMD report states, there are strong indications that the listed substances may be capable of harm similar to cannabinoids already controlled under the 1971 Act (currently Class B).

2.2. Controlling these substances under the Misuse of Drugs Act 1971, as opposed to allowing the substances to be covered under the Psychoactive Substances Act 2016, provides a more effective restriction of their supply as follows:

a. Control under the 1971 Act offers stricter offences of production and distribution under any circumstances without a licence. The offences in the 2016 Act only prohibit the production and distribution of psychoactive substances to be consumed for psychoactive effect. The higher control under the 1971 Act therefore provides a clearer legal framework to restrict the supply of particular substances even more narrowly than the 2016 Act.
b. The maximum penalty for committing an offence involving a class B or C drug is 14 years imprisonment. This contrasts with the 7 year maximum sentence under the 2016 Act. These higher tariffs may prove a stronger deterrent to the supply of these substances.
c. The 2016 Act provides a non-substance specific approach with lighter touch exemptions, most notably with regard to healthcare related activities and research. Where there are no legitimate uses for specified drugs (as in this case), the Misuse of Drugs Act 1971 requires licence to be issued to allow exemptions to offences and this would only be for research or other special purpose.
d. Control under the 1971 Act also involves the imposition of a possession offence, which restricts the scope to be in simple possession of these compounds further and again, only under licence.

2.1. These differences reflect that drugs controlled under the 1971 Act have been subjected to a full harms assessment by the ACMD and that they are being or appear to the ACMD likely to be misused and of which the misuse is having or appears to them capable of having harmful effects sufficient to constitute a social problem.

. C. Objectives

3.1. The policy objective is to protect the public from the harms associated with synthetic cannabinoids, in line with the Government's Drug Strategy to restrict the supply of drugs; prevent harmful drug use and build recovery for those dependent on drugs.

3.2. As part of this a key objective will be a reduction in the demand, availability and misuse of these compounds and raised awareness of the harms of these substances.

D. Options

4.1. Two options have been considered in respect of synthetic cannabinoids: :

OPTION 1: Do nothing and allow these compounds to be covered by the Psychoactive Substances Act 2016.

OPTION 2: Control, designation and scheduling under the Misuse of Drugs Act 1971 and its subordinate legislation, as recommended by the ACMD.

Description of controls

- Under the Misuse of Drugs Act 1971, on indictment the maximum penalties for offences relating to class B drugs are - for supply, production, importation/exportation up to fourteen years' and/or an unlimited fine. On summary conviction, the maximum penalties for offences relating to supply, production or importation/exportation are six months' imprisonment and/or a prescribed fine (including, for the latter offences, one determined by the value of the drugs if greater than the prescribed amount).

- Possession of a class B drug carries a maximum penalty of 3 months imprisonment and a £2,500 fine on summary conviction and a maximum of 5 years imprisonment on indictment.

The Government's preferred option is option 2, which is aligned with the ACMD's advice and presents the best means of restricting the availability and reducing the risk of misuse and associated harm to the public.

E. Appraisal

OPTION 1: This is the baseline option, meaning that the costs and benefits of option 2 are assessed relative option 1 (i.e. additional costs and benefits above the do nothing scenario).

OPTION 2:

COSTS

Business

5.1. Some substances covered by the generic definition have been found to have legitimate medical uses and have been excluded by name from the definition and will therefore not

be subject to control. Following consultation with BIS, the MHRA and the chemical and pharmaceutical industry, any remaining compounds covered by the definition have been identified as having no legitimate industrial or medicinal use. As a result, no wide impacts/costs on legitimate business are expected.

5.2. Whilst the open trade in psychoactive substances to be consumed for their psychoactive effect would be restricted by the 2016 Act (option 1), this leaves open a theoretical market for other uses. Control under the Misuse of Drugs Act restricts supply for any purpose, which could theoretically mean that business conducting research incur further costs. However, as these businesses are likely to be in possession of a Home Office Licence anyway, the cost is likely to be minimal.

Public Sector (enforcement agencies, CJS, regulators)

5.3. Any real and opportunity costs associated with option 2 cannot be predicted in light of limited data on the prevalence and use of the listed substances to be controlled in the UK. It is expected that minimal costs arising from option 2 will be subsumed into the law enforcement and regulatory response to the control of other drugs under the 1971 Act. As such the law enforcement response can reasonably be managed within existing resources, informed by policy and operational prioritisation. The police and other law enforcement agencies will prioritise resources towards tackling crime, including drug related crime, with a focus on those offences which cause the most harm.

Personal and society

5.4. It is unlikely that personal costs will differ significantly between options 1 and 2, which would both have a restrictive effect on the supply of these substances. We are unable to monetise these costs due to a lack of information on the current size of the market in these substances.

BENEFITS

Business

5.5. No benefits accrue to businesses from this policy.

Public Sector (enforcement agencies, CJS, regulators)

5.6. Whilst it is difficult to compare the costs with the enforcement under the 2016 Act, the greater evidential burden under that Act means that further forensic testing and expert evidence are required to discharge the evidential burden. These costs are difficult to monetise, but are likely to make prosecutions more expensive under the 2016 Act. As such the costs of enforcement of offences involving class B drugs are likely to be lower for enforcement agencies.

5.7. Benefits are expected to arise from consistency in enforcement and regulatory response to harmful substances; the listed compounds are believed to have a similar level of harm to other substances currently listed under the Misuse of Drugs Act. This includes currently controlled synthetic cannabinoids (class B). In practical terms this provides

enforcement agencies with a consistent set of powers to restrict the supply of substances assessed to be harmful, rather than disparate regimes. This is likely to be more efficient to enforce, saving time and costs.

Personal and society

5.8. The effect of options 1 and 2 will be similar in this regard. As noted above though, control under the 1971 Act may restrict the supply of the compounds even further than the 2016 Act. Personal benefits arise from this direct protection against potential harms of the listed substances through this reduced availability.

5.9. In contrast to the blanket ban on supply of option 1, it is expected that controlling these substances will also reinforce to the public their potential harms by underlining that their harms have been assessed as commensurate with other class B drugs. This specific targeting may reduce the harms caused by the substances. The 2016 Act contains no such harms assessment and therefore does not differentiate between the harms of specific drugs.

NET EFFECT

5.10. Overall it is considered likely that the benefits from the proposals will outweigh the costs, although it has not been possible to quantify these benefits and costs. The main benefits to arise from the proposals are that they reduce the prevalence and harms produced by synthetic cannabinoids by providing enforcement agencies with wider powers, stricter offences and higher penalties surrounding the trafficking in these substances. This in turn is likely to make it easier for them to restrict the supply of these substances than under option 1. Additionally this option makes possession without a licence unlawful and therefore control and availability even tighter than would be imposed under the Psychoactive Substances Act 2016. This in turn reinforces that the synthetic cannabinoids are harmful and encourages targeted action by law enforcement to tackle the trade.

F. Risks

6.1. There is a limited risk that voluntary, charity or private sector research organisations or institutions: manufacturers, distributors and wholesalers that produce, supply, import or export these substances or use them for the synthesis of non-controlled pharmaceuticals may become adversely affected due to the potential costs of updating or applying for a licence. However, organisations dealing with permanently controlled scheduled drugs will already possess a licence to undertake activities involving those synthetic cannabinoids which will be covered by the generic definition inserted into Schedule 1 of the Misuse of Drugs Regulations. Due to the absence of evidence of legitimate business use and the negligible costs that would be associated with any use, the assumption is made that there are no cost implications to business.

G. Enforcement

7.1. Enforcement of the proposed legislation will be undertaken by Police Forces, Border Force, the Home Office Drug Licensing Unit and other relevant agencies responsible for enforcing the legislative and regulatory framework for controlled drugs in the UK. Police enforcement will form part of their wider approach to tackling new psychoactive substances as well as other drug controlled under the 1971 Act. Border Force will enforce import controls by seizing suspected substances at the ports, also as part of their wider customs role. There will be no interference with the regulatory framework and processes implementing temporary control measures in law enforcement and regulatory agencies as part of their routine activities.

H. Summary and Recommendations

8.1. The table below outlines the costs and benefits of the proposed changes.

Table H.1 Costs and Benefits

Option	Costs	Benefits
2	£NK	£NK
	- There are no significant costs to the preferred option.	- Control under the 1971 Act is likely to be less resource-intensive to enforce than the Psychoactive Substances Act 2016 and provides wider powers, producing a more restrictive effect on supply. - It will also reinforce public awareness of the harms of the substances by making clear they are of concern, by classifying them according to harm and providing stricter penalties for offences.

8.2. Taking option 1 (do nothing) would mean the synthetic cannabinoids be covered by the Psychoactive Substances Act.

8.3. Option 1 is the least preferred option. The Psychoactive Substances Act is very different regime of control, aimed at those substances which have not had their harms assessed. It contains lower penalties, more narrowly defined offences and a higher evidential burden for prosecuting agencies. To allow the substances to lapse to coverage under the Psychoactive Substances Act 2016 would not be commensurate with the assessment of harm that the ACMD have already made. Forensic testing and expert advice will be required to determine whether the substances are capable of having a psychoactive effect (the evidential requirement under the Act). The costs of testing, and length of time it will take, are difficult to

monetise, and will depend on operational requirements, but will make prosecutions more expensive under the 2016 Act. The lower penalties, specific *mens rea*, civil penalties and no possession offence are a weaker signal to the public.

8.4. Option 2 is the preferred option and is aligned with the ACMD's advice. The use of the 1971 Act and its Regulations to control the listed substances provides the best means to reduce availability and potential harm to the public. The resultant clear message to the public that these compounds have harms commensurate with current class B controlled drugs may also assist in dissuading the use, as alluded to in the ACMD's evidence.

I. Implementation

9.1. The Government plans to implement these changes via an affirmative resolution Order, subject to Parliament's approval.

J. Monitoring and Evaluation

10.1. As part of its statutory duties under the 1971 Act the ACMD keeps the situation relating to the misuse of drugs under review. Together with the Government, they will continue to monitor the listed compounds by gathering data on their prevalence and misuse (particularly whilst under temporary drug control) through UK and EU drugs early warning systems, the health sector and the regulatory framework governing legitimate activities (predominately research) in relation to these drugs. The Home Office, as the regulatory authority on licensing of activities relating to all controlled drugs and as lead department working with other Government departments to deliver the Drug Strategy, will continue to monitor the situation in relation to compliance with the regulatory framework.

K. Feedback

11.1. Information gathered from the monitoring and evaluation process will inform future ACMD advice on the (re)classification, designation and scheduling of these drugs.