Title: Amendments to the definition of 'third generation' synthetic cannabinoids under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015. **IA No:** HO0341 **RPC Reference No:** N/A **Lead department or agency:** The Home Office **Other departments or agencies:** Advisory Council on the Misuse of Drugs (ACMD)	**Impact Assessment (IA)** **Date:** September 2019 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries:** emma.nichols5@homeoffice.gov.uk

Summary: Intervention and Options

RPC Opinion: Not applicable

Cost of Preferred (or more likely) Option (in 2016 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£0m	£0m	£0m	Non-qualifying

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

In December 2016, SI No. 1109/2016 controlled the 'third generation' of synthetic cannabinoids under a generic definition, as Class B drugs under the Misuse of Drugs Act 1971 ("1971 Act"). SI No. 2016/1124 and SI No 2016/1125 designated 'third generation' synthetic cannabinoids under the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 and placed them in Schedule 1 of the Misuse of Drugs Regulations ("2001 Regulations"). However, this has captured some compounds which were not intended to be captured, inadvertently impacting on legitimate research. Government intervention is necessary to reduce the number of compounds that were unintentionally captured.

What are the policy objectives and the intended effects?

The objective of this legislative amendment is to reduce the number of compounds unintentionally captured by the generic definition of 'third generation' synthetic cannabinoids which came into force on 14 December 2016, while retaining those compounds which have been found to cause harm.

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

Option 1: Do nothing - make no changes.

Option 2: Introduce the amendments recommended by the Advisory Council on the Misuse of Drugs (ACMD) to the generic definition of 'third generation' synthetic cannabinoids.

Option 2 is the Government's preferred option. This option will help to reduce some of the burdens of capturing a wide range of compounds, and inadvertently impact on legitimate research by the healthcare and medicines research community.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** N/A

Does implementation go beyond minimum EU requirements?		No		
Is this measure likely to impact on trade and investment?		No		
Are any of these organisations in scope?	**Micro** 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, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Kit Malthouse Date: 17 October 2019

Summary: Analysis & Evidence

Policy Option 2

Description: To amend the generic definition of the 'third generation' synthetic cannabinoids to remove compounds unintentionally captured by the generic definition, whilst retaining compounds which are known to be harmful.

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	**PV Base Year** 2019	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low:	**High:**	**Best Estimate:** **0**

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low		0		
High				
Best Estimate	0		0	**0**

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

None.

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

There may be familiarisation costs for businesses, police forces and Border Force, although they are likely to be negligible.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low		0		
High				
Best Estimate	0		0	**0**

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

None.

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

There may be a potential benefit to the public and industry through increased investment and scale of scientific research. Research organisations will no longer need to pay for a Schedule 1 Home Office licence to use the compounds removed from the generic definition for research.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There remains a possibility that the revision will still leave some compounds with no cannabinoid activity subject to controls. The Home Office is looking at other options within the legislative framework to alleviate these concerns which does not require further amendments to the generic definitions.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m:**
Costs: N/A	**Benefits:** N/A	**Net:** N/A	N/A

A. Strategic Overview

A.1 Background

Further to advice received from the Advisory Council on the Misuse of Drugs (ACMD) a further range of synthetic cannabinoids (known as the third-generation synthetic cannabinoids) were classified as Class B under the Misuse of Drugs Act 1971 ('the 1971 Act') and listed as Schedule 1 drugs in the Misuse of Drugs Regulations 2001 ('the 2001 Regulations'), which means they have no, or no known, medicinal use in the UK. They were also designated under the Misuse of Drugs Designation Order 2015 meaning that these compounds can only be made available for research or other special purposes or for use by practitioners, pharmacists and persons lawfully conducting retail pharmacy business under licence or other authority issued by the Home Office. These amendments came into force on 14 December 2016 by way of a generic definition designed to address concerns associated with controlling specific compounds, such as potential modifications to their structures. As such, this change covered (and controlled) a broader range of compounds.

However, this had an unintended consequence on the research community. For example, they have stated that some 40,000-90,000 compounds are captured by this wide definition which were not synthetic cannabinoids by their pharmacological action and therefore were and therefore were not intended to be controlled under the 1971 Act and associated legislation.

In December 2017, the ACMD recommended amending the generic definition to reduce the number of compounds unintentionally captured by the generic definition while retaining those compounds that have been found to cause harm. On 15 January 2019, the Minister of State for Crime, Policing and the Fire Service accepted the recommendation to amend the generic definition as a partial solution towards resolving this matter.

A legislative change to the generic definition is required to resolve the consequences of unintentionally capturing such a wide range of compounds which should not have been controlled.

A.2 Groups Affected

- Businesses – those that are involved in this field of research.
- Police forces and Border Force – they will need to enforce this new legislation.
- Home Office Drugs and Firearms Licensing Unit – they will no longer need to process licenses for the compounds under consideration.
- General Public – further research in this field could affect healthcare outcomes to the general public.

A.3 Consultation

Within Government

No departments were formally consulted. Department for Business, Energy and Industrial Strategy, Department of Trade and Industry and Department of Health and Social Care were informed of the proposed changes.

Public Consultation

The research community and Association of the British Pharmaceutical Industry (ABPI) were consulted on 10th December 2018 and confirmed that the ACMD's proposed definition was helpful to reduce some of the burdens on research.

B. Rationale for intervention

In December 2016 a range of synthetic cannabinoids were classified as Class B under the 1971 Act and Schedule 1 drugs under the 2001 Regulations. This had unintended consequences on the research community, as the broad definition covered many compounds, some of which are

used for legitimate research purposes and should not have been controlled, as they did not have any cannabinoid activity. This scheduling introduced a licence fee for using such compounds, imposing an additional cost to the healthcare and medical industry. Government intervention is required as they are the only actor that can introduce legislative changes that can reverse this barrier posed to the research community.

C. Policy objective

The objective of this legislative amendment is to reduce the number of compounds unintentionally captured by the generic definition which came into force on 14 December 2016, removing them from Class B of the 1971 Act, Schedule 1 of the 2001 Regulations and Designation Order 2015, while retaining those compounds which have been found to cause harm or have the potential to cause harm.

D. Description of options considered.

The options considered in this Impact Assessment are:

Option 1: Do nothing - make no changes.

Option 2: Introduce the amendments recommended by the Advisory Council on the Misuse of Drugs (ACMD), to the generic definition of synthetic cannabinoids.

The Government's **preferred option is option 2**. This option will help to reduce some of the burdens of capturing a wide range of compounds that inadvertently impact on legitimate research by the healthcare and medicines research community.

E. Appraisal.

Assumptions

There are no assumptions used in this impact assessment.

Costs

Monetised costs

Government

Under the current legislation, a license is needed to conduct research on the compounds under consideration. This new legislation would mean there will be loss of revenue for the government due to the forgone license fee. However, this will be offset by the saved time that would have been spent processing licences, given that the cost of the current license fee is charged on a 'full cost recovery' basis[1].

Non-monetised costs

1. Familiarisation costs

1a. Businesses

Businesses that undertake research will need to familiarise themselves with the legislation change. However, given that these businesses have been requesting this legislation change, they are mostly already aware of the likely new guidance before it is implemented. Therefore, the familiarisation costs to businesses are likely to be negligible.

1b. Police forces and Border Force

[1] https://www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns#licence-fees

The police and Border Force will need to familiarise themselves with the legislation change. However, given the small number of compounds affected and that the classification of illicit substances changes on a regular basis, the familiarisation costs to police forces and Border Force are likely to be negligible.

Ongoing costs

2a. Businesses

Businesses will not be required to take any action following this change, given that it is regulatory. It is unlikely that they will therefore face any ongoing costs.

Total Costs

As this proposal has no quantifiable costs, the total cost is £0.

2. Benefits

3.0 Monetised benefits

There are no monetised benefits.

3.1 Non-monetised benefits

There will be time saved for the Home Office as they will no longer need to process licence applications for the compounds under consideration. However, as the licence fee is changed on a 'full cost recovery' basis, this benefit will be offset by the loss of revenue.

There will likely be benefits from this proposal through further research, as the current licence fee potentially poses a deterrent for businesses to invest in research. For context the cost of a license is typically £326 for a paper-based renewal and up to £1,371 where a re-visit is required. However, due to the uncertainty surrounding additional research that may come about due to this proposal, this benefit cannot be quantified.

Total Benefits

As this proposal has no quantifiable benefits, the total benefit is £0.

Net present value (NPV), BNPV and EANDCB

As this policy has no quantifiable costs or benefits, the NPV is £0. Similarly, there are no costs to business therefore the Business Net Present Value (BNPV) is £0 and the equivalent annual net direct cost to business (EANDCB) is also £0.

This policy has an administrative exemption from the Business Impact Target (BIT) and therefore it has not been calculated.

Businesses involved in this field of research may benefit by the reduction in costs, as they no longer need to pay a license fee to conduct research on the compounds under consideration. However, as there is no data available against this, this benefit cannot be quantified.

F. Proportionality.

As this policy is deregulatory and has no quantifiable costs or benefits, there is limited scope for detailed analysis.

G. Risks.

1. Analytical risks

There is a risk of not quantifying the benefits of this legislation change, as this provides limited information on which to take a policy decision. However, this risk is mitigated as the costs of this policy are likely to be negligible, given that it is a deregulatory change which requires minimal resource to implement.

2. Policy risks

There is a possible risk of this change excluding too many compounds, which could increase health harms through harmful substances becoming uncontrolled.

There is also a risk of not exempting enough compounds, which could mean this change does not have the intended benefit to the research community. These risks are mitigated by following ACMD advice on amending the generic definition.

H. Wider impacts

The potential increase in research that may come about from this policy could have a benefit to society, for example by facilitating technological advancements.

I. Trade Impact.

With a potential fall in the costs of research for the healthcare and medical industry, there may be an increase in foreign investment, although this is uncertain and cannot be quantified.

J. Implementation date, monitoring and evaluation (PIR if necessary), enforcement principles.

There is no specific review date for this policy change. The effects of this legislation will be monitored through related government statistics like crime statistics, drug use statistics or if any concerns are raised by stakeholders.

The effects of this legislation will also be monitored and evaluated as part of a wider, ACMD longer-term review on synthetic cannabinoids, due in Summer 2020.

Note: Each of the specific impact tests have been considered but there are no specific impacts arising from these proposals arising.