Title:	Impact Assessment (IA)
Impact assessment of the control and scheduling of families of NBOMe and Benzofuran substances **IA No:** HO **Lead department or agency:** HOME OFFICE **Other departments or agencies:** DEPARTMENT OF HEALTH, DEPARTMENT FOR BUSINESS INNOVATIONS AND SKILLS AND LAW ENFORCEMENT AGENCIES	**Date: 07/02/2014** **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries:** Desmond Niimoi (desmond.niimoi@homeoffice.gsi.gov.uk) 020 7035 3533

Summary: Intervention and Options

RPC Opinion: Not in scope

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, Two-Out?**	**Measure qualifies as**
N/A	N/A	N/A	No	N/A

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

NBOMe and benzofuran compounds and their related substances are derivatives of, or related to controlled Class A phenethylamine compounds or phenethylamine type-materials. A number of these substances are currently controlled as temporary class drugs under the Misuse of Drugs Act 1971. These compounds have been assessed by the Advisory Council on the Misuse of Drugs (ACMD) as harmful drugs, posing a serious health threat, and therefore warranting permanent control. Government intervention is necessary to take immediate action on these compounds, in order to prevent them from gaining a foothold in the UK drugs market and to protect the public from their immediate harms.

What are the policy objectives and the intended effects?

The policy objective is to protect the public from the harms posed by these drugs.

The intended effect is to curb availability and enable law enforcement agencies to take appropriate action to tackle the unauthorised activities of production, supply and import/exportation and possession relating to these substances, and to deter misuse.

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

Option 1 - Do nothing

Option 2 – Permanently control, and schedule, families of NBOMe and benzofuran compounds using generic definition under the Misuse of Drugs Act 1971.

Option 2 is the preferred option on the basis of the current evidence and the ACMD's advice on the harms and misuse associated with compounds that have no known legitimate outside of laboratory research.

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

Does implementation go beyond minimum EU requirements?			Yes / No / N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** No	**Small** No	**Medium** No	**Large** No
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: Norman Baker Date: 26 February 2014

Summary: Analysis & Evidence

Policy Option 2

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** N/A

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

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

We have not been able to monetise any of the costs associated with this policy.

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

This policy is expected to impose costs on those businesses that are no longer able to legitimately sell NBOMe or Benzofuran or related substances, and those individuals who are no longer able to consume these substances.

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

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

We have not been able to monetise any of the benefits associated with this policy.

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

This policy is expected to reduce costs to the public sector resulting from crime and health harms associated with these substances, and will protect individuals from the harms associated with these substances.

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

There is a risk that the control of these substances will lead to new, uncontrolled substances appearing on the market. This risk is mitigated by the ACMD's continual review of the situation regarding both controlled and non-controlled drugs.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:						In scope of OITO?	Measure qualifies
Costs:	**N/A**	**Benefits:**	N/A	**Net:**	N/A	No	N/A

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

A.1.a NBOMe compounds and related substances (from 2013 ACMD report[1])

1. The NBOMe compounds (25I-NBOMe, 25B-NBOMe etc) are variants of the 2C-X series of the psychoactive phenethylamines which are currently controlled as Class A drugs under the 1971 Act by generic definition. They are highly potent hallucinogens and were used as 'legal' alternatives prior to temporary control to escape control measures. In May 2013, the Advisory Council on the Misuse of Drugs (ACMD) identified them as more potent compounds than the Class A phenethylamines that can be probably regarded as alternatives to Lysergic acid diethylamide (LSD).

2. Users have reported that 25I-NBOMe produces effects that can last up to 6 to 10 hours. While the ACMD reported general effects of using the drug, it also reported that the highly negative effects include confusion, shaking, nausea, insomnia, paranoia and unwanted feelings.

3. The ACMD assessed NBOMe compounds as probable alternatives to LSD and recommended urgent action due to the high risk of overdose and due to Serious and Organised Crime Agency Reports of large volumes entering the UK.

4. The UK Focal Point also reported that the 25I-NBOMe compound was linked to a series of 7 serious non-fatal intoxication cases in January 2013. Clinically observed features included tachycardia, hypertension, agitation and aggression, visual and audio hallucinations, seizures, hyperpyrexia, clonus, elevated white blood cell count and metabolic acidosis. Two patients required admission to intensive care. One patient had severe rhabdomyolysis leading to renal failure, and all of the cases had elevated creatine kinase to varying degree. Another hospital case reported in December 2012 had used alcohol in combination with other substances including 25I-NBOMe and had suffered kidney function impairment and required sedation and the use of a ventilator. Data from the Home Office's Forensic Early Warning System (FEWS) also confirmed cases of severe organ toxicity in the UK associated with 25I-NBOMe. A number of presentations also reported severe harms relating to the controlled Class A 2C-X type materials, 2CI and 2CT-7.

5. 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, NBOMe compounds and related substances were identified as having no legitimate industrial or medicinal use. The MHRA also confirmed that there are no marketing authorisations for medicines containing these compounds. One compound from the family being controlled, 25I-NBOMe, is currently used in laboratory research for positron emission tomography (PET) scans.

6. In light of the compelling evidence of health harms posing a serious threat, the ACMD recommended that NBOMe compounds and related substances should be subject to a temporary class drug order under the Misuse of Drugs Act 1971 (the 1971 Act). Temporary control measures for twelve months came into force on 10 June 2013.

7. In line with its statutory duties and the joint working protocol, the ACMD gathered further evidence while the temporary class drug order was in force, and has provided a full independent expert assessment of the harms of the listed compounds. The ACMD assessment confirmed the potential harms identified in its earlier advice and concluded that these compounds are drugs that are being, or are likely to be, misused, and that misuse is having, or is capable of having, harmful effects. The ACMD has recommended that this family of substances should be subject to permanent control under the 1971 Act as Class A drugs and placed in Schedule 1 to the Misuse

[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/261786/NBOMe_compounds_report.pdf

of Drugs Regulations 2001 as they have no known legitimate uses outside of research. Schedule 1 drugs are the most strictly controlled and can lawfully only be dealt with under a Home Office licence.

A.1.b Benzofuran compounds and related substances (from 2013 ACMD report[2])

8. Benzofuran compounds (5- and 6-APB – 1-(benzofuran-5-yl)-propan-2-amine and 1-(benzofuran-6-yl)-propan-2-amine – etc) and related substances , including 5-IT (2-(1*H*-Indol-5-yl)-1-methylethylamine) and 6-IT (2-(1*H*-Indol-6-yl)-1-methylethylamine) are phenethylamine-type materials, related to controlled Class A methylenedioxyphenethylamines such as ecstasy (MDMA) and 3, 4-methylenedioxyamphetamine (MDA). A number of these substances were subject to temporary control at the same time as the NBOMe compounds in June 2013. They are most commonly sold under the brand name 'Benzo Fury' and prior to temporary control were marketed as legal alternatives to ecstasy, available in the form of powders or tablets (referred to as "pellets" to circumvent current legislation). They are also mixed with other substances including controlled drugs and other new psychoactive substances. The temporary control also restricted use of substances derived from modifications of these compounds.

9. The ACMD assessed benzofuran compounds as probable alternatives to MDMA (ecstasy). Users have reported that the consumption of these substances can cause insomnia, increased heart rate and anxiety, with some users reporting MDMA like symptoms. Several deaths and hospitalisations in the UK have been associated with the use of these compounds. Research indicates that there is a potential risk of cardiac toxicity associated with the long-term use of 5- and 6-APB.

10. Following consultation with BIS, the MHRA and the chemical and pharmaceutical industry, the listed benzofuran compounds and related substances were identified as having no legitimate industrial or medicinal use, though there may be some limited use for research purposes and (albeit, very limited) scope following research activity for them to be used in the synthesis of non-controlled pharmaceuticals. The MHRA also confirms that there are no marketing authorisations for medicines containing these compounds.

11. The ACMD recommended that the listed benzofuran compounds and related substances should be subject to a temporary class drug order. The ACMD's assessment states that these compounds are drugs that are being, or are likely to be, misused, and that misuse is having, or is capable of having, harmful effects.

12. In line with its statutory duties and the joint working protocol, the ACMD has gathered further evidence during the operation of the temporary class drug order, and has provided a full independent expert assessment of the harms of the listed compounds. The ACMD assessment confirmed the potential harms identified in its earlier advice and concluded that these compounds are drugs that are being, or are likely to be, misused, and that misuse is having, or is capable of having, harmful effects. The ACMD has recommended that this family of substances should be subject to permanent control under the 1971 Act as Class B drugs and placed in Schedule 1 to the Misuse of Drugs Regulations 2001 as they have no known legitimate uses outside of research.

A.2 Groups Affected

13. The 'legal high' market ('head shops' and internet suppliers) selling these substances as 'legal high' branded products, UK law enforcement agencies and criminal justice system and members of the public, especially young people and young adults.

A.3 Consultation

Within Government

[2] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/261783/Benzofuran_compounds_report.pdf

14. The Home Office has consulted with the MHRA, BIS and the chemical/pharmaceutical industry. The Government is currently conducting a review into new psychoactive substances in order to enhance our legislative framework to control these substances[3].

Public Consultation

15. The Government has considered the recommendations of the ACMD.

B. Rationale

16. The misuse of drugs, including new psychoactive substances or so called "legal highs", imposes a high cost on society in terms of crime and health services. Consumption also imposes health costs on the users themselves. The substances being controlled have been assessed as dangerous or otherwise harmful and have no known legitimate uses outside of research. The market does not take into account the costs that misuse of these drugs imposes on society. Government intervention is therefore necessary to prevent the listed compounds from taking a foothold in the UK and to protect the public from their harmful effects.

C. Objectives

17. The policy objective is to reduce the risk of harm from new psychoactive substances in support of the Government's commitments. This is in line with the Government's overarching Drug Strategy to take a preventative, enforcement and recovery-based approach to drug-related issues supported by the available evidence and expert advice of the ACMD. Due to the ability of new psychoactive substance suppliers to rapidly market new drugs, it is essential for the Government to be vigilant and use the ACMD's ongoing reviews to assess new substances.

18. The measure is also an essential intervention to deliver the objectives of the cross government NPS Action Plan, published on 17 May 2012, which combines legislative measures alongside public health, prevention and international policy approaches to tackle new psychoactive substances.

19. A successful outcome will be a reduction in the demand for, availability of and misuse of these compounds and increased awareness of the harms of new psychoactive substances or so called "legal highs".

D. Options

20. Two options have been considered in respect of these substances:

    OPTION 1: Do nothing – allow the temporary control order to expire (June 2014) and remove restrictions on these substances.

    OPTION 2: Control and schedule the NBOMe and benzofuran compounds, and related substances, under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.

21. The Government's preferred option is **option 2** and is supported by the ACMD's further advice. The use of the 1971 Act and its Regulations to permanently control the listed substances provides the best means to reduce availability and potential harm to the public.

E. Appraisal (Costs and Benefits)

OPTION 2 – To control and schedule the NBOMe and benzofuran compounds and related substances

COSTS

[3] https://www.gov.uk/government/speeches/drugs-policy-review-into-new-psychoactive-substances

Business

22. The ACMD reports that intelligence from police and the Serious and Organised Crime Agency indicated that both NBOMe and benzofuran were available online and that NBOMe was being distributed in the UK in sizeable quantities. This report indicates that a permanent ban could impose substantial costs on businesses by preventing them from profiting from legitimate trade in these substances. However, there is very little data available on the size of the market. This is partly due to the fact that the substances have been subject to temporary control since June 2013. As such, it is not possible to make a robust estimate of the cost this measure will impose on businesses.

23. There is a possibility that the control of these substances will lead to substitutes being developed and appearing on the market. If this is the case, this measure may not impose substantial costs on businesses due to substitution.

24. 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.

Public Sector (enforcement agencies, CJS, regulators)

25. The law enforcement response to this measure would involve using intelligence to tackle supply and trade and disrupting criminal activities relating to these drugs. Since these activities are currently used to tackle other controlled drugs, any costs arising from option 2 will be subsumed into current law enforcement and regulatory activities. The law enforcement response will 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. As such, operational activity may focus on Class A and B drugs as well as new psychoactive substances.

Individuals and society

26. Private costs will be incurred by people who can no longer derive benefits from legitimate use of NBOMe and benzofuran compounds and their related substances. We are unable to monetise these costs.

BENEFITS

Business

27. No benefits are expected to accrue to businesses from this policy.

Public Sector (enforcement agencies, CJS, regulators)

28. The ACMD regards that the misuse of these substances is having, or is capable of having, harmful effects. As such, we assume that their misuse would impose substantial costs on the health service and that controlling their consumption would result in substantial savings. These savings cannot be quantified due to the novelty of the substances and of the challenges that they may pose to healthcare and treatment services.

29.

Individuals and society

30. Benefits to individuals arise from the protection against potential harms of the listed substances. Evidence suggests that the 25I-NBOMe compound was linked to a series of 7 serious non-fatal intoxication cases in January 2013.

NET EFFECT

31. Overall it is considered that the benefits from the proposals will outweigh the costs, although it has not been possible to quantify the net effect. While the permanent control of these substances may impose substantial costs on businesses seeking to sell them, restricting their misuse is expected to protect society from the harmful effects that they may have on health. This will result in benefits to public health and in public sector savings from reduced healthcare costs. As these drugs are considered to be substitutes for other controlled drugs (such as LSD and MDMA) and to have dangerous and potentially fatal side effects, it is reasonable to assume that there will be net benefits from permanent control.

32. The total net benefits cannot be quantified due to a lack of robust data but are believed to outweigh the costs. The Home Office will be seeking more evidence in general on the costs and benefits of new psychoactive substances during an upcoming review.

ONE-IN-TWO-OUT (OITO)

33. This proposal does not create new regulation. It is adding new drugs to an existing regulatory framework. This policy is therefore not in scope of one-in-two-out.

F. Risks

34. There are risks associated with option 2 on the basis of evidence and expert advice that the 'legal high' market will look to synthesise and advertise chemical derivatives of some of these or other controlled drugs, or alternative new psychoactive substances imitating their effects, to circumvent the control measures being implemented.

35. This risk is mitigated by the ACMD, which has a duty to review the situation in relation to both controlled and non-controlled drugs (including new psychoactive substances) and temporary class drugs.

36. There is a risk that there may be costs to the research sector. However, with the exception of one compound currently used outside the UK in animal research, there is no known legitimate use of these compounds. In respect of the 5- and 6-APB and related substances, there could be potential use for the synthesis of non-controlled pharmaceuticals. However, the use of these compounds is expected to be minimal, if at all, as there are other Class A substitute phenethylamines available for this research for which relevant organisations already possess a Schedule 1 licence. The cost of a licence is between £3,000 and £4,700[4]. In the unlikely event that a licence would be required for research into these drugs, the maximum cost imposed on any research organisation would be £4,700.

37. 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 face the costs of updating or applying for a license. However, organisations dealing with permanently controlled scheduled drugs are assumed to already possess a licence in order to undertake activities involving temporary class drugs.

G. Enforcement

38. Enforcement of the proposed legislation will be undertaken by police forces, the UK Border Force (UKBF), 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. The UKBF will enforce import controls by seizing suspected substances at the ports, also as part of their wider customs role.

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

H. Summary and Recommendations

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

Table H.1 Costs and Benefits		
Option	**Costs**	**Benefits**
2	Non-monetised costs to businesses and individuals who are no longer able to legitimately sell or purchase these substances.	Non-monetised benefits to the public sector from reduced health and crime costs associated with the use of these substances.

39. Option 2 is the preferred option. The harms associated with the use or misuse of these groups of compounds require Government to act swiftly through effective legislation to protect the public. There are benefits to be derived from implementing the proposal through a reduction in medical costs associated with the misuse of these drugs.

I. Implementation

40. The Government plans to implement these changes via an affirmative resolution Order, and subject to Parliamentary approval in May 2014.

J. Monitoring and Evaluation

41. As part of its statutory duties under the 1971 Act the ACMD keeps the situation relating to drugs under review. Together with the Government, they will continue to monitor the compounds being controlled by gathering data on their prevalence and misuse through UK and EU drugs early warning systems, the health sector and the regulatory framework governing legitimate activities (predominantly 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

42. Information gathered from the monitoring and evaluation process will inform future ACMD advice on classification/reclassification and rescheduling as well as health advice on these drugs.