



Home Office

**PROPOSED CONTROL OF
GAMMA-BUTYROLACTONE (GBL)
AND 1,4-BUTANEDIOL (1,4-BD)**

A consultation paper

21 May 2009

Introduction

1. The Government has decided that the control of Gamma-butyrolactone (GBL) and 1,4-butanediol (1,4-BD) is necessary to prevent their misuse. The purpose of this consultation paper is to draw attention to, and invite comments on, the options to control both GBL and 1,4-BD under the Misuse of Drugs Act 1971 or otherwise. In particular, the consultation provides industry and commerce the opportunity to set out to the Government the potential impacts of the different approaches and to inform the approach that Government takes forward.

2. This consultation has been prepared pursuant to the advice of the Advisory Council on the Misuse of Drugs (ACMD), the independent body established to advise the Government on drug misuse issues. **Responses should arrive no later than 13 August 2009.**

Misuse and harms of Gamma-butyrolactone and 1,4-butanediol

3. Gamma-butyrolactone (GBL) and 1,4-butanediol (1,4-BD) are precursor chemicals that have legitimate purposes but are also being misused as “drugs of misuse”. They are pro-drugs of gamma-hydroxybutyrate (GHB), meaning that when either substance is ingested it is rapidly converted to GHB. The effects and risks associated with the use of GBL and 1,4-butanediol are similar to those of GHB whose use is associated with unconsciousness, a risk of death by intoxication and a dependence syndrome if used regularly.

4. GHB has been controlled as a Class C drug under the Misuse of Drugs Act 1971 since July 2003 but, at present, there are no domestic controls that restrict or impose sanctions on the possession, supply or importation of GBL or 1,4-BD.

5. There has been concern that users of GHB are switching to GBL and 1,4-BD use as a consequence of GHB control under the 1971 Act. There are no firm baseline figures for GBL and 1,4-BD users. The evidence of use to date in the UK is limited. It appears to be generally isolated to the gay communities and clubbing scene rather than the wider community. However, in these communities there has been a small yet significant increase in presentations for treatment, though it is difficult to isolate those due to GBL and 1,4-BD misuse from that of GHB. As with GHB, GBL and 1,4-BD have the potential to be used in drug-facilitated sexual assault.

6. The Advisory Council on the Misuse of Drugs’ (ACMD) report which sets out a comprehensive assessment of GBL and 1,4-BD can be found at : <http://drugs.homeoffice.gov.uk/publication-search/acmd/report-on-gbl1>. The ACMD considers that the harms and misuse of GBL and 1,4-BD are commensurate with Class C of the Misuse of Drugs Act 1971 and classification in Schedule 1 to the Misuse of Drugs Regulations 2001 (having no recognised medicinal use). It has provisionally recommended that GBL and 1,4-BD be brought under control of the Misuse of Drugs Act and that licensing arrangements are made for their legitimate industrial use. This is one of the options set out below. In giving this advice, the ACMD called on the Government to consult in order to allow the Government to gauge the scale and scope of the use of GBL and to ensure that a control option is chosen that minimises the impact on industry.

The legitimate use of GBL and 1,4-BD

7. GBL and 1,4-BD as chemicals have a wide variety of legitimate uses, which have a reputation for being safe and environmentally friendly. As far as can be identified, they are not produced in the UK. However, both chemicals are imported and used in large volumes by the manufacturing industry and on a smaller scale by chemical distribution companies. The Chemical Business Association – which represents many of the companies that handle GBL and 1,4-BD – report that 1000 tons of GBL and 5000 tons of 1,4-BD are imported to the UK per year. The majority of this volume is used by a few large companies.

8. GBL is used as a solvent which is fully spent in some manufacturing processes and is not part of the end-product. It is also found as a component in the manufacture of various cleaning agents and paints where it remains part of the finished product. Similarly, 1,4-BD is used as a raw material in the production of plastics and rubber, but also as a solvent or binding agent in the manufacture of other products, for example paints and coatings.

Diversion sources

9. Many, but not all, of the companies that handle GBL and 1,4-BD in the UK are members of the Chemical Business Association (CBA) and enter into a voluntary code to safeguard health and safety within the industry, including diversion of potentially harmful chemicals. As the ACMD concluded, due to the large volumes of GBL and 1,4-BD handled by UK companies, small-scale diversion either by purchase or by theft from these legitimate sources remains a risk. The cornerstone for control will continue to be good co-operation between producers of, and traders in, such chemicals on the one hand and the authorities on the other.

10. GBL and 1,4-BD are available to the general public in retail products, in both a “pure form” or where they form part of the end product. Information on latest trends suggests that the source of supply in the UK for misuse is targeted at the small-scale consumer promotion via UK and non-UK internet sites.

EU Aspects

11. Unlike GHB, GBL and 1,4-BD are not controlled internationally. At an European level, they are included on the European Community's Voluntary Monitoring List of Non-Controlled Chemicals, which means that individual member states are required to provide industry with information and guidance on these substances. However, the Voluntary Monitoring List does not impose any legal obligations on industry. A number of EU countries have brought forward national legislation to control one or both precursors on the grounds of public health. Any option discussed below would be subject to ensuring compliance with EU law in this field .

Key questions for the consultation

- 1. Which model of control do you think provides the best protection to the public while balancing the needs of industry and commerce?**
- 2. What impact will the proposed methods of control have on you/your business?**

Proposal

The proposals have been developed by the Home Office. They are aimed at restricting the availability of GBL and 1,4-BD to legitimate use only. The Home Office has identified 3 options.

OPTION 1 : Bring GBL and 1,4-BD under control of the Misuse of Drugs Act 1971 as a Class C drug (and place in Schedule 1 to the Misuse of Drugs Regulations 2001 as having no medicinal purpose) prohibiting possession, supply, production and importation/exportation with no concession for legitimate use by industry.

12. This option has the advantage of clarity and provides the highest possible level of public protection for the UK. However, it would have the highest impact on industry, where it would necessitate finding alternative chemicals and removing otherwise legitimate products from the shop shelves, including those products where the GBL and 1,4-BD form part of the end product.

OPTION 2 : Bring GBL and 1,4-BD under control of the Misuse of Drugs Act 1971 as a Class C drug (and place in Schedule 1 to the Misuse of Drugs Regulations 2001 as having no medicinal purpose) prohibiting possession, supply, production and importation/exportation BUT subject to licensing regime for industrial use.

13. This is the provisional recommendation of the ACMD. It provides a balance between control and allowing use by industry but necessarily requiring the withdrawal of products where GBL and 1,4-BD are sold in a “pure form” or where they form part of the end product.

14. Companies that need to possess and/or supply GBL and 1,4-BD for legitimate use would require a “domestic licence” issued by the Home Office Drug Licensing and Compliance Unit. Similarly, those needing to import or export GBL and 1,4-BD would require an import or export licence (for every consignment). Both are easily available from the Home Office and applications can be made on-line. The Drug Licensing and Compliance Unit will undertake a “verification process” with the purpose of ensuring that the business of the company is legitimate and that the company is equipped to self-regulate with Standard Operating procedures (SOPs) in place and an understanding of the security issues. Companies will be under an obligation to advise on any changes to the business or adverse or suspicious incidents. The licences issued by the Home Office could also set out additional safe custody and record keeping requirements to help to minimise diversion.

15. Whilst this proposal would mitigate the impact on the industrial use of GBL and 1,4-BD, it would prohibit the sale of GBL and 1,4-BD of all products where they were in a “pure form” or in a form in which these chemicals form part of the end product. We anticipate that this might have cost implication and impact. In respect of the key questions raised above, we particularly need to identify the scale and value of the market of such products, including secondary sales by the major importers as well as smaller-scale distributors.

OPTION 3 : Banning possession and supply of GBL and 1,4-BD where they are intended for human use only.

16. This option, based on the US model, would enable the banning of possession and supply of these substances where they are intended for human use. The

offence could also be extended to production as well as imports and exports. It would avoid including legitimate businesses in the control regime, removing any licensing regime for the chemical industry, and would enable any products containing GBL and 1,4-BD to be available to the public but on the basis that the products were not sold for human consumption.

17. This legislative option would look to target the current trend of supply of sales via internet websites of amounts commensurate with human consumption and promoted as such. However, whilst this may have the desired impact, in bringing forward this option, we are mindful that the illicit market could divert and establish itself more in legitimate products. Equally, it is likely to be significantly harder to enforce this offence because of the difficulties in showing that the seller intended or believed that the drug would be consumed. This option would also make it more difficult to seize GBL where it was encountered at the border as HM Revenue & Customs would have to prove the intention of the importation.

Impact of options

18. A consultation stage impact assessment has been prepared in line with the options sets out above (see accompanying Annex).

Responding to this consultation

19. Implementation of the proposed changes will take place as early as possible, subject to comments received in response to this document, views of Ministers and the timescale for the parliamentary process. We would welcome any comments on the proposed measures and on the partial impact assessment in the Annex accompanying this document.

Circulation of Proposals and Consultation Responses

20. A copy of this letter and attachment is also available at <http://www.homeoffice.gov.uk/about-us/haveyoursay/current-consultations/> and www.drugs.gov.uk . You should contact the address given below (in paragraph 21) if you require a copy of this consultation paper in any other format, e.g. braille, large font, audio.

21. The Government would welcome your views on the proposals contained in this document. Please send written comments to:

Drug Legislation Section
Drug Strategy Unit
4th Floor, Peel
Home Office
2 Marsham Street
LONDON SW1P 4DF

or by email to : Drugconsultation2009@homeoffice.gsi.gov.uk .

22. **Comments must be received by 13 August 2009.**

23. A summary of responses will be published before or alongside any further action.

Responses: Confidentiality & Disclaimer

24. The information you send us may be passed to colleagues within the Home Office, the Government or related agencies. Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 [FOIA], the Data Protection Act 1998 [DPA] and the Environmental Information Regulations 2004).

25. If you want other information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

26. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

27. The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Government Code of Practice on Consultation

28. The Consultation follows the Government's Code of Practice on Consultation – the criteria for which are set out below:

Criterion 1 – When to consult – Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 – Duration of consultation exercises – Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 – Clarity of scope and impact – Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 – Accessibility of consultation exercises – Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 – The burden of consultation – Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 – Responsiveness of consultation exercises – Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 – Capacity to consult – Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

29. The full Code of Practice on Consultation is available at:
<http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html> .

Consultation Co-ordinator

30. If you have a complaint or comment about the Home Office's approach to consultation, you should contact the Home Office Consultation Co-ordinator, Nigel Lawrence. Please **DO NOT** send your response to this consultation to Nigel Lawrence. The Co-ordinator works to promote best practice standards set by the Government's Code of Practice, advises policy teams on how to conduct consultations and investigates complaints made against the Home Office. He does not process your response to this consultation.

31. The Co-ordinator can be emailed at:
Nigel.Lawrence@homeoffice.gsi.gov.uk or alternatively you can write to him at:

Nigel Lawrence, Consultation Co-ordinator
Home Office
Performance and Delivery Unit
Better Regulation Team
3rd Floor Seacole
2 Marsham Street
London
SW1P 4DF

Summary: Intervention & Options		
Department /Agency: Home Office	Title: Impact Assessment of Proposed Changes to the Misuse of Drugs Legislation	
Stage: Consultation	Version:	Date: 21 May 2009
Related Publications:		

Available to view or download at:

<http://www.homeoffice.gov.uk/about-us/haveyoursay/current-consultations/>

Contact for enquiries: Angela Scrutton

Telephone: 020 7035 0458

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

GBL and 1,4-butanediol (1,4-BD) are drugs of misuse. They are pro-drugs of gamma-hydroxybutyrate (GHB). When either substance is ingested it is rapidly converted to GHB. The effects and risks are similar to those of GHB whose use is associated with unconsciousness, a risk of death by intoxication and a dependence syndrome if used regularly. Although GHB has been controlled under the Misuse of Drugs Act 1971 since July 2003, GBL/ 1,4-BD are not controlled.

What are the policy objectives and the intended effects?

To restrict the use of GBL and 1,4-BD for personal consumption by one of the three options outlined below, thereby reducing the personal and social costs of misuse.

What policy options have been considered? Please justify any preferred option.

Option 1- Bring GBL/1,4-BD under control of the Misuse of Drugs Act 1971 as a Class C drug with no concession for legitimate use by industry.

Option 2- Bring GBL/1,4-BD under control of the Misuse of Drugs Act 1971 as a Class C drug BUT subject to licensing regulation.

Option 3- Ban possession and supply of GBL and 1,4-BD where they are intended for human use only.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? At an appropriate future date.

Ministerial Sign-off For consultation stage Impact Assessments:

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:

..... Date:

Summary: Analysis & Evidence

Policy Option:

Description:

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups' Will be informed by consultation
	One-off	Yr	
	£ Unknown		
	Average Annual Cost		
	£ Unknown		Total Cost (PV)
Other key non-monetised costs by 'main affected groups' Will be informed by consultation			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups' Will be informed by consultation
	One-off	Yr	
	£ Unknown		
	Average	Annual	
	£ Unknown		Total Benefit (PV)
Other key non-monetised benefits by 'main affected groups' Will be informed by consultation			

Key Assumptions/Sensitivities/Risks Will be informed by consultation

Price Base	Time Period	Net Benefit Range (NPV) £ Unknown	NET BENEFIT (NPV Best estimate) £ Unknown
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What is the geographic coverage of the policy/option?	UK
On what date will the policy be implemented?	To be decided
Which organisation(s) will enforce the policy?	Home Office
What is the total annual cost of enforcement for these	£ Unknown
Does enforcement comply with Hampton principles?	Yes/No

Will implementation go beyond minimum EU requirements?		Yes/No		
What is the value of the proposed offsetting measure per		£ Unknown		
What is the value of changes in greenhouse gas emissions?		£ Unknown		
Will the proposal have a significant impact on competition?		Yes/No		
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	Yes/No	Yes/No	N/A	N/A
Impact on Admin Burdens Baseline (2005 Prices)		(Increase - Decrease)		
Increase	£ Unknown	Decreases	£ Unknown	Net
				£ Unknown
Evidence Base (for summary sheets)				

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

This is a partial Impact Assessment forming the first step in identifying costs and benefits of the proposals set out in the consultation paper to make changes to the Misuse of Drugs legislation. This is a continuous process and respondents are invited to submit any figures, costing or other details of relevance to help refine the final stage regulatory impact assessment.

Rationale for Intervention

GBL and 1,4-butanediol (1,4-BD) are drugs of misuse. They are pro-drugs of gamma-hydroxybutyrate (GHB), meaning that when either substance is ingested it is rapidly converted to GHB.

The effects and risks associated with the use of GBL and 1,4-butanediol are similar to those of GHB whose use is associated with unconsciousness, a risk of death by intoxication and a dependence syndrome if used regularly.

GHB has been controlled as a Class C drug under the Misuse of Drugs Act 1971 since July 2003 but, at present, there are no domestic controls that restrict or impose sanctions on the possession, supply or importation of GBL or 1,4-BD.

There has been concern that users of GHB are switching to GBL and 1,4-BD use as a consequence of GHB control under the 1971 Act. There are no firm baseline figures for GBL and 1,4-BD users. The evidence of use to date in the UK is limited but appears to be generally isolated to the gay communities and clubbing scene rather than the wider community. However, in these communities there has been a small yet significant increase in presentations for treatment, though it is difficult to isolate those due to GBL and 1,4-BD misuse from that of GHB. As with GHB, GBL and 1,4-BD have the potential to be used in drug-facilitated sexual assault, but there is no evidence to date to support this.

However, there is evidence that this situation is being exploited by suppliers and users alike and that a market for GBL and 1,4-BD has been established as shown through importation seizure evidence and the promotion of sales via UK and non-UK internet sites. There is also the

possibility that there is some diversion from legitimate suppliers who use GBL and 1,4-BD for legitimate purposes.

Objective

To restrict the use of GBL and 1,4-BD for personal consumption by one of the three options outlined below, thereby reducing the personal and social costs of misuse.

Appraisal

OPTION 1 : Bring GBL/1,4-BD under control of the Misuse of Drugs Act 1971 as a Class C drug (Schedule 1 as having no medicinal purpose) prohibiting possession, supply, production and importation/exportation with no concession for legitimate use by industry.

Description:

Option 1 is effectively a complete ban on the possession and use of GBL/1,4-BD and related products.

The costs to industry associated with this option might include the costs of switching to GBL/1,4-BD substitutes and/or the loss of sales of products in which they are used. Other costs would include the public costs of effectively policing a ban both in locations where GBL/1,4-BD are frequently used and in terms of customs control.

The benefits of an outright ban could be quantified as the reduction in the social and economic costs associated with continued misuse of GBL/1,4-BD. Of the three options, an outright ban might be expected to reduce this cost by the largest amount, as it would make misuse most difficult.

The size of the costs and benefits is likely to depend on the following:

Costs

1) Industry costs relating to the products for which GBL and 1,4-BD are key manufacturing components. Information to be considered:

- GBL and 1,4-BD import figures.
- The products in which these are used and the sales revenue these generate.
- The availability and cost of a suitable substitute.
- The costs involved with switching to a substitute.
- Details of distribution networks associated with these products.

2) Compliance/Administration costs for industry. Information required:

- Costs associated with the removal of current products which would become illegal.
- Any other administration/compliance costs.
- The number of companies affected.

3) Enforcement costs relating to policing, customs etc. Information required:

- The scale of GBL/1,4-BD misuse.
- The cost of enforcing a domestic personal use ban.
- The cost of enforcing an import/export ban.

4) Additional costs not included above.

Benefits

1) Benefits associated with decreased misuse. Information to be considered:

- The scale of misuse.
- The social and economic cost of GBL/1,4-BD misuse.

- The ease with which personal users could switch to an alternative drug incurring similar societal costs.
- SUMMARY: The reduction in misuse resulting from option 1.

OPTION 2: Bring GBL/1,4-BD under control of the Misuse of Drugs Act 1971 as a Class C drug (Schedule 1 as having no medicinal purpose) prohibiting possession, supply, production and importation/exportation BUT subject to licensing regime for industrial use.

Description:

Option 2 is the same as Option 1 but with the addition of a licensing system to allow legitimate uses of GBL/1,4-BD to continue.

The costs to industry could be expected to be less than Option 1 because the majority of GBL/1,4-BD usage would be able to continue under licensing, so sales revenue loss ought to be minimal. The only extra costs incurred would be the administration time required for compliance with the licensing process, which should be almost negligible. Enforcement costs may also be less as imports would remain legal provided they were for legitimate industrial use.

The benefits of Option 2 are likely to be less than Option 1 due to the possibility of individuals extracting GBL/1,4-BD from legitimate/licensed products for personal use and the danger of part or all of legitimate imports being siphoned off for personal use.

The size of the costs and benefits is likely to depend on the following:

Costs

1) Industry costs relating to products. Additional information to be considered:

- The volume of products in which GBL and 1,4-BD are sold in pure form or where they form part of the end product.

2) Compliance/ Administration costs for industry, particularly the licensing costs both for domestic manufacture/distribution and import/export. Information to be considered:

- The number of companies affected.
- The cost of administrative time required to fulfil licence obligations.
- Any other costs associated with licensing.

3) Enforcement costs. Information required:

- The cost of enforcing the licensing system.

4) Additional costs not included above.

Benefits

1) Benefits associated with decreased misuse. Additional information required:

- The risk of divergence from legitimate industrial use – that is, the ease with which GBL/1,4-BD could be obtained from licensed products.
- The risk associated with siphoning off legitimate imports for personal use.
- SUMMARY: By how much would social and economic costs be reduced from Option 2.

Option 3 ; Banning possession and supply of GBL and 1,4-BD where they are intended for human use only.

Description:

Option 3 removes any onus from industry and simply makes it illegal to possess or supply GBL/1,4-BD for personal consumption.

The costs to industry could be expected to be less than for Options 1 and 2 because products and sales would be completely unaffected, with the exception of sales that buyers intend for personal consumption. The only cost therefore might be the use of labelling or other warning devices to ensure their products are not used for personal consumption.

Enforcement costs would be likely to increase with Option 3, however, as policing a drug that would be effectively legally available and importable may be more costly.

The benefits of Option 3 are likely to be less than for Options 1 and 2 due to the increased possibility of divergence from legitimate products and the continued availability of almost pure GBL/1,4-BD products.

The size of the costs and benefits is likely to depend on the following:

Costs

1) Industry costs relating to products. Additional information to be considered:

- The volume of UK sales for human use only.

2) Compliance/ Administration costs for industry. Information to be considered:

- The number of companies affected.
- The cost of labelling or other information provision to ensure products are not intended for human use.

3) Enforcement costs. Information to be considered:

- The additional enforcement costs associated with distinguishing between legitimate and illegitimate possession and distribution.

4) Additional costs not included above.

Benefits

1) Benefits associated with decreased misuse. Additional information required:

- The additional risk of divergence from legitimate products.
- The deterrent effect of labelling/information provision.
- SUMMARY: By how much would social and economic costs be reduced by Option 3.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	Yes/No	Yes/No
Small Firms Impact Test	Yes/No	Yes/No
Legal Aid	Yes/No	Yes/No
Sustainable Development	Yes/No	Yes/No
Carbon Assessment	Yes/No	Yes/No
Other Environment	Yes/No	Yes/No
Health Impact Assessment	Yes/No	Yes/No
Race Equality	Yes/No	Yes/No
Disability Equality	Yes/No	Yes/No
Gender Equality	Yes/No	Yes/No
Human Rights	Yes/No	Yes/No
Rural Proofing	Yes/No	Yes/No

Annexes

The Advisory Council on the Misuse of Drugs' Report GBL & 1,4-BD: Assessment of Risk to the Individual and Communities in the UK. (see <http://drugs.homeoffice.gov.uk/publication-search/acmd/report-on-gbl1> .