

**SUMMARY OF RESPONSES TO THE HOME
OFFICE CONSULTATION PAPER,
“PROPOSED CONTROL OF GAMMA-
BUTYROLACTONE (GBL) AND 1,4-
BUTANEDIOL (1,4-BD)”**

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CONTENTS

Introduction.....	3-4
Summary of Responses.....	5-10
Other Relevant Information.....	11
Outcome and Progress of the Proposal.....	12
List of Respondees.....	13

INTRODUCTION

1. On 21 May 2009, the Home Office published a consultation paper, "Proposed control of Gamma-Butyrolactone (GBL) and 1,4-Butanediol (1,4-BD)", seeking views on the Government's proposals for GBL and 1,4-BD to be controlled under the Misuse of Drugs Act 1971 and its associated subordinate legislation. The proposals were prepared in consultation with, and on the advice of, the ACMD. The consultation period closed on 13 August 2009. 35 submissions ranging from the UK chemical industry, to the police, to the healthcare sector were received.

GBL and 1,4-BD

2. GBL and 1,4-BD are precursor chemicals that have legitimate purposes but are also being misused. 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-BD 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.
3. GHB has been controlled as a Class C drug under Misuse of Drugs Act 1971 since 1 July 2003. However, there have previously been no controls that restrict or impose sanctions on the possession, supply or importation of GBL or 1,4-BD.
4. In January 2006, the then Home Secretary asked the ACMD to consider the issue of Drug Facilitated Sexual Assault. As a result of its findings, the ACMD undertook a specific examination of the harms of GBL and 1,4-BD and measures to restrict their availability to prevent misuse. The ACMD found that GBL was increasingly being used as a legal substitute for GHB, which has been cited in cases of date-rape.
5. In its 2008 Report, "GBL & 1,4-BD: Assessment of the Risk to the Individual and Communities in the UK" - see <http://drugs.homeoffice.gov.uk/publication-search/acmd/report-on-gbl1?view=Binary> - the ACMD made a provisional recommendation that GBL and 1,4-BD are brought under control of the Misuse of Drugs Act 1971 as Class C (and Schedule 1 of the Misuse of Drugs Regulations 2001 as having no recognised medicinal use) with a licensing arrangement for legitimate industrial use. Conscious of the potential impact of control upon legitimate use, the ACMD recommended that the Government specifically consulted to assess this impact.
6. The consultation paper outlined three potential measures for control:

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.

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.

***OPTION 3: Banning possession and supply of GBL and 1,4-BD where they are intended for human use only.
(The offence could be extended to production as well as importation and exportation).***

7. This document summarises the 35 responses received.

SUMMARY OF RESPONSES

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.

Overall

8. This was the option least favoured by the UK chemical industry, with a general consensus that this option would be very damaging, imposing significant financial hardship on them. There was little or no support from other respondents either.

Specific Responses

9. The Cefic BDO & Derivatives Sector Group of the European Chemical Industry Council provided details of the size of worldwide production of GBL and 1,4-BD. The estimated annual production capacity for GBL is 200,000 tonnes, with the European Union accounting for 50,000 tonnes. The estimated annual production capacity for 1,4-BD is 1,900,000 tonnes with 3 European producers manufacturing 500,000 tonnes.
10. It reports that there is no economically viable way in which these chemicals could be easily substituted by other chemicals. They conclude that if these chemicals were banned in the UK, the probable outcome would be a shift of some manufacturing processes to other countries where the chemicals would still be available and available for illicit import into the UK.
11. The UK Chemical Business and Chemical Industries Associations considered that prohibiting GBL and 1,4-BD, with no clear evidence of diversion of them from the UK chemical supply chain was unjustified. They also considered that the consequences of prohibiting possession would result in a costly process to determine if alternative chemicals are viable or could result in the closing down of production of sites that use or convert these substances in the UK, in favour of non-regulated countries.
12. Their responses provide 4 examples where GBL and 1,4-B-D are used in the UK - ranging from use as a process intermediate, use in coating applications, use as a reagent in the manufacture of a chemotherapy drug and as a reaction solvent used in a large UK petrochemical plant – and describe the potential impact of this option. They suggest that it is almost impossible to calculate a monetary value from all the potential losses that a ban would impose but estimate that it could result in a cost to the UK industry and society of tens of millions of pounds per annum, more particularly if production facilities had to be closed with employment and financial consequences.

13. Various other industry associations and individual companies endorsed this position. The British Coatings Federation, representing 100 member companies and a £2.5 billion value industry, advised that this option would have significant impact on the UK coating industry, where GBL-containing coatings are a significant proportion of sales, placing it at a significant disadvantage to overseas companies. Similarly ESMA, which represents manufacturers of materials for the specialist printing industry, note that option 1 will in effect mean that UK manufacturers will suffer competitive disadvantage, since they will be unable to supply to the European market, whereas there will be no such restriction imposed on European manufacturers outside of the UK.
14. Picon, which represents a wide range of companies that supply the printing industry, points out that if this option is implemented then there would need to be a substantial period of time for industry to review alternative chemicals to replace GBL taking into consideration the toxicology impact upon operatives using the alternative chemicals. There would also be an adverse effect upon the environment because all known alternatives would have a detrimental impact upon climate change and the UK commitments on this issue.

Summary

15. In summary the key objections to option 1 are :
 - a. Significant financial hardship to the UK chemical industry (estimated by them to be tens of millions of pounds per annum), with potential for wider costs, more particularly if production facilities had to be closed with employment and financial consequences;
 - b. UK chemical industry would be at a competitive disadvantage in EU and wider world markets;
 - c. Conflict with the goal of “harmonisation” within the European/global chemical industry;
 - d. No – or no readily available - alternative for either chemical with GBL a more favourable environmental toxicity rating compared to other solvent materials; and
 - e. Other chemical materials with a narcotic effect are not generally banned by the UK chemical industry and so they would be unfairly penalised with no clear evidence of diversion of them from the UK chemical supply chain.

OPTION 2: Bring GBL and 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.

Overall

16. Whilst the UK chemical industry considered this to be a better proposal than option 1, they did raise several significant concerns.

Specific Responses

17. The UK Chemical Business and Chemical Industries Associations consider that this will introduce an unnecessary level of bureaucracy relating to import and export of these substances, which will incur additional costs and liability for those who handle these substances for bona fide purposes. Further, they consider that different licensing or registration systems in different markets make life complicated for multinational chemical companies operating in Europe; if the UK was to adopt a unique set of requirements then it would make the UK a less attractive place to do business. Finally, they consider that a licensing system that imposes extra costs on business would do nothing to stop “rogue trading” on the internet.
18. The Cefic BDO & Derivatives Sector Group also draw attention to their concern that the drug control licensing regime which generally licenses drugs for pharmaceutical use in kilogrammes or less quantities does not lend itself easily to the industrial accounting process which deals with large tonne quantities and so cannot assure stringent controls of kilogramme quantities in the same way that is required ordinarily by drug licensing control.
19. Picon advise that there are a substantial number of products sold by this industry that contain GBL. Any controls necessitating the withdrawal of these products would have a major adverse impact upon this industry resulting in the loss of potentially Euros 50 million. There would also be the added cost of disposal of products already manufactured and in the distribution chain. Further, the use of GBL in printing cleaning products gives advantages that alternative solvents will not provide. If this option was adopted, it calls for industry products in which GBL is only part of the product being sold should be excluded since the extraction of GBL from their products would prove extremely difficult.
20. ESMA notes that the licensing scheme would only allow in-house industrial use and that this regime would favour some UK industries and would unfairly disadvantage others sectors.
21. The Cosmetic, Toiletry and Perfumery Association, which represents the 85% UK cosmetic industry, advise that GBL is used as both a

22. Though the British Coatings Federation did not favour this option they thought it was workable but subject to further clarification of the licensing regime and costs of administering the licence. It also asks whether a lower concentration limit, below which a product need not be licensed, could be considered. The ukcpi (UK Cleaning Products Industry Association) favoured this option – but subject to the clarification on the term “end product” to allow for business to business transaction of their products to continue and for a “de minimis” exemption included as it was not possible to guarantee an end product will be absolutely free of GBL.
23. Option 2 is supported by ACPO (though no further detail is provided in their response) and ACPOS. ACPOS, whilst acknowledging cost to industry, state that for the criminal justice system this option offers a greater degree of public protection than option 3. Further, ACPOS recognises that there are continued legitimate uses for GBL and option 2 would allow legitimate businesses to continue to function.
24. Community Pharmacy Scotland supported option 2 as a measure in the public interest, with licensing minimising the risk of diversion. The BMA, Royal College of Physicians and PharMAG also believe that this option is a proportionate response. Aberdeen City Alcohol & Drug Partnership considered that option 2 ensured clarity and consistency in the control of these substances, including for law enforcement purposes, and promotion of the dangers and risks of these substances to the general population.
25. Dialdruglink call for option 2, as young people often equate “legal” with “safe” and do not always understand that a “legal high” carries equal or more risk as illicit drugs. Dialdruglink support good information and making it plain that it is illegal for human use. South Ayrshire Community Planning Partnership supported option 2 or option 3 (below) as a public health measure.
26. One individual response supported option 2 reasoning that GBL should be treated on the same basis as GHB and called for the withdrawal of products containing GBL from the high street. It called for consideration of the human, social and economic costs to be fully taken into account.

Summary

27. The UK chemical industry and others raised the following concerns that:

- a. The sheer quantities of both GBL and 1,4-BD traded internationally make this option extremely difficult to achieve in practice;
- b. A licensing system imposes an unnecessary level of bureaucracy and additional costs for those that handle them for legitimate purposes;
- c. If the UK adopted a unique set of requirements, then it would make the UK a less attractive place to do business;
- d. Impact costs with the removal of products containing GBL was estimated:
 - i. by the Printing industry at potentially 50 million Euros of trade; and
 - ii. by the Cosmetic industry, where GBL is used as both a fragrance ingredient and a vital ingredient in nail enamel remover pads, wipes and sponges, at millions per year.
- e. Our drug control licensing system does not lend itself easily to industrial accounting process which deals with large tonne quantities; and
- f. In any event, such a licensing regime would fail to “stop rogue trading on the internet”.

OPTION 3: Banning possession and supply of GBL and 1,4-BD where they are intended for human use only.
(The offence could be extended to production as well as importation and exportation).

Overall

28. This option was most favoured by industry.

Specific Responses

29. Each of the responses from industry recognised their responsibilities and there was a commitment to help ensure that these chemicals were used for legitimate industrial purposes only. The industry had adopted voluntary Codes of Practice with regard to GBL in 1999 to prevent misuse. More recently these had been extended to 1,4-BD. These voluntary control measures lay down specific handling procedures. Picon state that a previous similar voluntary scheme was applied to Methyl Ethyl Ketone and Acetone to prevent use as precursors in drug production.

30. The UK Chemical Business and Chemical Industries Associations' response calls for the better policing by Health & Safety Executive and Local Government Trading Standards Officers of existing legal requirements (via user safety data, warning labels on packaging and only sales to know customers) and addition of denaturants in non-medicinal consumer products as more appropriate routes of action.
31. The Cosmetic, Toiletry and Perfumery Association was concerned that option 3 would also impact on the legitimate availability of their members products as their products are of course sold for human use (though not ingestion).
32. Whilst the Scottish Government supported option 2 and the ACMD's position in principle, it recognised that the impact of this option could be considerable and that option 3 at this time would seem to be the most logical response. This is partly because option 2 would mean that a number of everyday products would effectively be removed from the shelves and because there is not comparable substitute readily available. The Scottish Government intend to monitor the situation in Scotland and wish to explore alternative measures.

Summary

33. This option was supported by industry because:
 - a. Taken in conjunction with its own self-regulating controls, this option facilitates the legal, responsible use of GBL and 1,4-BD within the UK chemical industry without unrealistic controls amid reports of small quantities of GBL and creation of trade barriers; and
 - b. It was recognised that this option would enable the authorities to prosecute illicit dealing to give better protection to the public and help to prevent misuse.

OTHER RELEVANT INFORMATION

34. The UK Chemical Business and Chemical Industries Associations' response draws an analogue with the multi-layered approach to the control of ethanol, which is also widely used as an industrial intermediate chemical. It advises that industry trades freely in ethanol without restriction but as soon as ethanol-based products become available to the consumer market, then taxation, licensing and denaturants are introduced. It is therefore possible to operate two tier (industrial and consumer) solutions, rather than single solutions to stop misuse.
35. Representations were also received that the EU as a whole should look at increasing controls for these two chemicals to ensure a pan European response. This is because, at present, GBL and 1,4-BD are not controlled internationally. At a 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.
36. One submission was received from Baxenden, a Chemtura company, which highlighted the situation in USA, stating that the misuse is limited to a very small population. This company supported option 3.
37. A handful of responses, including Releases', were received questioning any legislative intervention and proposed criminalisation of users and the impact with new legal drugs being developed, which are potentially more dangerous than GBL and 1,4-BD.
40. We received a few responses supporting the control of GBL as a result of personal experiences with the drug.

OUTCOME AND PROGRESS OF THE PROPOSAL

38. In light of the 35 responses to the consultation, in particular those from the UK chemical industry, the Government proposes, subject to parliamentary approval, that GBL and 1,4-BD should be controlled under the Misuse of Drugs Act 1971 as Class C drugs prohibiting possession, supply, production and importation/exportation where they are intended for human ingestion only. The penalties will be up to two years in prison, or an unlimited fine, or both, for possession for the purposes of human ingestion, and up to 14 years in prison, or an unlimited fine, or both, for dealing where the drug is intended for ingestion.
39. It is the Government's assessment from the submissions that the impact of a greater level of control over and above the offence of human ingestion – with industry acting under a licensing regime but with the withdrawal of consumer products containing these chemicals, which would have considerable financial impact, potentially millions – is not a justified or proportionate step at this time. Further, in the light of this evidence of limited misuse, this option has not been adopted. We will continue to monitor the situation, including the impact of this level of control in preventing misuse.
40. Having re-consulted ACMD – see at <http://drugs.homeoffice.gov.uk/publication-search/acmd/gbl-consultation-letter?view=Binary> - they are generally supportive of this approach. Whilst they would like to see parity of legislation between GBL and GHB, which is already a Class C drug, they recognise that the Government has had to take a “pragmatic approach”.
41. There are a number of non-legislative steps we can pursue with industry to combat diversion and misuse. For instance, we will look at ways in which the existing voluntary industry codes of practice can be strengthened and at other regulatory controls, such as appropriate labelling and packaging enforced by the Health and Safety Executive.
42. The Government is committed to raising awareness about the harms of these drugs, more particularly when taken with alcohol. One of the key strands of the 2008-2018 drug strategy is public information, communications and community engagement. Frank launched a “legal highs” campaign in September, known as the “Crazy Chemist”, to warn “clubbers” and students going clubbing of the harms of “legal highs” during freshers’ week. The campaign consists of the distribution of leaflets, posters and wristbands in nightclubs across England, digital activity and a partnership with Mixmag, the leading magazine for the “clubbing” industry. The campaign signposts people to www.talktofrank.com where they can find out more information about the risks and effects of legal highs.

LIST OF RESPONDEES

Organisations

1. Aberdeen City Alcohol & Drug Partnership
2. The Association of Chief Police Officers for England, Wales and Northern Ireland
3. The Association of Chief Police Officers in Scotland
4. BASF The Chemical Company
5. Baxenden, a Chemutra Company
6. BEMA – British Essence Manufacturers' Association
7. British Coatings Federation Ltd
8. British Medical Association
9. Cefic BDO & Derivatives Sector
10. Chemical Business Association and Chemical Industries Association (Joint Response)
11. Community Pharmacy Scotland
12. The Cosmetic Toiletry & Perfumery Association Ltd
13. Cranston (Glow Project)
14. Crew 2000
15. Department of Health and Social Care (Drug Referral Team), Edinburgh
16. Dialdruglink
17. Dow Chemical Company (Deutschland)
18. Fujifilm Sericol UK Limited and ESMA Health & Safety Committee
19. INCITE, Aberdeenshire
20. Lyondellbasell
21. PharmMAG
22. Picon – Printing Industry Confederation
23. Release
24. Royal College of Obstetricians and Gynaecologists
25. Royal College of Physicians
26. Schloetter Plating Technology
27. The Scottish Government
28. South Ayrshire Community Planning Partnership
29. Subterra (Pipeline Rehabilitation)
30. UK Border Agency
31. ukcpi – UK Cleaning Products Industry Association
32. Welsh Pharmaceutical Committee of the Welsh Assembly Government

Other Responses

31-35. Individual responses.