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Division of Dockets Management (HFA-305)
Food and Drug Administration
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Re: "International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; AH-7921; Gamma-Butyrolactone; 1,4-Butanediol; Ketamine; 9 Additional Substances; Request for Comments," 80 Fed. Reg. 4283 (January 27, 2015), FDA Docket No. FDA-2015-N-0045

To Whom It May Concern:

The Semiconductor Industry Association ("SIA") submits these comments in response to the request of the Food and Drug Administration ("FDA") for input to help inform the position of the United States Government on the recommendation of the World Health Organization ("WHO") to the United Nations Commission on Narcotic Drugs ("CND") to list gamma-butyrolactone ("GBL") and 1,4-butanediol ("BDO") under Schedule I of the 1971 United Nations Convention on Psychotropic Substances ("Psychotropic Convention"). We very much appreciate this opportunity to provide information and comments on this WHO recommendation in advance of its consideration by the CND at its upcoming meeting in Vienna on March 9-17, 2015.

SIA strongly urges the U.S. Government ("USG") to oppose the listing of GBL and BDO as psychotropic substances under the Psychotropic Convention. Moreover, we urge the USG to engage actively with other members of the CND to ensure that these substances are not listed.

As discussed below, both GBL and BDO are ubiquitous and legitimate industrial chemicals that are vital to the semiconductor industry, and thus ultimately to all the other industries that utilize semiconductor products, including the electronics, telecommunications, machinery, transport, aerospace, and defense sectors. Although we recognize that there are legitimate concerns about the potential diversion of these chemicals to illicit uses under certain circumstances, there is no meaningful potential for diversion within the semiconductor industry. Nevertheless, a Schedule I-listing would effectively prohibit use of these chemicals in the semiconductor industry, as well as in many other industries that use GBL and/or BDO for legitimate purposes. Listing under other Schedules would similarly be extremely problematic. Such onerous results are unnecessary, since there are other mechanisms besides listing under the Psychotropic Convention that can be and are being used, by the governments of the U.S. and several other countries, to effectively protect against diversion of GBL and BDO.

For these reasons, which are elaborated on below, listing is not appropriate for these two chemicals. Indeed, the Critical Review Reports prepared and submitted to the WHO Expert Committee on Drug Dependence ("ECDD") concluded that "controlling [GBL or BDO] as a psychotropic substance ... would not likely result in benefits sufficient to justify the burdens such

controls would impose.” See WHO Secretariat, Critical Review Reports for [GBL](#) at 7, and for [BDO](#) at 7 (June 2014). Moreover, the U.S. Government recently stated to WHO that GBL and BDO “should not be considered for control under the 1971 Convention.” See [USG Response to WHO Questionnaire for Review of Dependence-Producing Psychoactive Substances for the Thirty-sixth Expert Committee Meeting on Drug Dependence](#) at pages 11 (GBL) and 14 (BDO).

Under the Convention, the CND has wide discretion to depart from the WHO’s recommendations – after taking due account of the WHO’s conclusions on medical and scientific issues – in light of relevant socio-economic impacts and other factors. See Article 2.5. SIA urges the USG to maintain its position on these substances at the upcoming CND meeting, and otherwise to work actively to ensure that these two essential chemicals are not listed under the Psychotropic Convention.

Background on SIA

SIA is a membership organization of U.S. companies that manufacture and design semiconductors, accounting for over 80 percent of the semiconductor production of this country. We promote policies and regulations that fuel innovation, propel business, and drive international competition in order to maintain a thriving semiconductor industry. Semiconductors are the micro-circuits (sometimes referred to as “chips” or “computer chips”) that are the enabling technology for all modern electronics found in computers and cell phones, transportation and health care devices, information and communications systems, and numerous aspects of our national defense. Because semiconductors are a foundational technology for virtually all areas of our economy, continued U.S. leadership in semiconductor technology is essential to America’s continued global economic leadership and our national security. Semiconductors are one of the nation’s top exports, and the industry directly employs about 250,000 employees and supports over 1 million indirect jobs. Additional information on SIA is available at www.semiconductors.org.

Vital Importance of GBL and BDO to the Semiconductor Industry

GBL and BDO are of critical importance to the semiconductor industry, in a number of different ways. GBL is of particular importance as a key ingredient in several chemical formulations used in photolithography, which is the main process by which microscopic circuits are printed onto a substrate material to create semiconductor products. More specifically, GBL is present in concentrations ranging from 1% to 70% in the following photolithography formulations:

- photoresists;
- antireflective coatings;
- polyimide;
- photosensitive polyimide developers;
- chemical shrinks;
- metal hard masks;
- edge bead removal reagents;
- photoresist strippers; and
- polyimide adhesives.

GBL is vital to all of these formulations because of its unique combination of physical and chemical properties, such as solubility, stability, flash point, drying rate, ability to form uniform films, and compatibility with other chemicals and machinery used in the photolithography process.

There are no alternatives to GBL currently available. Future replacement of GBL – if possible, which is not clear – could take over a decade and substantial investment to complete, due to the difficulty and time needed for (a) identifying a potential substitute, (b) developing new chemical formulations, (c) testing to ensure such formulations would be compatible with a variety of existing manufacturing processes, (d) making sure the new formulations would not adversely affect the quality of semiconductor products, and (e) developing supply chains for manufacture and distribution of the new formulations that would be able to ensure timely delivery of sufficient quantities of high-quality formulations to facilities throughout the world.

BDO is generally not used directly by the semiconductor industry, but is still of vital importance because it is an essential precursor to the production of GBL in the chemical industry. See, e.g., Critical Review Report for BDO at 20 (“Sizable quantities of 1,4-BD are ... used to make gamma-butyrolactone, which has outlets in electronics”). Any disruption in the supply of BDO, therefore, would also result in a similar interruption in the supply of GBL.

GBL is also used within the chemical industry as an intermediate to produce n-methyl pyrrolidone (“NMP”), which is another chemical used extensively by the semiconductor industry, for example as an ingredient in cleaners for silicon wafers and in photoresist strippers. See, e.g., Critical Review Report for GBL at 15 (“one significant use of GBL is as an intermediate in the manufacture of pyrrolidones, which are widely used industrial chemicals”). This is yet another way that GBL, and BDO as an industrial precursor to GBL, are of critical importance to the semiconductor industry.

Finally, GBL is present as an important constituent in some batteries and other electrical components that are frequently used in conjunction with semiconductor products. It is commonly used in the electrolytes for lithium-carbon monofluoride batteries (commonly known as “BR” cells). Similarly, it is used in the electrolytes for certain types of capacitors.

Broader Importance of GBL and BDO

Inasmuch as GBL and BDO are vital to the production of semiconductors (and batteries and other electrical components), as discussed above, they are also vital to all the other industries that rely on these products, and their customers/consumers. As “intelligent” features are being built into an ever-expanding array of products, the affected industries include such diverse sectors as electronics, transport, telecommunications, medical devices, toys, aerospace/defense, and appliances. Indeed, because of the central role of computers and other electronics in managing the modern activities of business and government, every corner of the U.S. and world economies would likely be affected.

GBL and BDO are also more directly important to a number of industries (in addition to the semiconductor industry, as discussed above). In the case of GBL, the WHO Secretariat has noted that the chemical is used as an intermediate in the production of pharmaceuticals, herbicides, and a variety of other industrial chemicals, as well as a solvent in the manufacture of numerous polymers (*e.g.*, polystyrene and methylacrylate polymers). See Critical Review Report for GBL at 15. The Drug Enforcement Administration (“DEA”) has pointed out that GBL is a carrier in various film-forming products, such as inks, automotive coatings, and varnishes, as well as part of the delivery system for some agricultural chemicals. See [73 Fed. Reg. 66,815, 66,817-18 \(November 12, 2008\)](#). In addition, some foods and food flavorings contain food-grade GBL at part-per-million levels. *Id.*

In the case of BDO, the WHO Secretariat has noted that the largest use of the chemical is to make the building blocks of several common polymer products, such as spandex, polyesters, and urethane rubber. See Critical Review Report for BDO at 20. In addition, BDO is used as an intermediate in the production of pharmaceuticals, and as an ingredient in some coatings and solvents.

Clearly, GBL and BDO are common – even ubiquitous – industrial chemicals with an exceptionally wide range of legitimate and important uses throughout the economy. Moreover, their common usage and their high value for critical industrial applications makes these substances fundamentally different from the other substances that have been targeted for control under the Psychotropic Convention. As discussed in more detail below, the Convention was clearly not designed for, and is fundamentally unsuitable for, control of substances that have significant legitimate industrial uses (*i.e.*, uses that are not limited to narrow pharmaceutical or research purposes, which are susceptible to burdensome controls on production, distribution and use). It is fully appropriate under the Convention for the CND to take these factors into account and to decide not to list the substances as recommended by the WHO.

Minimal Potential for Diversion in the Semiconductor and Other Industries

There is no meaningful potential for GBL and BDO to be diverted to illicit purposes from the semiconductor industry. As an initial matter, as noted above, BDO is generally not handled within the industry, although it is used by the chemical industry to produce chemicals that are used in manufacturing semiconductors (*i.e.*, GBL and NMP). Although GBL is used within the industry, it is only used as an ingredient in formulations, from which it would be difficult to extract “clean” GBL. The formulations are costly, because they are designed, made, and marketed for specific functions in the semiconductor manufacturing process and must meet the demanding quality standards of the industry in order to avoid compromising the microscopic circuitry in the semiconductor products. The formulations are safeguarded consistent with their high value, and because of the need to preserve their quality for optimal manufacturing performance, to ensure worker safety, and to protect against release to the environment. Moreover, the semiconductor manufacturing facilities in which the formulations are stored and used employ extensive security and control measures (*e.g.*, security check stations, tight inventory controls, and “clean rooms”) in order to protect against damage to capital equipment, theft of intellectual property, and even the slightest degree of contamination. In light of these circumstances, it is

difficult to imagine anyone trying, much less succeeding, in obtaining the formulations and extracting GBL in a form that would be amenable to abuse. Indeed, SIA is not aware of any instances in which GBL has ever been diverted to illicit purposes from a semiconductor manufacturing facility.

Although SIA has only limited knowledge about the specifics in other industrial sectors, DEA has indicated that most industrial mixtures containing GBL are similarly not susceptible to diversion. Among the reasons cited by the agency are (a) the difficulty in extracting GBL from the mixtures, (b) the high cost of the mixtures, (c) limited knowledge by users about the presence of GBL, and (d) widespread good business practices such as knowing one's customers. See 73 Fed. Reg. at 66,817-18. It was on this basis that DEA exempted broad categories of GBL mixtures from regulation (*e.g.*, mixtures with less than 70% GBL, and completely formulated paints and coatings), as discussed in more detail below. See 21 C.F.R. §§ 1310.12(c) and (d)(2). Although DEA does not regulate BDO, and thus has had no occasion to address industrial mixtures containing the chemical, such mixtures would likely also present minimal diversion risks, for the same reasons. While we are not trying to minimize the potential for diversion under extraordinary circumstances, we believe that in legitimate industrial settings, the potential risks of diversion for both GBL and BDO are essentially non-existent.

Severe Impacts of Listing under the Psychotropic Substances Convention

If GBL and BDO were listed under Schedule I of the Psychotropic Convention, as recommended by WHO, the chemicals would effectively be prohibited from legitimate industrial use. Article 7(1) of the Convention explicitly states that “[i]n respect of substances in Schedule I, the Parties shall ... [p]rohibit all use except for scientific and very limited medical purposes by duly authorized persons.” The only exception appears to be if a Party notifies the UN Secretary-General within 180 days of the listing that, due to “exceptional circumstances,” it is not in a position to apply all of the requirements of the Convention for Schedule I substances to the specific chemical. See Article 2.7. In practice, however, this narrow exception seems unlikely to be able to provide meaningful relief from the broad prohibition on industrial use, since it would require each country handling GBL, BDO, and products containing these chemicals to quickly take individual action to declare exceptional circumstances. The complex and global nature of the supply chain in the semiconductor industry, in which the production and use of the components and final formulation of photolithography preparations might involve trade among dozens of countries that may change over time, means that reliance on a patchwork of individual country-level exemptions would be unworkable in practice for our industry.

Moreover, Parties declaring exceptional circumstances would still be obligated to “take into account, as far as possible” the prohibition on industrial uses. See Article 2.7(a). In addition, they would be obligated to require licenses for manufacture of the chemicals (including formulation of preparations), as well as for trade, distribution, import, and export. *Id.* (and provisions cited therein). Such licensing requirements would pose significant operational, administrative, and practical burdens to the semiconductor industry and other industries that legitimately use GBL and BDO, with minimal benefits in terms of additional controls to avoid diversion, given the fact that the potential for diversion in these industries is already extremely low (as discussed above).

Indeed, to the extent that Parties, in large numbers, might take these steps to avoid the full impacts of the general prohibition on industrial use, that might erode the very concept of “exceptional circumstances” and undermine the stringent controls established under the Convention for other Schedule I substances (*e.g.*, LSD and mescaline), which clearly have no legitimate industrial uses. Listing GBL and BDO as Schedule I substances is especially unwarranted, given that the key concern is that they can be converted into gamma-hydroxybutyric acid (“GHB”) in the human body or in a clandestine laboratory, but GHB – which, to our knowledge, has no legitimate industrial uses – is listed only as a Schedule II psychotropic substance. Clearly, a Schedule I listing is not justified, and could even be counterproductive to the cause of controlling narcotics and psychotropic substances.

Listing under one of the other Schedules under the Psychotropic Convention would similarly be extremely problematic. Article 4(b) of the Convention does allow a Party to permit “[t]he use of [Schedule II-IV] substances in industry for the manufacture of non-psychotropic substances or products,” but only under strict conditions that are unlikely to enable continued legitimate use of the chemicals. As an initial matter, each country handling GBL, BDO, and products containing these chemicals would have to quickly take individual action to allow industrial use. The chemicals and formulations would have to be fully regulated up to the point where they “present no, or a negligible, risk of abuse and the [relevant] substance cannot be recovered by readily applicable means in a quantity liable to abuse.” See Articles 4(b) and 3.2. Moreover, even after that point, the preparations/products would apparently have to be subjected, at a minimum, to licensing for manufacture, detailed recordkeeping, and certain restrictions on import and export. See Article 3.3. Such requirements might well be an insurmountable obstacle to vital and legitimate uses of GBL and BDO, assuming they could even be adopted by all the relevant countries in a timely fashion. Individual countries could also declare that they are unable to apply all the requirements for Schedule II-IV substances, based on exceptional circumstances, but for much the same reasons as discussed above with respect to Schedule I, this would not be a viable solution to the problems created by listing under the Convention.

Alternatives to Listing for Protecting Against Diversion

There are several other means besides listing under the Psychotropic Convention that can be, and are being, used to protect against diversion of GBL and BDO. The United States, for example, has developed rules that are designed to carefully balance the need for preventing diversion of these two chemicals and not creating undue obstacles to their vital use in industry. In particular, the distribution of either chemical for purposes of human consumption can be (and has been) prosecuted as an illegal distribution of an “analogue” of GHB, which is classified as a Schedule I substance under the Controlled Substances Act (“CSA”). See, *e.g.*, 21 U.S.C. § 813. GBL is also classified as a List I chemical under the CSA, and thus is subject to certain limited controls on manufacture, distribution, possession, import, and export. See 21 C.F.R. § 1310.02(a)(24). However, DEA has exempted chemical mixtures containing less than 70% GBL, as well as certain other products containing GBL, such as “completely formulated paints and coatings.” See 21 C.F.R. §§ 1310.12(c) and (d)(2). DEA also provides a process by which other chemical mixtures can be exempted on a case-by-case basis. See 21 C.F.R. § 1310.13.

The United States has not been alone in developing national legislation to protect against the diversion of GBL and BDO. Indeed, the Critical Review Reports prepared by the WHO Secretariat provided partial lists of the rules currently in place, or in development, to control these chemicals in many countries around the world. See Critical Review Reports for GBL at 18-20, and for BDO at 25-26. To the extent that other countries may need to adopt further legislation for GBL and/or BDO, they can be encouraged to do so using their existing legal frameworks, which generally provide flexibility to strike a reasonable balance between diversion control and allowing continued legitimate use. Such an approach is manifestly preferable to listing under the Psychotropic Convention, which would have the effect of requiring inflexible prohibitions/controls that are simply unworkable for chemicals like GBL and BDO that have such a wide range of legitimate and essential uses throughout industry.

SIA Recommendation for U.S. Government Action

Based on the critical importance of GBL and BDO to the semiconductor industry and the economy more broadly, the essentially non-existent potential for diversion in most industrial settings, the potentially devastating impacts of listing under the Psychotropic Convention, and the availability of other mechanisms for diversion control, SIA strongly urges the U.S. Government to oppose listing of these chemicals under the Convention.

Moreover, we ask the USG to work actively with other governments, as necessary, to ensure these substances are not listed under the Convention. (SIA has no objection to the listing of the other chemicals covered by the WHO recommendation, since they are not used in the semiconductor industry and, as far as we are aware, have no legitimate industrial uses in other sectors.)

Thank you once again for this opportunity to provide our input toward development of the U.S. position on the WHO recommendation regarding GBL and BDO. If you need any additional information, or if there is any other way we can be of assistance, please do not hesitate to contact me at disaacs@semiconductors.org or (202) 446-1709.

Best regards,



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cc: Eric Green, Director of Office of Policy Coordination, Bureau of Narcotics and Law Enforcement, U.S. Department of State

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