Canada Gazette
Welcome to the official newspaper of the Government of Canada published since 1841

Vol. 139, No. 24 — June 11, 2005

Order Amending Schedule VI to the Controlled Drugs and Substances Act

Statutory authority

Controlled Drugs and Substances Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Order.*)

Description

The purpose of this proposed initiative is to amend Schedule VI to the *Controlled Drugs and Substances Act* (CDSA) and the *Precursor Control Regulations* (PCR) to strengthen the regulatory framework and minimize any negative impact of the Regulations on the legitimate trade of precursors. Among other things, the proposed amendments will add six substances to the CDSA and the PCR: gamma-butyrolactone (GBL), 1,4-butanediol (BDO), red phosphorus, white phosphorus, hypophosphorous acid, and hydriodic acid.

The CDSA prohibits the import, export, and possession for export of precursors, except as authorized by regulation. It also provides the authority to develop regulations governing, controlling, limiting and authorizing the importation into Canada, the exportation from Canada, the production, packaging, sending, transportation, delivery, sale, provision, administration, possession, or obtaining of, or other dealing in any precursor or any class thereof. Contravention of the Regulations is an offence under section 46 of the CDSA.

The PCR, which came into force between January 2003 and January 1, 2004, provide a regulatory framework for the control and monitoring of precursor chemicals frequently used in the clandestine production of illicit drugs. These Regulations enable Canada to fulfill its international obligations under the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988* (1988 UN Convention).

There are two classes of precursors under the PCR: Class A and Class B. Class A precursors are essential components of illicit substances such as methamphetamine, MDMA (ecstasy), cocaine, heroin, LSD, and PCP. Class B precursors are mostly solvents and reagents used in clandestine manufacturing processes.

The PCR include a licence and permit scheme for import and export of Class A precursors; a licence requirement for the production, packaging and sale of Class A precursors; a registration and export permit scheme for Class B precursors; and general record keeping and reporting requirements for both Classes. The Regulations also include a scheme to exempt products which are mixtures or preparations of precursor chemicals that have been demonstrated to pose little risk of diversion to clandestine laboratories.

Most of the precursors listed in these Regulations have a wide legitimate use in common products such as pharmaceuticals, fragrances, flavouring agents, petroleum products and paints. The Regulations must enable Canada to fulfill its international obligations and address domestic needs to control precursors, while at the same time remaining sensitive and responsive to the licit uses of these chemicals.

When the PCR were published in the *Canada Gazette*, Part II, in October 2002, the Government committed to an ongoing assessment of the legitimate use and diversion of precursors in Canada and to further the development of effective regulatory policy and enforcement strategies. The Government now has over two years of experience with this new regulatory framework. Over this period, Health Canada and stakeholders have identified several issues which can only be effectively resolved through the amendment of the Regulations.

Information obtained from law enforcement agencies and drug analysis laboratories at Health Canada have highlighted the need to bring six new substances under the CDSA and the PCR framework due to their extensive use in the illicit manufacture of methamphetamine and another controlled drug, gammahydroxybutyrate (GHB).

Law enforcement agencies have identified the need for changes to the regulatory framework, which will enhance their ability to detect and take appropriate action when diversion of precursors to the illicit manufacture of controlled drugs is identified. Similarly, Health Canada has identified the need for better tools to assess applications for a licence and to take administrative action in cases where non-compliance with the Regulations is noted.

Industry stakeholders have drawn Health Canada's attention to instances where the PCR have imposed an unnecessary regulatory burden by extending the control framework to certain legitimate trade practices and to certain preparations of precursor chemicals which pose a very low risk of diversion of these substances for use in clandestine laboratories.

Amendments to Schedule VI to the *Controlled Drugs and Substances Act* and the Schedules to the *Precursor Control Regulations*

Addition of GBL and BDO to Parts 1 (Class A) and 3 (Preparations) of Schedule VI to the Controlled Drugs and Substances Act *and the* Precursor Control Regulations

GBL and BDO are chemical and metabolic precursors used in the illicit production of the controlled substance GHB. GHB is a central nervous system depressant which is listed in Schedule III to the CDSA and Part G to the *Food and Drug Regulations* (FDR). Although there are presently no products containing GHB approved for market in Canada, GHB has legitimate medical uses to treat alcohol withdrawal and narcolepsy. Over the past years, GHB has increasingly become a substance of abuse in clubs and at all-night dance parties. It has become known as a "date rape drug" and implicated in a number of sexual assault cases. GHB is abused for its ability to produce euphoric and sedative effects, as well as for its alleged role as a growth hormone. Canadian law enforcement agencies and drug analysis laboratories at Health Canada have identified GBL and BDO as being used for the illicit manufacture of GHB in clandestine laboratories. Both these substances have also been promoted and sold in the United States in dietary supplements with claims, albeit unsubstantiated, to build muscles, improve physical performance, enhance sex, reduce stress and induce sleep.

BDO and GBL are unique precursors because when ingested, they are rapidly converted to GHB within the body. Both substances can also be used in a laboratory environment to produce GHB. GBL can easily be converted to GHB with the addition of an alkali; however, the conversion of BDO to GHB is more complex. GBL and BDO are considered essential precursors to GHB since they cannot be easily substituted.

While GBL and BDO are not included in the 1988 UN Convention, a number of countries have elected to impose stricter controls over these substances because of their illicit use in the synthesis of GHB. GBL is explicitly controlled as a List I Chemical under the *Controlled Substances Act* (CSA) in the United States; both GBL and BDO are also interpreted to be analogues of GHB under the CSA. GBL and BDO are on the voluntary monitoring list of the Drug Precursors Committee of the European Commission.

Both GBL and BDO have a wide range of industrial uses. GBL is used as a solvent in detergents, air fresheners, sun lotions, printing inks, household cleaners and paint removers, as a chemical intermediate for herbicides and insecticides, and in photochemical etching. BDO is used as an intermediate for the chemical and textile industries, as an industrial solvent in the manufacture of polyurethanes and thermoplastics, and in the production of cellular plastics, thermoplastic polyesters, hot-melt adhesives and plasticisers. Most of these preparations have a low risk of diversion because GBL or BDO cannot be readily extracted or otherwise used in the illicit production of GHB. To minimize undue regulatory burden on industry, it is proposed that certain activities involving GBL and BDO be exempted from the requirements of the PCR under paragraph 3(*c*). This applies to mixtures or preparations containing GBL or BDO in a total concentration equal to or less than 10 percent, for specific industrial uses including in photochemical etching, biofermentation for polyester production, and as an ingredient in pesticides, melamine coatings, automotive coatings, and urethane catalyst systems and catalyst packages.

GBL can also be used in fragrances or flavourings. These amendments propose to add

GBL to the list of Class A precursors included in section 3 that are exempted when used for this purpose in a total concentration equal to or less than 20 percent.

Some products containing very high concentrations of GBL or BDO (e.g. 70 percent to 99.8 percent) are sold through the Internet as nail polish remover or printer ink remover. These products are at much higher risk of diversion to the illicit market to be consumed or otherwise used to produce GHB.

Except where the criteria described above are met, it is proposed that GBL, BDO and all preparations containing these substances be regulated as Class A precursors by adding GBL and BDO to Part 1 and Part 3 of Schedule VI to the CDSA.

Addition of red phosphorus, white phosphorus and hypophosphorous acid and its salts and derivatives to Part 1 of Schedule VI to the Controlled Drugs and Substances Act and the Precursor Control Regulations

Red phosphorus, white phosphorus and hypophosphorous acid are important chemicals used in the illicit production of methamphetamine. Methamphetamine is a central nervous system stimulant which is listed in Schedule III to the CDSA and Part G of the FDR. While there are no approved drug products containing methamphetamine currently marketed in Canada, it is available in the United States to treat attention-deficit hyperactivity disorder (ADD) and narcolepsy. Methamphetamine is abused for its rapid ability to produce euphoria, increased alertness and enhanced performance. It has become a "party or clubs" drug of choice. Canadian law enforcement agencies and drug analysis laboratories at Health Canada have found red and white phosphorus and hypophosphorous acid in illicit methamphetamine laboratories.

Red phosphorus, white phosphorus and hypophosphorous acid are not presently included in the 1988 UN Convention. In the United States, they are controlled as List I Chemicals under the *Controlled Substances Act* (CSA).

Phosphorus is a non-metallic element that exists in three main allotropic forms: red, white and black. Red phosphorus is more stable and less toxic than white phosphorus and is the most common phosphorus compound found in clandestine laboratories in Canada. White phosphorus will easily ignite when exposed to air and therefore must be stored in water; consequently, it is used to a lesser extent. The black solid form of phosphorus is very stable and not reactive enough to be used in clandestine laboratories.

Hypophosphorous acid and many of its salts can be used in clandestine laboratories, the most common being sodium hypophosphite. Detailed recipes describing the production of methamphetamine using red phosphorus, white phosphorus and hypophosphorous acid can be easily found on the Internet.

Red and white phosphorus and hypophosphorous acid have many industrial applications. Red phosphorus is used in the manufacture of pyrotechnics, safety matches, phosphoric acid and other phosphorus compounds, fertilizers, incendiary shells, smoke bombs, tracer bullets, and pesticides. White phosphorus is used in the industry in the production of phosphorus derivatives. Hypophosphorous acid is used in the bleaching industry and as a colour stabilization or decolouring agent for plastics, synthetic fibers (primarily polyester) and chemicals. It also has applications as a reducing agent and an antioxidant.

Preparations containing red and white phosphorus and hypophosphorous acid, its salts and derivatives have a low risk of diversion because they cannot be easily used in the illicit production of methamphetamine. For this reason, it is proposed that these three substances be added only to Part 1 of Schedule VI to the CDSA, meaning that only these chemicals, and not preparations containing these chemicals, will be brought under the control of the CDSA and the PCR.

Addition of hydriodic acid (HI) to Part 1 of Schedule VI to the Controlled Drugs and Substances Act *and the* Precursor Control Regulations

Hydriodic acid has been identified as another essential chemical used in the illicit production of methamphetamine. It is most often used in combination with red phosphorus and acts as the main reducing agent in the synthesis of methamphetamine from ephedrine or pseudoephedrine. Hydriodic acid is also used as a reducing agent to produce amphetamine from phenylpropanolamine.

Hydriodic acid is not included in the 1988 UN Convention; however, a number of countries have elected to impose stricter controls over this substance because of its illicit use in the synthesis of methamphetamine. It is controlled as a List I Chemical under the CSA in the United States and is controlled in Australia and the Bahamas.

Hydriodic acid, a solution of hydrogen iodide gas in water, is a strong, corrosive acid and a reducing agent. It can be produced from iodine in the presence of hydrogen sulfide or by mixing iodine with red phosphorus and water. Hydriodic acid has a number of legitimate industrial applications as a disinfectant, analytical agent, chemical intermediate, raw material in pharmaceutical applications, and to make iodine salts.

Preparations containing hydriodic acid have a low risk of diversion because they cannot be easily used in the illicit production of methamphetamine. For this reason, it is proposed that HI be added to Part 1 of Schedule VI to the CDSA but excluded from Part 3 of the same Schedule, meaning that only this chemical, and not preparations containing this chemical, will be brought under the control of the CDSA and the PCR.

Amendment of Item 17 in Part 1 of Schedule VI to the Controlled Drugs and Substances Act

Item 17 in Part 1 of Schedule VI to the CDSA, safrole, will be amended to exclude essential oils containing 4 percent or less safrole. Safrole is used in the illicit production of ecstasy (MDMA). Several essential oils including mace oil, nutmeg oil and cinnamon leaf oil are used in a wide variety of products ranging from spice mixtures to processed meats. These preparations have a low risk of diversion to clandestine laboratories because the safrole cannot be readily extracted or otherwise used in the illicit production of controlled substances. This amendment would remove undue regulatory burden placed on the fragrance and flavour industry by the PCR as they currently exist and would clarify the intent of the regulatory framework.

Amendments to the *Precursor Control Regulations*

Strengthening the regulatory framework

A new provision (section 6.1) will add a requirement for a licence to possess a precursor for the purpose of producing a controlled substance, such as methamphetamine. Possession of a precursor is not currently prohibited under the CDSA, unless the precursor is being used to conduct an activity which would require a licence under the PCR. The production of a controlled substance is prohibited under the CDSA (section 7) and is a licensed activity under other regulations to the Act. An explicit requirement for a licence to possess a precursor to produce a controlled substance is required in the PCR to facilitate charges being laid by law enforcement agencies when clandestine laboratories are investigated and it is clear that illicit production of drugs is taking place despite the absence of any controlled substances at the location at the time of seizure.

Proposed amendments to section 14 require additional information in the Class A precursor licence application, such as the description of the nature of the business, clientele and suppliers, and the establishment licence number and a drug identification number, if applicable. This information is required to assist Health Canada in validating the legitimacy of the applicant's business and determining whether it would be in the public interest to issue a precursor licence to the applicant. A new provision (section 15.1) will also be included to provide authority for Health Canada to conduct pre-licence inspections to verify information contained in a licence application as required.

Amendments are proposed [paragraphs 17(1)(*e*), 23(1)(*e*), 45(1)(*c*), 63(1)(*e*) and 67(1)(*e*)] to give explicit authority to consider information obtained from a peace officer (which includes a police officer) in making a decision regarding the refusal, revocation, or suspension of a licence or permit when the information raises a reasonable belief that a licensed dealer has been involved in the diversion of a controlled substance or precursor to an illicit market or use. Presently, only information from international sources, competent authorities and the International Narcotics Control Board can be considered under these paragraphs.

Subsection 8(1) would be amended to require more information to be included in an end-use declaration, such as the business name and contact information. This will improve the quality of data captured on transactions for which the purchaser does not require a licence, thereby facilitating the monitoring of precursor use in Canada and the detection of potential diversion.

Another provision [subsection 9(1.1)] is proposed to require that appropriate documentation accompanies the shipment when transporting a Class A precursor in quantities greater than the quantity or package size stated in the Schedule to the PCR. This documentation will facilitate the detection of unlicensed transactions by law enforcement agencies.

The amendment of subsection 20(1) is proposed to require pre-approval of any changes to the security measures for Class A precursors described in the original application for a licence. This measure will ensure that such changes would not in any way increase the risk of diversion.

A new requirement is proposed under sections 28.1 and 72.1 for a declaration to be filed following the import or export of a precursor. Confirmation that the transaction has been completed as per the permit issued will enhance Health Canada's ability to monitor the movement of these chemicals across Canada's borders and to meet Canada's obligations under the 1988 UN Convention.

A new provision is proposed (section 87.1) to require licensed or registered dealers to notify Health Canada in advance if they intend to close a site or remove all precursors from the site. This is necessary to maintain a chain of accountability for the precursor chemicals held at the site and to minimize the risk of diversion.

Minimizing regulatory burden

An amendment to section 2 is proposed to facilitate the sale or provision of preparations of narcotic and controlled drugs which also contain a Class A precursor. The existing provision in the PCR which exempts any drug in dosage form that contains a Class A precursor listed in Schedule F will be amended to add controlled substances. Pharmaceutical preparations containing controlled substances are subject to an appropriate level of control under the *Narcotic Control Regulations* (NCR) and Part G to the FDR. The proposed amendment will remove the requirements for end-use declarations and record keeping for transactions currently regulated under the NCR and FDR.

Proposed amendments to sections 3 and 4 will exempt certain activities such as import, export and sale or provision of preparations containing Class A precursors which have been deemed to be of little risk of diversion for illicit use. This exemption will only apply once the finished product has been produced and the precursor cannot be used in a clandestine laboratory; therefore, a licence will be required to produce.

New provisions will be added in Part 4 to facilitate the dispensing of pharmaceutical preparations containing a Class A precursor in quantities or package sizes over the threshold stated in the Schedule to the PCR, pursuant to a prescription. The PCR, as currently written, state that only licensed dealers can sell/provide Class A precursors over the quantity or package size stated in the Schedule to the PCR. Ephedrine preparations for veterinary use exceed the 400 mg threshold; for example, horses require 1.2 gm of ephedrine for a legitimate course of therapy and, currently, a pharmacist or veterinarian would require a Class A precursor licence to sell or provide these larger quantities.

The requirements under Part 4 concerning refills, transfers and record keeping are consistent with, albeit somewhat less restrictive than, the other regulatory frameworks for controlled prescription drugs under the CDSA. It is anticipated that the restrictions placed on the sale or provision of ephedrine and pseudoephedrine at the wholesale distribution level may lead to clandestine laboratory operators seeking new sources of supply, such as pharmacies and other retail outlets. The requirements for record keeping, security measures and reporting of thefts and losses are necessary to ensure accountability and provide extra measures to prevent these products from being diverted for illicit use.

Clarification and technical amendments

Subsection 9(1) will be amended to permit the transport of Class A precursors by end-users or their representatives. The Regulations as written permit only licensed dealers and their representatives the transport of these substances. This restriction is not consistent with the policy framework for control of precursor chemicals.

The provisions of the Regulations related to Exemptions for Preparations and Mixtures will be transformed into an authorization scheme to address a technical legal drafting

issue. The effect of the scheme remains the same: to allow certain activities involving products containing precursor chemicals which have a demonstrated low risk of diversion to be conducted without a requirement for a licence, registration or permit as relevant.

An amendment to subsection 47(1) will clarify that these provisions apply to licensed dealers when they destroy precursor chemicals. It was not the intent to restrict other parties from destroying precursor chemicals.

Amendments to section 90 are proposed to clarify and streamline the requirements for reporting of lost or stolen precursors or authorization documents including licences, registrations, permits or authorization certificates.

Amendments to a number of other provisions are proposed to ensure consistent use of terminology throughout the Regulations, and to update cross-references between provisions required as a result of renumbering of new or amended provisions. As well, certain inconsistencies between the English and French are corrected. Definitions for the terms "hospital," "peace officer," "prescription," "pharmacist," and "retail" will be added to section 1 to add clarification to the new provision in Part 4 of the PCR and the amendments related to grounds for refusal, revocation or suspension of a licence or permit.

Alternatives

Scheduling of new substances

In general, Health Canada considers that the voluntary monitoring and other measures implemented by operators to minimize diversion of the six chemicals identified is not adequate to prevent the illicit use.

GBL and BDO

As previously mentioned, BDO and GBL are unique precursors because, when ingested, they can be converted by the body to GHB. Because of this pharmacological effect, consideration must also be given to scheduling these chemicals as controlled substances in one of Schedules I to V to the CDSA.

Three alternatives for scheduling were considered. The alternative of scheduling GBL and BDO under Part 2 of Schedule VI (Class B precursors) was not considered as it would not provide adequate control over the distribution to meet the policy objective of minimizing the availability of these chemicals for illicit manufacture of GHB. Alternative 2 is the recommended alternative for the control of GBL and BDO.

Alternative 1: Schedule III to the *Controlled Drugs and Substances Act* and the Schedule to Part J to the *Food and Drug Regulations*

Listing GBL and BDO in Schedule III to the CDSA would put them in the same Schedule as GHB. As such, these substances would be subject to offences under the CDSA for possession, importation, exportation, trafficking, production and possession for the purpose of exportation or trafficking.

Because GBL and BDO do not have any therapeutic applications, they meet the criteria to be classified as restricted drugs, which are listed in the Schedule to Part J to the FDR. Generally, activities related to restricted drugs are authorized for scientific research purposes only.

This is not a viable alternative. Application of the regulatory framework for restricted drugs to GBL and BDO would severely impede the legitimate industrial use of GBL and BDO.

Alternative 2: Part 1 (Class A) and Part 3 of Schedule VI to the *Controlled Drugs and Substances Act*

Part 1 of Schedule VI to the CDSA lists chemical substances classified as Class A precursors; Part 3 captures all preparations and mixtures containing a precursor listed in Part 1 or 2.

Under this alternative, GBL and BDO, as well as mixtures and preparations containing GBL and BDO, would be controlled as Class A precursors. Regulatory requirements include a licence and permit for the import and export of Class A precursors, a licence for their production and sale, and general record keeping.

The additional control proposed for the preparations and mixtures will minimize their diversion; however, the control of all mixtures and preparations containing GBL and BDO would have a significant and unnecessary negative impact on legitimate industry. For this reason, it is proposed that activities regarding mixtures or preparations which pose little risk of diversion for illicit use be exempted from the regulatory framework.

This alternative is recommended because it provides appropriate monitoring and control mechanisms without causing undue hardship on industry.

Alternative 3: Addition to Part 1 (Class A) and exclusion from Part 3 of Schedule VI to the *Controlled Drugs and Substances Act*

Under this alternative, GBL and BDO would be controlled as Class A precursor chemicals and regulated under the PCR. However, the regulatory requirements for a licence and permit for import and export, a licence for production and sale, and general record keeping would not be applicable to mixtures or preparations containing GBL or BDO, such as nail polish remover or furniture stripper, which are known to be diverted for illicit use.

This alternative would therefore not afford adequate monitoring and control mechanisms necessary to minimize diversion of GBL and BDO and their use in the illicit manufacture of GHB.

Red phosphorus, white phosphorus and hypophosphorous acid and its salts and derivatives and hydriodic acid (HI)

Three alternatives for scheduling were considered for these phosphorus chemicals and hydriodic acid (HI). Alternative 3 is proposed for the control of red phosphorous, white phosphorus and hypophosphorous acid, its salts and derivatives, and hydriodic acid.

Alternative 1: Part 2 (Class B) of Schedule VI to the *Controlled Drugs and Substances Act*

Regulations for Class B precursors include a registration requirement for import, export and production for the purpose of sale only. There are no requirements to keep records of sales of these substances.

The phosphorus chemicals and hydriodic acid are significant chemicals used in the illicit production of methamphetamine. This alternative is not recommended because it does not provide an adequate level of monitoring or control to minimize and detect diversion.

Alternative 2: Part 1 (Class A) and Part 3 of Schedule VI to the *Controlled Drugs and Substances Act*

Part 1 of Schedule VI to the CDSA lists chemical substances classified as Class A precursors; Part 3 captures all preparations and mixtures containing a precursor listed in Part 1 or 2.

Under this alternative, the four chemicals and all their preparations and mixtures would be controlled as Class A precursors. Regulatory requirements include a licence and permit for the import and export, a licence for their production and sale, and general record keeping.

The mixtures and preparations of phosphorus chemicals and hydriodic acid pose little risk of being used in clandestine laboratories. Consequently, this level of control would put undue burden on the legitimate industry.

Alternative 3: Addition to Part 1 and exclusion from Part 3 of Schedule VI to the *Controlled Drugs and Substances Act*

Under this alternative, the four chemicals would be controlled as Class A precursor chemicals and regulated under the PCR; however, the regulatory requirements for a licence and permit for import and export, a licence for production and sale, and general record keeping would not be applicable to mixtures or preparations containing the phosphorus chemicals and HI.

The mixtures and preparations of phosphorus chemicals and hydriodic acid pose little risk of being used in clandestine laboratories to manufacture methamphetamine.

This is the recommended alternative because it provides for an appropriate level of monitoring and control to minimize diversion for illicit use while minimizing the regulatory burden on industry.

Amendments to the Precursor Control Regulations

These amendments are necessary to respond to issues identified since the implementation of the PCR with respect to its administration and enforcement. The status quo is unacceptable, as it compromises the ability of Health Canada and law enforcement agencies to ensure that precursor chemicals are only used for legitimate purposes and

not diverted to the illicit manufacture of controlled substances. Further, the existing Regulations extend the control framework to preparations and products which have a low risk of diversion and, in doing so, impose an unintended and unnecessary regulatory burden on legitimate industry. No other alternatives were considered.

Benefits and costs

This initiative constitutes amendments to an existing regulatory framework; therefore, an exhaustive analysis was not deemed necessary. The reader is instead referred to the Regulatory Impact Analysis Statement published in the *Canada Gazette*, Part II (SOR/DORS/2002-359; Vol. 136, No. 21), on October 9, 2002, for a more detailed examination of the benefit and cost issues. This section will highlight the additional benefits to be gained and potential costs to be incurred by these amendments.

Benefits

The net benefits of this regulatory amendment are similar to the initial Regulations and cannot be fully estimated. Given the lack of quantitative information associating the control of precursor chemicals to illicit drug availability or use and their direct and indirect harmful effects on health and safety, the benefits have not been quantified or valued in monetary terms. These Regulations are based on the benefits stemming from Canadian values with respect to public safety and Canada's commitments under international drug control conventions.

The benefits of these regulatory amendments are predicated on the belief that reducing the opportunity for diversion of precursor chemicals will reduce the production, distribution, and use of illicit substances. The proposed amendments to the control measures will further help protect the health and safety of Canadians through reduction of the risk of diversion, clandestine production of illicit substances, and unsafe disposal of chemicals. Social benefits to Canadians may also result from further reductions in impacts on human health through reductions in illicit drug use, associated accidents and crime, as well as the contamination of the environment.

Costs

The total social costs associated with the controls on precursor chemicals consists of the costs to the private sector and to participating government agencies at the federal, provincial/territorial and municipal levels.

An important concept in the consideration of costs associated with regulations is that of incrementality; that is, the costs that arise from the regulations should only include cost that occur in addition to those costs from pre-existing activities. Given that there are already existing regulations governing precursor chemicals, the incremental costs incurred by these amendments is expected to be minor. Cost issues have not been a prominent subject in consultations regarding these amendments as most of the requirements are consistent with existing de facto practices in most of the industry.

Private sector producers, importers, exporters, distributors and retailers may incur additional costs associated with additional requirements for provision of information to Health Canada and record keeping. The cost to firms will be minor and most likely

absorbed without consequence. Any increase in cost to industry may be offset by decreased costs resulting from amendments aimed at eliminating unnecessary regulatory burden and clarifying the requirements of other provisions.

No negative impacts on trade or competitiveness are expected as these measures are consistent with practices in the United States.

The Government will incur minor costs to modify administrative processes, monitor compliance and take enforcement action where required, e.g. potential increase in criminal prosecutions. The social benefits accruing from these amendments outweigh the incremental costs to the Government.

Consultation

Health Canada conducts ongoing consultation on the regulatory framework through two working groups established when the regulatory framework was first being developed: the Precursor Advisory Working Group comprised members from industry and Government; and the Interdepartmental Working Group, including members from various federal government departments affected by the PCR. This consultative process ensures that an appropriate balance is maintained between measures to reduce the diversion of precursors and the need to minimize the impact on legitimate trade of these substances. Targeted consultation with law enforcement agencies were conducted through creation of a Law Enforcement Working Group which proposed amendments to strengthen the Regulations with respect to enforcement actions.

Notices to interested parties (NIs) were published in the *Canada Gazette*, Part I, regarding the proposal to add GBL and BDO and red phosphorus and white phosphorus to Schedule VI of the CDSA on June 21, 2003, and November 8, 2003, respectively. A total of 12 respondents submitted comments in response to the NIs. Generally, the responses were supportive of the initiatives; no substantive objections to the proposals were raised. A few concerns were expressed from industry that the proposed controls may be burdensome to implement.

Members of the Precursor Advisory Working Group were consulted directly regarding the proposed scheduling of hydriodic acid. No immediate concerns were expressed.

Compliance and enforcement

The proposed amendments will not significantly alter the compliance and enforcement strategies implemented when the PCR first came into force. They will, however, enhance Health Canada's ability to monitor compliance to the Regulations and will improve the ability of law enforcement agencies to detect illicit traffic and take appropriate enforcement action. Failure to comply with the proposed Regulations could lead to administrative sanctions such as suspension or revocation of a licence or permit. Persons involved in illicit activities with respect to precursor chemicals can be charged and prosecuted for offences under the CDSA.

Contact

Amal Hélal, Office of Controlled Substances, Drug Strategy and Controlled Substances

Programme, Healthy Environments and Consumer Safety Branch, Address locator 3503D, Ottawa, Canada K1A 1B9, (613) 946-0122 (telephone), (613) 946- 4224 (facsimile), OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca (electronic mail).

PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to section 60 of the *Controlled Drugs and Substances Act* (see footnote a), proposes to make the annexed *Order Amending Schedule VI to the Controlled Drugs and Substances Act*.

Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Amal Hélal, Drug Strategy and Controlled Substances Programme, Department of Health, Address Locator 3503D, Ottawa, Ontario K1A 1B9 (fax: (613) 946-4224; e-mail: OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Persons making representations should identify any of those representations the disclosure of which should be refused under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, June 6, 2005

EILEEN BOYD
Assistant Clerk of the Privy Council

ORDER AMENDING SCHEDULE VI TO THE CONTROLLED DRUGS AND SUBSTANCES ACT

AMENDMENTS

1. Item 17 of Part 1 of Schedule VI to the *Controlled Drugs and Substances Act* (see footnote 1) **is replaced by the following:**

17. Safrole (5-(2-propenyl)-1,3-benzodioxole) and any essential oil containing more than 4% safrole

18. Gamma-butyrolactone (dihydro-2(3H)-furanone)

19. 1,4-butanediol

20. Red Phosphorus

21. White Phosphorus

22. Hypophosphorous acid, its salts and derivatives

23. Hydriodic acid

2. Note 1 to Part 2 of Schedule VI to the French version of the Act is replaced by the following:

[1] Sont compris parmi les précurseurs de catégorie B les formes synthétiques de ceux-ci.

3. Item 1 of Part 3 of Schedule VI to the Act is replaced by the following:

1. Any preparation or mixture that contains a precursor set out in Part 1, except items 20 to 23, or in Part 2.

COMING INTO FORCE

4. This Order comes into force on the day on which it is registered.

[24-1-o]

Footnote a

S.C. 1996, c. 19

Footnote 1

S.C. 1996, c. 19

Top of page

Maintained by the Canada Gazette Directorate
Updated: 2005-06-10

Important Notices

Canada Gazette
Welcome to the official newspaper of the Government of Canada published since 1841

Vol. 139, No. 24 — June 11, 2005

Regulations Amending the Precursor Control Regulations

Statutory authority

Controlled Drugs and Substances Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

For the Regulatory Impact Analysis Statement, see the *Order Amending Schedule VI to the Controlled Drugs and Substances Act*.

PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to subsection 55(1) of the *Controlled Drugs and Substances Act* (see footnote a), proposes to make the annexed *Regulations Amending the Precursor Control Regulations.*

Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Amal Hélal, Drug Strategy and Controlled Substances Programme, Department of Health, Address Locator 3503D, Ottawa, Ontario K1A 1B9 (fax: (613) 946-4224; e-mail: OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca).

Persons making representations should identify any of those representations the

disclosure of which should be refused under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, June 6, 2005

EILEEN BOYD

Assistant Clerk of the Privy Council

REGULATIONS AMENDING THE PRECURSOR CONTROL REGULATIONS

AMENDMENTS

1. Section 1 of the *Precursor Control Regulations* (see footnote 1) **is amended by adding the following in alphabetical order:**

"hospital" means a facility that

(*a*) is licensed, approved or designated as a hospital by a province under the laws of the province to provide health care or treatment to persons or animals; and

(*b*) is owned or operated by the government of Canada or a province and that provides health services. (*hôpital*)

"peace officer" means a peace officer as defined in section 2 of the *Criminal Code*. (*agent de la paix*)

"prescription" means, in respect of a preparation or mixture containing a Class A precursor, an authorization from a practitioner stating that a specific amount of the preparation or mixture may be sold or provided for the individual or animal under the practitioner's care named in the authorization. (*ordonnance*)

"pharmacist" means an individual who

(*a*) is registered or otherwise authorized under the laws of a province to practise pharmacy; and

(*b*) is practising pharmacy in that province. (*pharmacien*)

"retail" means a sale or provision of goods for the purpose of end-use but not resale. (*vente au détail*)

2. Section 2 of the Regulations is replaced by the following:

2. With respect to a drug in dosage form, a person who sells or provides or possesses for

the purpose of sale or provision, or who conducts an activity mentioned in section 9 or 47, is exempt from the requirements of these Regulations in respect of that activity if the drug contains

(*a*) a Class A precursor listed in Schedule F to the *Food and Drug Regulations*; or

(*b*) a Class A precursor and one or more controlled substance listed in Schedule I, III or IV to the Act.

3. (1) The portion of section 3 of the Regulations before paragraph (*b*) is replaced by the following:

3. With respect to a Class A precursor that is a preparation or mixture, a person who conducts an activity mentioned in section 6, 9, 10 or 47 is exempt from the requirements of these Regulations, except requirements in respect of the production of the preparation or mixture or the possession of a precursor for the purpose of producing the preparation or mixture, if

(*a*) the preparation or mixture is a fragrance or flavouring

(i) containing anthranilic acid, N-anthranilic acid, gamma butyrolactone, phenylacetic acid, piperonal or piperidine in a total concentration equal to or less than 20% by weight or volume in the case of a solid or liquid, respectively, and

(ii) intended to be used in a food, drug, cosmetic or household product;

(2) Section 3 of the Regulations is amended by adding the word "or" at the end of paragraph (*b*) and by adding the following after paragraph (*b*):

(*c*) it contains gamma butyrolactone or 1,4-butanediol in a total concentration equal to or less than 10% by weight or volume in the case of a solid or liquid respectively, and is intended to be used in the following products or processes:

(i) a control product as defined in the *Pest Control Products Act*, R.S., c. P-9, before the coming into force of subsection 2(1) of the *Pest Control Products Act*, S.C. 2002, c. 28,

(ii) a pest control product as defined in the *Pest Control Products Act*, S.C. 2002, c. 28, after the coming into force of subsection 2(1) of that Act,

(iii) photochemical etching,

(iv) biofermentation for polyester production,

(v) melamine coatings,

(vi) automotive coatings, or

(vii) urethane catalyst systems or urethane catalyst packages.

4. Sections 4 and 5 of the Regulations are replaced by the following:

4. (1) A person who uses a Class A precursor that is described in section 3 or is the subject of an authorization certificate under section 49, to produce another Class A precursor that is a preparation or mixture, is exempt from the requirements of these Regulations in respect of that production.

(2) With respect to a preparation or mixture produced under subsection (1), a person who conducts any activity mentioned in section 6, 9, 10 or 47 is exempt from the requirements of these Regulations in respect of the activity.

5. With respect to a Class A precursor, a person who sells or provides, or possesses for the purpose of sale or provision, is exempt from the requirements of these Regulations in respect of the activity if the person

(*a*) sells or provides a selection of goods that is not limited to chemicals or chemicals and equipment used in the chemical industry for the production, processing or storage of chemicals; and

(*b*) sells or provides Class A precursors

(i) only on a retail basis,

(ii) in the case of a precursor set out in column 1 of the schedule, only in a quantity, per transaction, that does not exceed the maximum quantity, expressed as an absolute amount or per package, specified for the precursor in column 2 of the schedule, and

(iii) in the case of a preparation or mixture containing a precursor set out in column 1 of the schedule, only in a quantity, per transaction, that does not exceed the maximum quantity, expressed as an absolute quantity or per package, specified for the contained precursor in column 2 of the schedule.

5. The Regulations are amended by adding the following after section 6:

6.1 No person may possess a Class A precursor for the purpose of producing a controlled substance unless the person is the holder of

(*a*) a licence issued under section G.02.003.2 or J.01.007.2 of the *Food and Drug Regulations*, section 21 of the *Benzodiazepines and Other Targeted Substances Regulations* or section 9.2 of the *Narcotic Control Regulations* that authorizes the production of the substance; or

(*b*) an exemption issued under section 56 of the Act.

6. (1) Subsection 8(1) of the Regulations is replaced by the following:

8. (1) A licensed dealer who intends to sell or provide, to a person who is not a licensed dealer, a Class A precursor set out in column 1 of the schedule in a quantity, per

transaction, greater than the maximum quantity, expressed as an absolute quantity or per package, specified for the precursor in column 2 of the schedule shall, before entering into the transaction, obtain an end-use declaration signed and dated by the person acquiring the precursor.

(1.1) The end-use declaration shall include

(*a*) the name of the licensed dealer, being, in the case of a corporation, its corporate name, as well as their address and telephone number and facsimile transmission number, if any;

(*b*) the name of the person acquiring the precursor, being, in the case of a corporation, its corporate name, as well as their address and telephone number and facsimile transmission number, if any;

(*c*) the name of all Class A precursors involved in the transactions mentioned in the end-use declaration;

(*d*) all uses for which the precursor is being acquired; and

(*e*) a certification by the signatory stating that the person is acquiring the precursor as the end user, for the uses mentioned in the end-use declaration.

(2) Subsection 8(3) of the French version of the Regulations is replaced by the following:

(3) La déclaration d'utilisation finale obtenue aux termes du paragraphe (1) ou (2) vaut pour toutes les transactions subséquentes, entre le distributeur autorisé et le signataire de la déclaration, qui ont lieu au cours de l'année civile pendant laquelle s'est effectuée la transaction visée aux paragraphes (1) ou (2) et qui visent le même précurseur de catégorie A et les mêmes usages que ceux spécifiés dans la déclaration.

7. (1) Subsection 9(1) of the Regulations is amended by adding the following after paragraph (*b*):

(*c*) the end user of the precursor; or

(*d*) a representative of the end user.

(2) Section 9 of the Regulations is amended by adding the following after subsection (1):

(1.1) A person sending, transporting or delivering a Class A precursor set out in column 1 of the schedule in a quantity greater than the maximum quantity, expressed as an absolute quantity or per package, specified for the precursor in column 2 of the schedule, shall ensure that the precursor is accompanied by documentation indicating

(*a*) the name and quantity of the precursor;

(*b*) the name of the licensed dealer selling or providing the precursor;

(*c*) the name of the person to whom the precursor is being sent, transported or delivered; and

(*d*) the date the precursor was purchased or otherwise acquired by the person to whom it is being sent, transported or delivered.

8. The Regulations are amended by adding the following after section 10:

Authorization Concerning Preparations and Mixtures

10.1 Despite sections 6 to 10 and 47, with respect to a Class A precursor that is a preparation or mixture, a person may sell, provide, send, transport, deliver, import, export, transport in transit through Canada, tranship in Canada, destroy or possess for those purposes if

(*a*) the preparation or mixture is the subject of an authorization certificate under section 49; and

(*b*) no notice indicating that the certificate has been revoked or is under suspension appears on the following Health Canada Internet site:

http://www.hc-sc.gc.ca/hecs-sesc/ocs/index.htm

9. (1) Paragraph 14(1)(*a*) of the Regulations is replaced by the following:

(*a*) the applicant's name or, if the applicant is a corporation, its corporate name, any other registered name with a province and any other trade name under which the applicant intends to carry out the activities set out in the licence or intends to identify itself;

(*a*.1) a description of the nature of the business conducted or intended to be conducted by the applicant;

(*a*.2) the length of time, if any, the applicant has been in business;

(2) Paragraph 14(1)(*b*) of the Regulations is amended by striking out the word "and" at the end of subparagraph (ii), by adding the word "and" at the end of subparagraph (iii) and by adding the following after subparagraph (iii):

(iv) if it is a drug containing a precursor for which a drug identification number has been assigned under section C.01.014.2 of the *Food and Drug Regulations*, the drug identification number;

(3) Paragraph 14(1)(*c*) of the Regulations is replaced by the following:

(*c*) for each precursor mentioned in the application,

(i) the Class A precursor activity referred to in section 6 that is sought to be licensed and that would be conducted at the site to which the licence would apply,

(ii) the names of the persons from whom the applicant intends to obtain the precursor, if applicable, and

(iii) the type of clientele to whom the applicant intends to supply the precursor;

(*c*.1) if an establishment licence under section C.01A.008 of the *Food and Drug Regulations* has been issued to the applicant in respect of a Class A precursor, the number of the licence;

(4) Paragraph 14(1)(*h*) of the Regulations is replaced by the following:

(*h*) a description of the proposed security measures to be used at the site and when a precursor is transported, sent or delivered, including the measures required under subsection 9(2), section 83 and subsection 85(3);

10. The Regulations are amended by adding the following after section 15:

Pre-licence Inspection

15.1 The Minister may, in respect of an applicant or a licensed dealer, at any reasonable time,

(*a*) require the inspection of the site used or intended to be used in producing, packaging, selling or providing a Class A precursor or to or from which a Class A precursor has been or is to be imported or exported;

(*b*) examine, as part of the inspection, the security measures used or put in place at the site and in respect of the sending, transportation or delivery of precursors;

(*c*) examine, as part of the inspection, the internal controls used or put in place at the site with respect to precursor activities and

(*d*) examine, as part of the inspection, the books, registers, electronic data and other records held or put in place in accordance with section 85.

11. (1) Paragraph 17(1)(*b*) of the Regulations is replaced by the following:

(*b*) the Minister has reasonable grounds to believe that any information or document included in the application is false or misleading;

(2) Paragraphs 17(1)(*e*) and (*f*) of the Regulations are replaced by the following:

(*e*) information received from a competent authority, the United Nations or a peace officer raises a reasonable belief that the applicant has been involved in the diversion of a

controlled drug or precursor to an illicit market or use;

(*f*) the applicant does not have in place the security measures required under subsection 9(2), section 83 and subsection 85(3) with respect to the precursors sought to be licensed;

12. The heading before section 19 of the English version of the Regulations is replaced by the following:

Amendment of Licence

13. (1) Subsection 20(1) of the English version of the Regulations is amended by striking out the word "or" at the end of paragraphs (*a*) and (*b*) and by adding the following after paragraph (*b*):

(*b*.1) making a change to the security measures used at the site with respect to Class A precursors kept there or described in the licence application under paragraph 14(1)(*h*) or in a request for approval under this section; or

(2) Subsection 20(3) of the Regulations is replaced by the following:

(3) When requesting an approval under paragraph (1)(*b*.1) or (*c*), the licensed dealer must provide the Minister with the information and documents that permit the Minister to make an evaluation required under paragraphs 17(1)(*f*) and (*i*).

14. Subsection 23(1) of the Regulations is amended by striking out the word "and" at the end of paragraph (*d*) and by replacing paragraph (*e*) with the following:

(*e*) information received from a competent authority, the United Nations or a peace officer raises a reasonable belief that the licensed dealer has been involved in the diversion of a controlled substance or precursor to an illicit market or use; or

(*f*) the continuation of the licence would likely create a risk to public health, safety or security, including the risk of a Class A precursor being diverted to an illicit market or use.

15. Section 24 of the Regulations is replaced by the following:

24. The Minister shall suspend a licence without prior notice if the Minister has reasonable grounds

(*a*) to believe that the suspension is necessary to protect public health, safety or security; or

(*b*) to suspect that the continuation of the licence presents a risk of a Class A precursor being diverted to an illicit market or use.

16. The Regulations are amended by adding the following after section 28:

Declaration

28.1 (1) Within 15 days after a shipment containing a Class A precursor is released from customs under the *Customs Act*, the holder of the Class A import permit for the shipment shall provide the Minister with a declaration containing the following information:

(*a*) the name of the holder and number of the permit for the shipment;

(*b*) the port of entry in Canada for the shipment;

(*c*) the date the shipment was released from customs;

(*d*) the name of the precursor being shipped or a description of its chemical composition, as stated in the permit; and

(*e*) the quantity of the precursor being shipped and, if it is a preparation or mixture, the quantity of all of the precursors set out in Part 1 of Schedule VI to the Act that it contains.

(2) The declaration shall

(*a*) be signed by the responsible person in charge or the alternate responsible person in charge for the licensed site to which the shipment will be transported after being released from customs; and

(*b*) include a statement that all information set out in the declaration is correct and complete to the best of the knowledge of the signatory.

17. Subsection 30(1) of the Regulations is replaced by the following:

30. (1) Subject to subsection (2), the Minister shall revoke a Class A import permit in accordance with subsection 84(1) if

(*a*) a circumstance described in any of paragraphs 23(1)(*a*) to (*f*) exists with respect to the licence pertaining to the Class A precursor to be imported; or

(*b*) the permit was issued on the basis of false or misleading information or false or falsified documents.

18. Paragraph 31(*b*) of the Regulations is replaced by the following:

(*b*) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health, safety or security;

(*b*.1) the Minister has reasonable grounds to suspect that the continuation of the permit presents a risk of a Class A precursor being diverted to an illicit market or use; or

19. The Regulations are amended by adding the following after section 35:

Declaration

35.1 (1) Within 15 days after a shipment containing a Class A precursor is exported, the holder of a Class A export permit for the shipment shall provide the Minister with a declaration containing the following information:

(*a*) the name of the holder and number of the permit for the shipment;

(*b*) the port of exit in Canada for the shipment;

(*c*) the date of export;

(*d*) the name of the precursor being shipped or a description of its chemical composition, as stated in the permit; and

(*e*) the quantity of the precursor being shipped and, if it is a preparation or mixture, the quantity of all precursors set out in Part 1 of Schedule VI to the Act that it contains.

(2) The declaration must

(*a*) be signed by the responsible person in charge or the alternate responsible person in charge for the licensed site from which the shipment will be transported to the port of exit; and

(*b*) include a statement that all information set out in the declaration is correct and complete to the best of the knowledge of the signatory.

20. Subsection 37(1) of the Regulations is replaced by the following:

37. (1) Subject to subsection (2), the Minister shall revoke a Class A export permit in accordance with subsection 84(1) if

(*a*) a circumstance described in any of paragraphs 23(1)(*a*) to (*f*) exists with respect to the licence pertaining to the Class A precursor to be exported; or

(*b*) the export permit was issued on the basis of false or misleading information or false or falsified documents.

21. Paragraph 38(*b*) of the Regulations is replaced by the following:

(*b*) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health, safety or security;

(*b*.1) the Minister has reasonable grounds to suspect that the continuation of the permit presents a risk of a Class A precursor being diverted to an illicit market or use;

22. Section 45(1) of the Regulations is amended by striking out the word "or" at the end of paragraph (*b*) and by replacing paragraph (*c*) with the following:

(*c*) information received from a competent authority, the United Nations or a peace officer raises a reasonable belief that the licensed dealer has been involved in the diversion of a controlled substance or precursor to an illicit market or use; or

(*d*) the continuation of the permit would likely create a risk to public health, safety or security, including the risk of a Class A precursor being diverted to an illicit market or use.

23. Section 46 of the Regulations is amended by striking out the word "or" at the end of paragraph (*a*) and by replacing paragraph (*b*) with the following:

(*b*) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health, safety or security; or

(*c*) the Minister has reasonable grounds to suspect that the continuation of the permit presents a risk of a Class A precursor being diverted to an illicit market or use.

24. Subsection 47(1) of the Regulations is replaced by the following:

47. (1) No licensed dealer may destroy a Class A precursor except in accordance with subsections (2) to (4).

25. The headings before section 48 of the Regulations are replaced by the following:

Preparations and Mixtures

Application for Authorization Certificate

26. (1) The portion of subsection 48(1) of the Regulations before paragraph (*a*) is replaced by the following:

48. (1) With respect to a Class A precursor that is a preparation or mixture, a person who produces or imports, or desires to do so, may apply for an authorization certificate with respect to the preparation or mixture by submitting an application to the Minister containing the following information and statements:

(2) Subsection 48(1) of the Regulations is amended by adding the following after paragraph (*b*):

(*b*.1) if the applicant is not the producer of the preparation or mixture, the name of the person who produced the precursor or, if the person is a corporation, its corporate name;

(*b*.2) the address, telephone number and facsimile transmission number, if any, of the person who produced the preparation or mixture;

(3) Paragraphs 48(1)(*d*) and (*e*) of the Regulations are replaced by the following:

(*d*) a statement, by the person who produced the preparation or mixture, that the preparation or mixture is made in such a way that no precursors set out in Part 1 of Schedule VI to the Act can be readily extracted, having regard to the complexity and cost of extraction, and that the preparation or mixture cannot be used in the production of a controlled substance; and

(*e*) a statement, by the person who produced the preparation or mixture, justifying the application for the certificate, and identifying the scientific principles and any other information in support of the statement under paragraph (*d*).

(4) The portion of subsection 48(2) of the French version of the Regulations before paragraph (*a*) is replaced by the following:

(2) La demande de certificat doit :

27. The heading before section 49 of the Regulations is replaced by the following:

Issuance of Authorization Certificate

28. (1) The portion of section 49 of the Regulations before paragraph (*a*) is replaced by the following:

49. (1) Subject to section 50, if an application complies with the requirements of section 48, the Minister shall issue to the applicant an authorization certificate that indicates

(2) Paragraph 49(1)(*b*) of the Regulations is replaced by the following:

(*b*) the name, if any, of the preparation or mixture that is the subject of the certificate, otherwise a description of its chemical composition, and its brand name, if any;

(3) Subsection 49(1) of the Regulations is amended by adding the following after paragraph (*c*):

(*c*.1) if the applicant is not the producer of the preparation or mixture, the name of the person who produced the precursor or, if the person is a corporation, its corporate name;

(4) Section 49 of the Regulations is amended by adding the following after subsection (1):

(2) The holder of an authorization certificate shall, on request, provide a copy of the certificate to any person conducting an activity in relation to the preparation or mixture to which the certificate applies.

29. Section 50 of the Regulations is replaced by the following:

50. The Minister shall refuse to issue an authorization certificate if, according to the information provided and scientific data or other information or evidence available, a precursor set out in Part 1 of Schedule VI to the Act can be readily extracted from the preparation or mixture that is the subject of the application, having regard to the complexity and cost of extraction, or the preparation or mixture can be used in the production of a controlled substance.

30. Sections 51 to 54 of the Regulations are replaced by the following:

51. A person who imports or exports a Class A precursor that is a preparation or mixture mentioned in an authorization certificate shall ensure that the shipment is accompanied by a document containing:

(*a*) a statement that the preparation or mixture is subject to an authorization certificate under section 49; and

(*b*) the number of the certificate for the preparation or mixture.

Revocation or Suspension of Certificate

52. The Minister shall revoke an authorization certificate at the request of the holder.

53. (1) The Minister shall, in accordance with subsection 84(1), revoke an authorization certificate if the certificate

(*a*) was issued on the basis of false or misleading information, or false or falsified documents; or

(*b*) has been the subject of a suspension under paragraph 54(*a*) and subsection 84(2) and the suspension has not been complied with.

(2) The Minister may revoke an authorization certificate if the holder fails to comply with a decision of the Minister to suspend the certificate under section 54, or if the situation giving rise to the suspension is not rectified.

54. The Minister shall, without prior notice, suspend an authorization certificate if

(*a*) new scientific evidence or other new information demonstrates that a precursor set out in Part 1 of Schedule VI to the Act can be readily extracted from the preparation or mixture mentioned in the certificate, having regard to the complexity and cost of extraction, or demonstrates that the preparation or mixture may be or has been used in the production of a controlled substance;

(*b*) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health, safety or security; or

(*c*) the Minister has reasonable grounds to suspect that the continuation of the permit presents a risk of a Class A precursor being diverted to an illicit market or use.

31. Sections 55 and 56 of the Regulations are replaced by the following:

55. With respect to a Class B precursor that is a preparation or mixture, a person who conducts an activity mentioned in section 57 is exempt from the requirements of these Regulations, except requirements applying to production for the purpose of sale or provision, if the preparation or mixture contains a precursor set out in Part 2 of Schedule VI to the Act and the contained precursor, either alone or with any other precursor of the same type, does not constitute more than 30% of the preparation or mixture by weight or volume, in the case of a solid or liquid, respectively.

56. A person who uses a Class B precursor that is described in section 55 or is the subject of an authorization certificate under section 77, to produce another Class B precursor that is a preparation or mixture, is exempt from the requirements of these Regulations in respect of that production.

32. The Regulations are amended by adding the following after section 57:

Authorization Concerning Preparations and Mixtures

57.1 Despite section 57, with respect to a Class B precursor that is a preparation or mixture, a person may import, export or possess for those purposes if

(*a*) the preparation or mixture is the subject of an authorization certificate under section 77; and

(*b*) no notice indicating that the certificate has been revoked or is under suspension appears on the following Health Canada Internet site:

http://www.hc-sc.gc.ca/hecs-sesc/ocs/index.htm

33. (1) Paragraph 63(1)(*b*) of the Regulations is replaced by the following:

(*b*) the Minister has reasonable grounds to believe that any information or document included in the application is false or misleading;

(2) Paragraph 63(1)(*e*) of the Regulations is replaced by the following:

(*e*) information received from a competent authority, the United Nations or a peace officer raises a reasonable belief that the applicant has been involved in the diversion of a controlled substance or precursor to an illicit market or use;

34. Paragraph 67(1)(*e*) of the Regulations is replaced by the following:

(*e*) information received from a competent authority, the United Nations or a peace officer raises a reasonable belief that the registered dealer has been involved in the diversion of a controlled substance or precursor to an illicit market or use;

(*e*.1) the continuation of the registration would likely create a risk to public health, safety or security, including the risk of a Class B precursor being diverted to an illicit market or use; or

35. Section 68 of the Regulations is replaced by the following:

68. The Minister shall suspend a registration and the corresponding certificate without prior notice if the Minister has reasonable grounds

(*a*) to believe that the suspension is necessary to protect public health, safety or security; or

(*b*) to suspect that the continuation of the registration and the certificate presents a risk of a Class B precursor being diverted to an illicit market or use.

36. The Regulations are amended by adding the following after section 72:

Declaration

72.1 (1) Within 15 days after a shipment containing a Class B precursor is exported, the holder of a Class B export permit for the shipment shall provide the Minister with a declaration containing the following information:

(*a*) the name of the holder and number of the permit for the shipment;

(*b*) the port of exit in Canada for the shipment;

(*c*) the date of export;

(*d*) the name of the precursor being shipped, if any, otherwise a description of its chemical composition, as stated in the permit; and

(*e*) the quantity of the precursor being shipped and, if it is a preparation or mixture, the quantity of all precursors set out in Part 2 of Schedule VI to the Act that it contains.

(2) The declaration must

(*a*) be signed by the responsible person in charge or the alternate responsible person in charge for the licensed site from which the shipment will be transported to the port of exit; and

(*b*) include a statement that all information set out in the declaration is correct and complete to the best of the knowledge of the signatory.

37. Subsection 74(1) of the Regulations is replaced by the following:

74. (1) Subject to subsection (2), the Minister shall revoke a Class B export permit in

accordance with subsection 84(1) if

(*a*) a circumstance described in any of paragraphs 67(1)(*a*) to (*f*) exists with respect to the registration of the holder of the permit; or

(*b*) the export permit was issued on the basis of false or misleading information or false or falsified documents.

38. Paragraph 75(*b*) of the Regulations is replaced by the following:

(*b*) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health, safety or security;

(*b*.1) the Minister has reasonable grounds to suspect that the continuation of the permit presents a risk of a Class B precursor being diverted to an illicit market or use;

39. The headings before section 76 of the Regulations are replaced by the following:

Preparations and Mixtures

Application for Authorization Certificate

40. (1) The portion of subsection 76(1) of the Regulations before paragraph (*a*) is replaced by the following:

76. (1) With respect to a Class B precursor that is a preparation or mixture, a person who produces for the purpose of sale or provision or imports, or desires to do so, may apply for an authorization certificate for the preparation or mixture, by submitting an application to the Minister containing the following information and statements:

(2) Subsection 76(1) of the Regulations is amended by adding the following after paragraph (*b*):

(*b*.1) if the person is not the producer of the preparation or mixture, the name of the producer or, if the producer is a corporation, its corporate name;

(*b*.2) the address and the telephone number and facsimile transmission number, if any, of the producer of the preparation or mixture;

(3) Paragraphs 76(1)(*d*) and (*e*) of the Regulations is replaced by the following:

(*d*) a statement, by the producer of the preparation or mixture, that the preparation or mixture is made in such a way that no precursor set out in Part 2 of Schedule VI to the Act contained in it can be readily extracted, having regard to the complexity and cost of extraction, and that the preparation or mixture cannot be used in the production of a controlled substance; and

(*e*) a statement, by the producer of the preparation or mixture, justifying the application for the certificate, and identifying the scientific principles and any other information in support of the statement under paragraph (*d*).

(4) The portion of subsection 76(2) of the French version of the Regulations before paragraph (*a*) is replaced by the following:

(2) La demande de certificat doit :

(5) Subparagraph 76(2)(*a*)(i) of the English version of the Regulations is replaced by the following:

(i) a person working for the applicant having supervisory responsibilities pertaining to the preparation or mixture and sufficient knowledge to confirm the information set out in the application, or

41. The heading before section 77 of the Regulations is replaced by the following:

Issuance of Authorization Certificate

42. (1) The portion of section 77 of the Regulations before paragraph (*a*) is replaced by the following:

77. (1) Subject to section 78, if an application complies with the requirements of section 76, the Minister shall issue to the applicant an authorization certificate that indicates

(2) Paragraph 77(1)(*b*) of the Regulations is replaced by the following:

(*b*) the name, if any, of the preparation or mixture that is the subject of the certificate, otherwise a description of its chemical composition, and its brand name, if any;

(3) Section 77 of the Regulations is amended by adding the following after subsection (1):

(2) The holder of an authorization certificate shall, on request, provide a copy of the certificate to any person conducting an activity in relation to the preparation or mixture to which the certificate applies.

43. Section 78 of the Regulations is replaced by the following:

78. The Minister shall refuse to issue an authorization certificate if, according to the information provided and scientific data or other information or evidence available, a precursor set out in Part 2 of Schedule VI to the Act can be readily extracted from the preparation or mixture that is the subject of the application, having regard to the complexity and cost of extraction, or the preparation or mixture can be used in the production of a controlled substance.

44. Sections 79 to 82 of the Regulations are replaced by the following:

79. A person who exports a preparation or mixture mentioned in an authorization certificate shall ensure that the shipment is accompanied by a document containing:

(*a*) a statement that the preparation or mixture is subject to an authorization certificate under section 77; and

(*b*) the number of the certificate for the preparation or mixture.

Revocation and Suspension

80. The Minister shall revoke an authorization certificate at the request of the holder.

81. (1) The Minister shall, in accordance with subsection 84(1), revoke an authorization certificate if the certificate

(*a*) was issued on the basis of false or misleading information, or false or falsified documents; or

(*b*) has been the subject of a suspension under paragraph 82(*a*) and subsection 84(2) and the suspension has not been complied with.

(2) The Minister may revoke an authorization certificate if the holder fails to comply with a decision of the Minister to suspend the certificate under section 82, or if the situation giving rise to the suspension is not rectified.

82. The Minister shall, without prior notice, suspend an authorization certificate if

(*a*) new scientific evidence or other new information demonstrates that a precursor set out in Part 2 of Schedule VI to the Act can be readily extracted from the preparation or mixture mentioned in the certificate, having regard to the complexity and cost of extraction, or demonstrates that the preparation or mixture may be or has been used in the production of a controlled substance;

(*b*) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health, safety or security; or

(*c*) the Minister has reasonable grounds to suspect that the continuation of the authorization certificate presents a risk of a Class B precursor being diverted to an illicit market or use.

45. (1) The portion of subsection 84(1) of the Regulations before paragraph (*a*) is replaced by the following:

84. (1) If the Minister proposes to refuse to issue, amend or renew, or proposes to revoke, a licence, a registration and the corresponding registration certificate, an authorization certificate, an import or export permit or a permit for transit or transhipment, issued under these Regulations, the Minister shall provide the applicant or the holder with

(2) Subsection 84(2) is replaced by the following:

(2) A decision of the Minister to suspend a licence, a registration and the corresponding registration certificate, an authorization certificate, an import or export permit or a permit for transit or transhipment, issued under these Regulations, takes effect as soon as the Minister notifies the holder of the decision and provides a written report of the reasons for the suspension.

46. Subsection 85(3) of the French version of the Regulations is replaced by the following:

(3) Le distributeur autorisé tient, à l'installation visée par la licence, un registre où sont consignés, chaque jour où une personne accède, à l'installation, à un lieu où sont conservés des précurseurs de catégorie A, le nom de cette personne ainsi que la date de son accès à ce lieu.

47. Section 87 of the Regulations is amended by striking out the word "and" at the end of paragraph (*a*) and by replacing paragraph (*b*) with the following:

(*b*) the quantity of each Class A precursor in physical inventory taken at the site at the end of the calendar year; and

(*c*) the name and quantity of any Class A precursor that has been lost or wasted in the course of conducting authorized activities during the calendar year.

48. The Regulations are amended by adding the following after section 87:

Notice of Precursor Removal

87.1 If a licensed dealer or registered dealer intends to close a site at which one or more Class A or B precursors are kept, or to remove all precursors from the site, the dealer shall, at least 30 days before the closure or removal, notify the Minister in writing of

(*a*) the date of the intended closure or removal;

(*b*) the site to which the precursors will be moved; and

(*c*) the quantity of each precursor to be moved.

49. Subsection 89(1) of the Regulations is replaced by the following:

89. (1) If a licence or a registration or authorization certificate is renewed, the holder shall, immediately after the effective date of the replacing document, return the replaced document to the Minister.

50. (1) The portion of subsection 90(2) of the Regulations before paragraph (*a*) is replaced by the following:

(2) If a licensed dealer or registered dealer experiences a theft of a precursor or an unusual waste or disappearance of a precursor that cannot be explained on the basis of normally accepted business activities, the licensed dealer or registered dealer

(2) Section 90 of the Regulations is amended by adding the following after subsection (2):

(3) If a licence, a registration or authorization certificate, an import or export permit or a permit for transit or transhipment issued under these Regulations, is lost or stolen, the holder of the document shall provide notice of the occurrence to the Minister, in writing, within 24 hours after becoming aware of the occurrence.

51. (1) The portion of subsection 91(4) of the Regulations before paragraph (*a*) is replaced by the following:

(4) The Minister may, for the purpose of verifying whether a precursor that is a preparation or mixture is the subject of an authorization certificate under these Regulations and may be imported, exported, transported in transit through Canada or transhipped in Canada without the appropriate permit under these Regulations, communicate the following information to a customs officer in Canada:

(2) Paragraphs 91(4)(*b*) and (*c*) of the Regulations are replaced by the following:

(*b*) the name of the preparation or mixture, if any, otherwise a description of its chemical composition, and its brand name, if any;

(*c*) the name of the person who applied for the authorization certificate, or if a corporation, their corporate name;

52. The Regulations are amended by adding the following after section 91:

PART 4

PHARMACISTS, PRACTITIONERS AND HOSPITALS

Non-Application

91.1 With respect to a Class A precursor, the requirements of subsections 6(1) and (2) and 9(1) concerning sale or provision, possession for the purpose of sale or provision and transport do not apply to a pharmacist, practitioner or hospital that sells or provides preparations or mixtures containing Class A precursors only on a retail basis.

Pharmacists

91.2 A pharmacist may, pursuant to a prescription, compound a preparation or mixture using a precursor.

91.3 (1) A pharmacist may sell or provide a preparation or mixture that contains a Class A precursor set out in column 1 of the schedule, in a quantity, per transaction, exceeding the maximum quantity, expressed as an absolute quantity or per package, specified for the contained precursor in column 2 of the schedule, if the pharmacist sells or provides preparations or mixtures containing Class A precursors exclusively on a retail basis and the transaction is made under a prescription.

(2) The prescription must be

(*a*) written, dated and signed by the practitioner who issued it;

(*b*) provided verbally by a practitioner; or

(*c*) transferred to the pharmacist in accordance with the requirements of section 91.7.

Information to Be Recorded

91.4 (1) A pharmacist who receives a verbal prescription for a preparation or mixture containing a Class A precursor must, before filling it, record the following information:

(*a*) the name and address of the individual or animal for whose benefit the prescription is provided;

(*b*) the date on which the prescription was provided;

(*c*) the name and quantity of the preparation or mixture specified in the prescription;

(*d*) the name of the recording pharmacist and the name of the practitioner who issued the prescription;

(*e*) the directions for use specified by the practitioner; and

(*f*) if the prescription is to be refilled, the number of times it may be refilled and, if applicable, the interval between refills.

(2) The pharmacist must retain, in accordance with section 91.95, a hard copy of the prescription or a written record of it.

91.5 (1) Subject to section 91.6, a pharmacist who fills a written or oral prescription for a preparation or mixture containing a Class A precursor must record the following information:

(*a*) the date the prescription was filled;

(*b*) the quantity of the preparation or mixture;

(*c*) the pharmacist's name or initials; and

(*d*) the number assigned to the prescription.

(2) A pharmacist who fills a written prescription shall retain the prescription in accordance with section 91.95.

Refill of Prescription

91.6 A pharmacist may only refill a prescription for a preparation or mixture containing a Class A precursor if

(*a*) the practitioner who issued the prescription expressly directs that it may be refilled and specifies the number of refills;

(*b*) the pharmacist makes a record of each refill in accordance with subsection 91.5(1), with any modifications that the circumstances require;

(*c*) at least one refill remains on the prescription; and

(*d*) if an interval between refills has been specified by the practitioner, the interval has expired.

Transfer of Prescription

91.7 (1) A pharmacist may transfer a prescription for a preparation or mixture containing a Class A precursor to another pharmacist or to a hospital.

(2) Before a pharmacist sells or provides a preparation or mixture containing a Class A precursor to an individual under a prescription transferred under subsection (1), the pharmacist shall

(*a*) in the case of a verbal transfer, record the information required by subsection 91.4(1);

(*b*) in the case of a written transfer, obtain from the transferring pharmacist a copy of

(i) the prescription written by the practitioner, or

(ii) the written record, made in accordance with subsection 91.4(2), of the practitioner's verbal prescription; and

(*c*) in all cases, record

(i) the name and address of the transferring pharmacist,

(ii) the number of authorized refills remaining and, if applicable, the specified interval between refills, and

(iii) the date of the last refill.

Practitioners

91.8 A practitioner may, with respect to a preparation or mixture containing a Class A precursor, prescribe it for, administer it to an individual or animal, or sell or provide it to or for an individual or for the benefit of an animal, only if

(*a*) the individual or animal is a patient that the practitioner is treating in their professional capacity; and

(*b*) the preparation or mixture is required to treat the individual's or animal's medical condition.

91.9 A practitioner who sells or provides a preparation or mixture containing a Class A precursor set out in column 1 of the schedule to a person for self-administration or administration to an animal in a quantity that exceeds the maximum quantity, expressed as an absolute quantity or per package, specified for the contained precursor in column 2 of the schedule, shall make a record of the following information:

(*a*) the name and quantity of the preparation or mixture;

(*b*) the name and address of the person to whom the preparation or mixture was provided; and

(*c*) the date on which the preparation or mixture was provided.

Hospitals

91.91 A hospital that sells or provides a preparation or mixture containing a Class A precursor exclusively on a retail basis may do so subject to sections 91.92 to 91.94.

91.92 (1) The person in charge of a hospital shall not permit a preparation or mixture containing a Class A precursor set out in column 1 of the schedule to be sold or provided to a patient or for the benefit of an animal under treatment as an in-patient or an out-patient of the hospital in a quantity, per transaction, that exceeds the maximum quantity, expressed as an absolute quantity or per package, specified for the contained precursor in column 2 of the schedule, unless the transaction is made under a prescription or another authorization of a practitioner practising in the hospital.

(2) The person in charge of the hospital shall keep the following information or ensure that it is kept:

(*a*) the name and quantity of the preparation or mixture provided when the prescription was filled;

(*b*) the name and address of the person for whom the prescription was issued;

(*c*) the date on which the prescription was filled; and

(*d*) the number assigned to the prescription.

91.93 The person in charge of a hospital shall not permit a prescription for a preparation or mixture containing a Class A precursor to be refilled by the hospital unless the requirements of section 91.6 are satisfied, with any modifications that the circumstances require.

91.94 The person in charge of a hospital shall not permit a preparation or mixture containing a Class A precursor to be sold or provided pursuant to a prescription that has been transferred to the hospital, unless the requirements of subsection 91.7(2) are satisfied, with any modifications that the circumstances require.

91.95 Information to be recorded and records to be kept under this Part shall be retained for two years after the date the information was obtained or the record was made.

Security Measures and Communication of Information

91.96 A pharmacist, a practitioner and a person in charge of a hospital who are subject to this Part shall

(*a*) take reasonable steps to ensure the security of the Class A precursors they sell, provide or possess;

(*b*) on discovering a theft or an unusual waste or disappearance of a Class A precursor that cannot be explained on the basis of normally accepted business practices, notify

(i) the appropriate police force within 24 hours of the discovery, and

(ii) the Minister, in writing, within 72 hours after making the discovery, and confirm that the notice required under subparagraph (i) has been provided;

(*c*) on request, making available to the Minister any information required to be kept under this Part; and

(*d*) on request, making available to the inspector, any prescription or other record required to be made or kept under this Part.

53. The schedule to the Regulations is amended by replacing the reference "*(sections 5, 8 and 92)*" after the heading "SCHEDULE" with the reference "*(sections 5, 8, 91.3, 91.9, 91.92 and 92)*".

54. The schedule to the Regulations is amended by adding the following after item 18:

Item	Column 1 Precursor set out in Part 1 of Schedule VI to the Act	Column 2 Maximum Quantity (expressed as an absolute amount or per package)
19.	Gamma-butyrolactone (dihydro-2(3H)-furanone)	0
20.	1,4-Butanediol	0
21.	Red Phosphorus	0
22.	White Phosphorus	0
23.	Hypophosphorous acid and its derivatives	0
24.	Hydriodic acid	0

55. The Regulations are amended by replacing the expression "registration or exemption certificate" with the expression "registration or authorization certificate" in:

(*a*) section 88;

(*b*) subsection 89(2);

(*c*) subsection 90(1); and

(*d*) paragraph 91(5)(*a*).

COMING INTO FORCE

56. These Regulations come into force on the day on which they are registered.

[24-1-o]

Footnote a

S.C. 1996, c. 19

Footnote 1

SOR/2002-359

NOTICE:
The format of the electronic version of this issue of the Canada Gazette was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.

Top of page

Maintained by the Canada Gazette Directorate

Important Notices

Updated: 2005-06-10