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Regulations Respecting 2-Butoxyethanol

Statutory authority

Canadian Environmental Protection Act, 1999

Sponsoring departments

Department of the Environment and Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

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

Description

Purpose

The purpose of the proposed *Regulations Respecting 2-Butoxyethanol* (hereinafter referred to as the "proposed Regulations") is to protect the health of Canadians by setting limits for the concentration of 2-Butoxyethanol (2-BE) in products designed for indoor use. This will reduce human exposure to 2-BE present in cleaning, painting and coating products. The proposed concentration limits will apply to products that are manufactured, imported, offered for sale, sold or used in Canada.

The proposed Regulations will come into force one year after the day on which they are registered.

Background

On August 9, 2003, the Ministers of the Environment and of Health published their final decision on the assessment of 2-BE in the *Canada Gazette* and recommended that 2-BE be added to the List of Toxic Substances in Schedule 1 under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). The final version of the assessment report concluded that 2-BE constitutes a danger in Canada to human life or health, under paragraph 64(*c*) of CEPA 1999. However, 2-BE is not considered harmful to the environment or the environment on which life depends. On March 9, 2005, an order adding 2-BE to the List of Toxic Substances in Schedule 1 of CEPA 1999 was published in the *Canada Gazette*, Part II.

2-BE was included in the second Priority Substances List. Based on investigations in experimental animals, the assessment report concluded that the critical health risk associated with 2-BE is alterations in blood associated with hemolytic anemia. These health risks were found to correspond to chronic exposure to 2-BE. The assessment report proposed a Tolerable Concentration (TC) to reduce health risks. A TC is the level of intake to which it is believed a person may be exposed daily over a lifetime without deleterious effect. The TC for 2-BE-induced hematological effects in humans should not exceed 11 milligrams/cubic metre (2.3 parts per million).

2-BE is used in a wide range of applications, including industrial, institutional and consumer products. Emissions of 2-BE from industrial sources do not result in atmospheric concentrations that may present a health risk to the Canadian population. Indeed, the assessment report indicated that levels of 2-BE in ambient air in Canada are lower than the TC.

2-BE is also used in cleaning, painting, and coating products, many of which are designed for indoor use. These products are used routinely by consumers and by institutions, such as schools and hospitals, where the general public is present. Consumer exposure modelling indicated that exposure resulting from the use of products containing 2-BE in indoor settings could potentially exceed the TC. Therefore, addressing the 2-BE content of indoor products used by consumers and institutions is essential for reducing the human health risk identified by the assessment report.

2-BE belongs to the category of glycol ethers, and substitutes available commercially are also glycol ethers. This substance is not manufactured in Canada. 2-BE is imported as a commodity chemical and as a component of formulated products. The quantity of 2-BE used in Canada grew during the 1990s and peaked in the year 2000 at almost 8 kilotonnes (kt). Starting in 2001, the quantities of 2-BE used in Canada have been declining steadily and fell to about 4.6 kt in 2004, which includes 1 kt used in consumer products and 3.6 kt used in industrial applications. This represents a decline of 42 percent between year 2000 and year 2004 and an average annual rate of decline of 12.6 percent. The declining trend in the use of 2-BE in Canada is largely due to the replacement of 2-BE with alternatives that have a lower volatile organic compound (VOC) potential.

It was estimated that a total of 444 cleaning, painting and coating products for indoor use, which are currently commercialized, contain 2-BE. Several of these products already show 2-BE concentrations below the proposed limits and are therefore not expected to be affected by the proposed Regulations. The proposed concentration limits are based on TC and exposure from product use. Other products, including 261 paints and coatings and 59 cleaning products, contain 2-BE in concentrations that exceed the proposed limits. It was estimated that a total of 702 tonnes of 2-BE was used in these products in

2004.

Proposed Regulations

The proposed Regulations set limits in the concentration of 2-BE in products designed for indoor use. These concentration limits will ensure that users and bystanders are not exposed to levels of 2-BE above the TC proposed by the assessment report. Table 1 shows the limits proposed for different categories of products.

Table 1: Proposed 2-BE concentration limits for indoor-use products

Products	**Concentration Limit (%)**
Cleaner* (pressurized aerosol product**)	5.0
Cleaner* (non-pressurized product)	6.0
Automobile cleaner***	10.0
Rug or carpet cleaner	10.0
Floor or baseboard stripper	2.0
Paint stripper or thinner	0.5
Paint or coating (pressurized aerosol product**)	0.1
Paint or coating (non-pressurized product)	0.5

* A product to be used to degrease and clean glass, floors and others surfaces, including bathroom and kitchen surfaces, but does not include rug or carpet cleaners, automobile cleaners, automobile degreasers, paint thinners, paint strippers and floor or baseboard strippers.

** Does not include pump sprays.

*** Does not include automobile degreasers.

In those cases where there are no technically or economically feasible alternatives or substitutes for 2-BE readily available, firms that manufacture and/or import products subject to the proposed Regulations will be able to apply for permits to continue using 2-BE in excess of the limits prescribed by the proposed Regulations. The applicant will have to demonstrate that there is no technically or economically feasible alternative or substitute for 2-BE readily available, and that a plan has been prepared for complying with the proposed concentration limits. In addition, the applicant will have to provide a timeframe for implementing the proposed plan. Permits will be issued for 24 months and will be renewable only once. The requirements for applying for a permit renewal are the same as those for applying for the original permit.

Manufacturers and importers of products specified in Table 1 whose products contain 2-BE in a concentration greater than 0.1 percent of the total product will be required to submit certain information to the Minister, including a declaration that the concentration of 2-BE in the product is equal to or less than the limits set out for that product. Submissions

may be accompanied with a request for confidentiality under section 313 of CEPA 1999 and the reason for the request. Submitters have to keep a copy of all information and accompanying documents submitted to the Minister for a period of at least five years.

Existing environmental controls on 2-BE

There are currently a series of measures aimed at reducing emission of and human exposure to 2-BE. These include the *Consumer Chemicals and Containers Regulations, 2001* (under the *Hazardous Products Act*), the Environmental Choice Labelling Program, and the *Guidelines for Volatile Organic Compounds in Consumer Products*.

The *Consumer Chemicals and Containers Regulations, 2001* (under the *Hazardous Products Act*) classify consumer products containing 2-BE based on their human health hazard. They also require precautionary labelling, in order to inform consumers of the hazards posed by particularly harmful products during normal use. In addition, a prohibition related to the toxicological properties of products eliminates consumer exposure to very harmful chemicals. The classification is completed on a whole product basis. Thus 2-BE content alone would not necessarily be indicative of the hazard rating for a particular product. This classification does not consider chronic toxic effects of products, only acute ones.

The Environmental Choice Labelling Program encompasses cleaning products, biologically based cleaning and degreasing compounds, and personal care products. Firms commercializing these products can use the EcoLogo only if the product does not contain 2-BE.

The federal *Guidelines for Volatile Organic Compounds in Consumer Products* recommend levels for total VOCs, including 2-BE, in product categories. Further, the Minister of the Environment and the Minister of Health intend to develop and implement, between 2004 and 2010, a series of measures to reduce emissions of VOCs from consumer and commercial products in accordance with the *Federal Agenda for Reduction of Emissions of VOCs from Consumer and Commercial Products*. 2-BE is a VOC, and any action taken for VOCs in consumer products may also indirectly reduce exposure to 2-BE.

Although these measures aim at reducing human exposure to 2-BE, they are unlikely to achieve the objective of reducing exposure below the TC. For example, the recommendation for total VOC content set out in the *Guidelines for Volatile Organic Compounds in Consumer Products* could be achieved without reducing the 2-BE content. In addition, these Guidelines and the Environmental Choice Labelling Program are voluntary in nature. Finally, the *Consumer Chemicals and Containers Regulations, 2001* address acute toxicity rather than chronic toxicity. Therefore, all existing controls on 2-BE were deemed inappropriate for dealing with the chronic human health risk evaluated by the assessment report.

Alternatives

Status quo

Consumer exposure modelling indicated that under current use patterns, people might be

exposed to unsafe levels of 2-BE. It was hence concluded that the status quo could not be allowed to persist, and that some form of control measure to reduce the exposure of consumers and bystanders to 2-BE would need to be undertaken.

Economic instruments

Economic or market-based instruments work by providing incentives aimed at changing consumer and producer behaviour. When properly used, market-based instruments promote cost-effective ways of dealing with environmental issues. In addition, they provide long-term incentives for pollution reduction and technological innovation. The analysis considered emission trading programs and environmental charges.

Emission trading programs could guarantee a reduction in the overall use of 2-BE in indoor-use products. However, the health risk posed by different products is varied, and emission trading could not discriminate among different products. Therefore, emission trading could not ensure that reductions would occur in those products that present the highest risk.

Environmental charges could be levied on products containing concentrations of 2-BE above the proposed thresholds. However, under section 328 of CEPA 1999, charges can only be raised to cover federal government administration costs. Thus, there is a high probability that they will not provide enough of an incentive for firms to switch or reformulate to substitutes for 2-BE. Therefore, the health risk of concern could persist despite the environmental charges.

Voluntary measures

The main concern with voluntary tools is their effectiveness in achieving the proposed risk management objective. Voluntary measures not being mandatory, they do not ensure an effective reduction in health risks and would not ensure a fair and level playing field.

Pollution prevention plans

Pollution prevention (P2) plans were considered to be potentially effective instruments for reducing human exposure below the TC levels. However, some important concerns remained, as they could not ensure a level playing field, since the flexibility of the P2 planning requirements in CEPA 1999 allows a regulatee to implement only as many of the factors to be considered for a P2 plan that the person is able to implement.

Adopting existing measures

Although existing measures aim at reducing human exposure to 2-BE, they are unlikely to achieve the objective of reducing such exposure below the TC. Therefore, all existing measures that could apply to 2-BE were deemed inappropriate for dealing with its risk to human health.

Regulations respecting 2-BE

The proposed Regulations were considered to be the most practical and effective way of

addressing the human health concerns associated with 2-BE. First, by setting mandatory concentration limits for the 2-BE content of indoor-use products, the Regulations would have the capacity to achieve the proposed risk management objective in an effective way. Finally, the proposed Regulations provide a level playing field in both the domestic and the international market.

Benefits and costs

Baseline scenario

The baseline scenario assumed that the observed trend in the declining of 2-BE use would continue for some time and that the quantity of 2-BE imported and used would further decline until about 2010. This is based on the judgment that manufacturers would continue to use 2-BE in proven products and would reduce its concentrations slowly but would use alternatives increasingly in newer products. The total use of 2-BE in consumer products is projected to fall to about 480 tonnes by year 2010, including 340 tonnes used in products affected by the proposed Regulations. From 2010 onward, the baseline scenario assumed that uses of 2-BE remain constant.

Regulated scenario

Most alternatives to 2-BE are already being produced in commercial volumes, and commercial supply is expected to meet the increased demand caused by the proposed Regulations. In addition to being available, several replacements for 2-BE are cost-effective substitutes in many applications. Therefore, the industry is expected to replace 2-BE in a large number of products and reduce 2-BE to allowable concentration limits in others. However, replacing 2-BE is expected to be difficult in some applications, where technical properties of 2-BE are rather unique or difficult to replicate in a cost-effective manner. In such instances, the permits system set out by the proposed Regulations will provide the industry with some flexibility and time to find a substitute.

Under the assumptions of the regulated scenario, the use of 2-BE in indoor-use products directly affected by the proposed Regulations is predicted to fall from about 340 tonnes under baseline to 151.6 tonnes by the year 2010. In the year 2017, the use of 2-BE in the affected products is expected to fall from 280 tonnes under baseline to 19.5 tonnes under the regulated scenario.

2-BE substitutes considered in this analysis also belong to the category of glycol ethers and pose lower health risks than 2-BE. In consequence, they are acceptable alternatives from a human health perspective.

Cost-benefit analysis framework

The key categories of costs and benefits included in the analysis are

- Industry compliance costs
    - Input substitution costs
    - Product reformulation costs
    - Reporting, permits and other administrative costs
    - Transitional costs

- Government costs
    - Enforcement costs
    - Compliance promotion costs
    - Permit and reporting system administration costs
- Health benefits

All costs were estimated in monetary terms to the extent possible. Whenever this was not possible, due to lack of appropriate data or difficulties in valuing certain components or data inputs, the cost item was evaluated in qualitative terms. Monetary estimates were estimated in constant prices (or in real terms)—in this case, in 2004 Canadian dollars (C$ 2004). When the source data were affected by inflation, the data were converted into C$ 2004 using Statistics Canada's industrial price index for chemical products. Benefits were not quantified due to lack of epidemiological data. Instead, a qualitative assessment of benefits was done.

The time horizon used for evaluating economic impacts was 20 years. In addition, sensitivity testing was conducted using a 25-year time horizon. The first year of the analysis was 2007, when the proposed Regulations are expected to come into force.

Calculation of the stream of benefits and costs was done in terms of the present value (PV). PV calculation involves discounting the stream of costs and benefits with an annual real discount rate. This study employed the discount rate of 5 percent and then conducted a sensitivity analysis using 3 percent and 7 percent discount rates to test the volatility of cost estimates to this specific parameter.

Uncertainty and risk related to the magnitude and timing of costs and benefits was dealt with through sensitivity analysis and risk analysis. The risk analysis used probability distributions constructed from median values and lower and upper ranges for each variable. Probability distributions were calculated for model variables, parameters and final results.

Costs

Costs to the private sector

Costs to the private sector include input substitution, product reformulation, and administrative and transitional costs. Initially, these compliance costs will be incurred by the industry. Depending on market characteristics, some or all of these costs might be passed on to consumers through higher prices. This analysis generated estimates of industry compliance costs but did not assess the extent to which they would be transferred to consumers.

Replacing 2-BE in product formulations is expected to create input substitution costs wherever substitutes are more expensive than 2-BE. Cost savings might occur if substitutes are more cost-effective than 2-BE. Input substitution costs were estimated using market prices and technical performance indicators. In addition, reformulation costs will be incurred in developing new formulations that contain 2-BE levels below the proposed concentration limits. These costs were estimated based on the research and development efforts required to substitute 2-BE with other glycol ethers.

In addition, the proposed Regulations require firms to submit reports and to apply for permits. As a result, firms will incur administrative costs associated with these requirements. Firms might also incur other administrative costs, such as new products certification and stock management. Finally, transitional costs were included in the analysis. These costs encompass marketing efforts associated with new or reformulated products, as well as potential incremental costs of producing separately for domestic and export markets. Manufacturers are expected to incur the latter costs in cases where the increased cost of reformulated products negatively affects their competitiveness in international markets, thus motivating them to keep separate production lines for domestic and export sales.

A summary of cost estimates is provided in Table 2. Reformulation and administrative costs are the most significant, representing almost two thirds of total private sector costs. In addition, the risk analysis carried out to reflect uncertainty associated with model variables and parameters indicated that total costs to the private sector will fall between C$8.79 million and C$21.90 million (2004) with an 80 percent probability. Sources of uncertainty included the large variance in prices of 2-BE substitutes and data-related uncertainty.

Table 2: Estimates of private sector costs, in present value

CATEGORY OF COSTS	Present Value (in Million C$ 2004)
Total Costs to the Private Sector	**$15.06**
Incremental Input Costs	$1.59
Reformulation Costs	$6.14
Administrative Costs	$4.34
Transitional Costs	$2.99

Costs to the Government

The federal government is expected to incur some costs in implementing the proposed Regulations. Government costs include compliance promotion, reporting system administration, permits system administration, and enforcement. Government cost estimates are presented in Table 3.

Table 3: Summary of Government cost estimates, in present value

CATEGORY OF COSTS	Present Value (in Million C$ 2004)
Total Costs to the Government	**$9.96**
Compliance promotion	$0.06
Reporting system administration	$0.25
Permits system administration	$0.02
Enforcement	$9.63

Enforcement costs are expected to be the most significant Government investment in implementing the proposed Regulations. The number of retailers that sell cleaning, painting and coating products containing 2-BE is unknown. Therefore, inspection and other enforcement activities will focus on manufacturers and importers. Enforcement cost estimates assumed that 25 percent of the manufacturers and importers of cleaning, painting and coating products will be inspected over a period of 10 years. It was also assumed that each manufacturer and importer has four product brands subject to the proposed Regulations.

The focus of enforcement efforts will be on-site inspections, with sampling of regulated products and review of documents related to the ingredients/formulation of those products. Inspections will centre on the categories of cleaning, painting and coating products for which the estimated rate of non-compliance is highest. In addition, there will be off-site inspection of documents that are required to be submitted by regulatees and on-site inspection of documents that regulatees are required to retain at their principal place of business in Canada.

Compliance promotion activities are intended to encourage the regulated community to achieve compliance. Compliance promotion activities during the first year could include mailing out the final Regulations, answering inquiries, developing and distributing promotional materials (e.g. a fact sheet, Web material) and workshops/information sessions to explain the Regulations. In year two, compliance promotion activities will be limited to sending a reminder prior to the Regulations coming into force, responding to and tracking inquiries, and contributing to the compliance promotion database. Year three compliance promotion activities will be at a maintenance level and will be limited to responding to and tracking inquiries and contributing to the compliance promotion database. A higher level of effort for compliance promotion may be required if, subsequent to enforcement activities, compliance with the Regulations is found to be low.

Reporting system administration activities will include developing a stakeholder database, entering and verifying received data from stakeholders, and answering inquiries. In the second year and onward, reporting system administration will encompass entering, updating and verifying new data from stakeholders, managing the database and answering inquiries.

Permits system administration activities will include developing permits, administering permits, verifying the received information from stakeholders, and answering inquiries. Because permits expire after 24 months, and because new requests for permits are estimated to be low after the first year, the costs will be negligible for the second year. In the third year, permits administration activities will include administering permits, verifying the received information from stakeholders and answering inquiries. In the fourth year and onward, the cost is estimated to be negligible for new permit requests.

Total costs

The total costs of the proposed Regulations are summarized in Table 4. The PV of total costs was estimated at C$25.02 million (2004). Sensitivity analysis was conducted to test the volatility of cost estimates to the discount rate and the time horizon. This analysis showed that using a discount rate of 3 percent would increase total costs by 14.5 percent and using a discount rate of 7 percent would reduce total costs by 12 percent. Extending the time horizon to 25 years would increase total costs by 3.5 percent. In addition, the risk

analysis indicated that total costs to Canadian society are likely to fall between C$18.75 million and C$31.86 million (2004) with an 80 percent probability.

Table 4: Total costs of the proposed Regulations, in millions of C$ 2004, present value

CATEGORY OF COSTS	Present Value (in Millions of C$ 2004)
Total Costs	**$25.02**
Government Costs	$9.96
Private Sector Costs	$15.06

Distribution of private sector costs

The distributional analysis was conducted using data on the number of affected products, the distribution of 2-BE imports, and the distribution of industrial establishments across Canada. This analysis showed that costs will be unevenly distributed among industry sectors. In particular, the paint and coating sector is expected to be the most affected, mainly because the concentration limits are the most stringent and they affect a relatively large number of product brands. The results of the distributional analysis by sectors are summarized in Table 5.

Table 5: Distribution of total costs by sector, in millions of C$ 2004, present value

Sectors	Present Value (in Millions of C$ 2004)
Total Costs to Industry	**$15.06**
Soap and Cleaning Compounds Sector	
Cleaners	$3.15
Automobile cleaners	$0.14
Rug and carpet cleaners	$0.39
Paints and Coatings Sector	
Floor, baseboard, paint strippers	$1.63
Paints and coatings	$9.75

The geographic distribution of costs is summarized in Tables 6 and 7. Ontario and Quebec are the provinces that are expected to experience the largest share of industry costs. This is a direct result of both provinces concentrating the majority of the industrial sectors affected by the proposed Regulations. An analysis of costs per capita showed that Ontario and Quebec might also experience the highest costs per capita, together with British Columbia. This applies particularly to the paints and coatings sector, where costs per capita were estimated to be almost double in Ontario compared with the rest of Canada (excepting Quebec and British Columbia).

Table 6: Geographic distribution of total industry costs of the proposed Regulations (in millions of C$ 2004)

	SOAP AND CLEANING COMPOUNDS INDUSTRY		PAINTS AND COATINGS INDUSTRY		TOTAL	
GEOGRAPHIC REGION	**SHARE**	**COST (in Million C$ 2004)**	**SHARE**	**COST (in Million C$ 2004)**	**SHARE**	**TOTAL COST (in Million C$ 2004)**
Ontario	41.2%	$1.52	48.7%	$5.54	46.7%	$7.06
Quebec	28.9%	$1.06	21.0%	$2.39	23.0%	$3.45
British Columbia	12.7%	$0.47	13.6%	$1.55	13.4%	$2.02
Rest of Canada	17.2%	$0.63	16.7%	$1.90	16.9%	$2.53
Total Industry Cost		**$3.68**		**$11.38**		**$15.06**

Table 7: Geographic distribution of industry costs per capita of the proposed Regulations, in C$ 2004

GEOGRAPHIC REGION	POPULATION, in MILLIONS	SOAP AND CLEANING COMPOUNDS INDUSTRY COST PER CAPITA in C$ 2004	PAINTS AND COATINGS INDUSTRY COST PER CAPITA, in C$ 2004
Ontario	12.39	$0.12	$0.45
Quebec	7.54	$0.14	$0.32
British Columbia	4.20	$0.11	$0.37
Rest of Canada	7.81	$0.08	$0.24
All of Canada	31.95	$0.12	$0.36

The distributional analysis also evaluated the impacts on small- and medium-sized enterprises (SMEs). There is some evidence that indicates that smaller establishments might incur a relatively larger cost than larger ones. For example, there are indications that multinational firms have already moved away from 2-BE and that most 2-BE uses are concentrated in SMEs. Moreover, smaller firms are expected to benefit less from economies of scale, such as those derived by large firms from their capacity to absorb fixed costs and their access to input price discounts.

Estimates of fixed costs per product brand were used to assess the impact on SMEs. To the extent that fixed costs do not change much with firm size, smaller firms are expected to be more affected than larger ones. The analysis found that fixed costs amount on average to $40,000 in PV. These costs are in the range of the annual salary for one employee in the affected sectors, which is not expected to be significant for most SMEs. However, because some of these costs will be incurred in the first years after the proposed Regulations come into force, they might represent a financial burden to some

SMEs.

Benefits

Health benefits

In this assessment, the human health benefits of the proposed Regulations are discussed in qualitative terms. The links between reduced human exposure and reduced health risks were not quantified because of the lack of epidemiological data and evidence. Therefore, the human health benefits were not quantified or monetized. Nevertheless, estimates of the reduction in the number of people exposed to 2-BE in indoor-use products were derived in order to provide an indicator of the order of magnitude of the benefits associated with the proposed Regulations. The proposed Regulations are expected to reduce the health risk associated with hemolytic anemia by bringing human exposure below the TC proposed by the assessment report.

Considering current market trends that show a tendency toward the declining use of 2-BE, the proposed Regulations are expected to benefit Canadians by accelerating this trend and by ensuring that human exposure does not rise above TC levels.

Reduced human exposure resulting from the proposed Regulations is particularly clear in the use of 2-BE-containing paints and coatings, and such ancillary products as paint thinners. The proposed concentration limits are very low and will essentially result in a large proportion of 2-BE-containing paint and coating products being removed from the consumer market. Similarly, the reductions in 2-BE concentrations in cleaning products will result in reduced human exposure to 2-BE.

It was estimated that, after the proposed Regulations come into force, about 600 000 people will have access to cleaning products that no longer contain 2-BE or contain levels of 2-BE that will ensure that health risks associated with hemolytic anemia are reduced below the TC levels. In addition, 300 000 users of paints and coatings will have access to products with very low levels of 2-BE or with no 2-BE at all. The estimates of cleaning product users and paints and coatings users cannot be added up without running the risk of duplication, as the same people who use cleaning products may also use paints and coatings.

A reduced human health risk may also translate into lower health care costs to governments across Canada.

Net benefits

Because benefits were not amenable to monetization, a monetary estimate of net benefits of the proposed Regulations was not derived. Instead, the analysis focuses on a qualitative assessment of the trade-off between costs and benefits.

The costs of the proposed Regulations were estimated to amount to C$25.02 million (2004). The risk analysis indicated that total costs to Canadian society are likely to fall between C$18.75 and C$31.86 million (2004), with an 80 percent probability. The federal government will incur an estimated C$9.96 million (2004) in implementing the proposed Regulations. In addition, industry is expected to bear incremental costs estimated at

C$15.06 million (2004), at least in the beginning. The extent to which the industry will be able to pass on these costs to consumers through higher prices will determine the end recipient of the incremental costs. From a distributional standpoint, the provinces of Ontario and Quebec will be the most affected, in absolute terms, given the larger size of the affected sectors in these provinces. In per capita terms, Ontario, Quebec and British Columbia will bear the highest costs. Also from a distributional perspective, the SMEs will suffer a disproportionate share of the costs in comparison to their size.

The benefits of the proposed Regulations will accrue to Canadians all across the country. Cleaning, painting and coating products that are subject to the proposed Regulations are used by consumers and institutions in all provinces and territories in Canada. By reducing the human exposure of users and bystanders, the proposed Regulations will result in a reduction in the health risk associated with hemolytic anemia. An estimated 300 000 users of paints and coatings and 600 000 users of cleaning products will directly benefit from the proposed Regulations.

Competitiveness

The proposed Regulations may have competitiveness impacts in some sectors of the Canadian economy. In particular, the analysis indicated that the SMEs may suffer an unequal share of compliance costs relative to larger companies and in relation to their size. Costs are expected to be particularly important for the SMEs during the first years of implementing the proposed Regulations. As a result, these firms might experience a loss in competitiveness in comparison to larger firms. The precise extent to which the unequal share of costs will affect the competitiveness of the SMEs relative to larger firms was not evaluated.

Because the proposed Regulations apply equally to domestic and foreign products, they are expected to provide a level playing field. From this perspective, the Canadian industry will not lose competitiveness relative to foreign producers. However, it was found that exporting firms might experience increased production costs if, for example, they have to separate production for the Canadian market from the production for the export market. Such potential increase in production costs might cause the Canadian industry to suffer a loss in competitiveness in export markets. Because exports of affected products represent a low percentage of total production, potential competitiveness losses are expected to be small.

Positive impacts to the competitiveness of the Canadian economy might result from the potential for innovation created by the proposed Regulations. For example, manufacturers might be able to use the knowledge acquired through reformulating products affected by the proposed Regulations to other areas of their business. The extent to which such positive competitiveness impacts will materialize is not yet certain.

Consultation

Three formal public consultation sessions were held with the industry, associations, environmental non-governmental organizations (ENGO) and government stakeholders throughout the risk management phase. The meetings were held in Toronto, on January 29, June 8 and November 18, 2004. Issues covered included the risk assessment report, the risk management strategy, the modelling and product-testing studies conducted in support of strategy development, and the choice of risk management instrument.

Participants were supportive of federal government efforts and commended the effective and participative consultation process. In addition, a technical workshop was organized with industry stakeholders to identify technical issues stemming from the working draft of the proposed 2-BE Regulations. The workshop took place in Ottawa on January 31, 2005.

A total of 22 written comments were received from stakeholders throughout the public consultation process: 18 from industry, 3 from ENGOs, and one from government. Many corresponded to questions of clarification. Comments received after the January 29, 2004 consultation session pointed to the uncertainties surrounding the relation between 2-BE product concentration, human exposure and the TC. Environment Canada and Health Canada conducted several modelling studies that analyzed these relations and served to develop the concentration limits in the proposed Regulations. The results of these studies were presented in the June 8, 2004 public consultation session.

Other comments were concerned with the exposure of consumers to multiple products containing 2-BE, as well as the exposure of children to such products. The assumptions used in the exposure modelling studies reflect the human receptors that would be exposed to the highest air concentrations of 2-BE and are therefore considered to be conservative enough to develop concentration limits that will provide a safe exposure to all the Canadian population.

Comments received after the November 18, 2004 consultation session dealt with the design of the proposed Regulations. One stakeholder suggested that the proposed Regulations focus on consumer products rather than on indoor-use products. The federal government decided to focus on indoor-use products instead of consumer products. This decision was made based on the fact that people may have access to commercial or professional products that are available through some commercial channels. Also, consumer products include some that are exclusively for outdoor use, which do not represent a concern in terms of human exposure to harmful levels of 2-BE.

Several stakeholders suggested that reporting requirements could be onerous for industry. In response, Environment Canada and Health Canada simplified the reporting format and requirements to minimize industry's administrative burden.

In addition, two stakeholders requested the exemption of institutional products and professional contractor paint products. These products were not exempted, because consumers may have access to them through some commercialization channels. Another stakeholder showed concern about a product they commercialize that has a higher content of 2-BE than the proposed limits. The stakeholder claimed that there is no technically feasible replacement available. The proposed Regulations have provisions that will allow manufacturers and importers to apply for permits for continuing to use 2-BE above the proposed concentration limits, in those cases where there are no technically or economically feasible alternatives or substitutes for 2-BE readily available, and where a plan has been prepared for complying with the proposed concentration limits. Permits will be issued for 24 months and will be renewable once.

Finally, one stakeholder suggested that a period of two years would be necessary for industry to comply with the proposed Regulations, including time for reformulating and for selling pre-Regulation inventories. Stakeholders have been provided advance notice through extensive consultations that began in January 2004. In addition, the proposed Regulations will come into force one year after they are registered. Therefore,

Environment Canada and Health Canada consider that industry has been given enough time to adapt to the proposed changes.

Compliance and enforcement

Since the proposed Regulations are promulgated under CEPA 1999, enforcement officers will, when verifying compliance with the Regulations, apply the Compliance and Enforcement Policy implemented under the Act.

The Policy also sets out the range of possible responses to violations: warnings, directions, environmental protection compliance orders, ticketing, ministerial orders, injunctions, prosecution, and environmental protection alternative measures (which are an alternative to a court trial after the laying of charges for a CEPA 1999 violation). Furthermore, the Policy explains when Environment Canada will resort to civil suits by the Crown for costs recovery.

When, following an inspection or an investigation, an enforcement officer discovers an alleged violation, the officer will choose the appropriate enforcement action based on the following factors:

- *Nature of the alleged violation*: This includes consideration of the damage, the intent of the alleged violator, whether it is a repeat violation, and whether an attempt has been made to conceal information or otherwise subvert the objectives and requirements of the Act.
- *Effectiveness in achieving the desired result with the alleged violator*: The desired result is compliance within the shortest possible time and with no further repetition of the violation. Factors to be considered include the violator's history of compliance with the Act, willingness to co-operate with enforcement officers, and evidence of corrective action already taken.
- *Consistency*: Enforcement officers will consider how similar situations have been handled in determining the measures to be taken to enforce the Act.

Contacts

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PROPOSED REGULATORY TEXT

Notice is hereby given, pursuant to subsection 332(1) (see footnote a) of the *Canadian Environmental Protection Act, 1999* (see footnote b), that the Governor in Council proposes, pursuant to subsection 93(1) of that Act, to make the annexed *Regulations Respecting 2-Butoxyethanol*.

Any person may, within 60 days after the date of publication of this notice, file with the

Minister of the Environment comments with respect to the proposed Regulations or a notice of objection requesting that a board of review be established under section 333 of that Act and stating the reasons for the objection. All comments and notices must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be sent to the Director, Chemicals Control Branch, Environmental Protection Service, Department of the Environment, Ottawa, Ontario K1A 0H3.

A person who provides information to the Minister may submit with the information a request for confidentiality under section 313 of that Act.

Ottawa, June 27, 2005

EILEEN BOYD
Assistant Clerk of the Privy Council

REGULATIONS RESPECTING 2-BUTOXYETHANOL

APPLICATION

1. These Regulations apply in respect of products set out in column 1 of Schedule 1 that contain 2-Butoxyethanol, which has the molecular formula $C_6H_{14}O_2$, except if they are

(*a*) designed for outdoor use;

(*b*) for use in a manufacturing or processing activity;

(*c*) for use as a solvent in a laboratory for analysis;

(*d*) for use in scientific research; or

(*e*) for use as a laboratory analytical standard.

PROHIBITIONS

2. (1) Subject to subsection (2), no person shall manufacture or import a product set out in column 1 of Schedule 1 if the concentration of 2-Butoxyethanol in the product exceeds the limit set out in column 2 for that product unless the person has been issued a permit under section 4.

(2) The prohibition in subsection (1) does not apply to the manufacturing or importing of a product for export only.

3. No person shall sell or offer for sale a product set out in column 1 of Schedule 1 if the concentration of 2-Butoxyethanol in the product exceeds the limit set out in column 2 for that product unless that product was manufactured or imported under a permit issued under section 4.

PERMITS

4. (1) Any person that, at the time of the coming into force of these Regulations, is importing or manufacturing a product set out in column 1 of Schedule 1 in which the concentration of 2-Butoxyethanol exceeds the limit set out in column 2 for that product, shall obtain a permit in order to continue that activity.

(2) The application for a permit shall be submitted to the Minister and contain the information specified in Schedule 2.

(3) Subject to subsection (4), the Minister shall issue the permit if the following conditions are met:

(*a*) there is no technically or economically feasible alternative to or substitute for the use of 2-Butoxyethanol available to the applicant;

(*b*) the applicant has taken all necessary measures to minimize or eliminate any harmful effect of 2-Butoxyethanol on human health;

(*c*) a plan has been prepared by the applicant identifying the measures to be taken by them so that the concentration of 2-Butoxyethanol in their product will be within the limit prescribed by these Regulations; and

(*d*) the period within which the plan is to be fully implemented does not exceed four years from the date on which a permit is first issued to the applicant.

(4) The Minister shall refuse to issue a permit if the Minister has reasonable grounds to believe that the applicant has provided false or misleading information in support of their application.

(5) A permit expires 24 months after the day on which it is issued and may, upon application, only be renewed once for the same use of 2-Butoxyethanol.

(6) The Minister shall revoke a permit if the conditions set out in paragraphs 3(*a*) to (*d*) are no longer met or if the Minister has reasonable grounds to believe that the permit holder has provided false or misleading information to the Minister.

(7) The Minister shall not revoke a permit unless the Minister has provided the permit holder with

(*a*) written reasons for the revocation; and

(*b*) an opportunity to be heard, by written representation, in respect of the revocation.

REPORTS

5. (1) Every person that, at the time of the coming into force of these Regulations, manufactures or imports a product set out in column 1 of Schedule 1 containing 2-

Butoxyethanol in a concentration that exceeds 0.1% shall submit to the Minister the information specified in Schedule 3 within six months after the day on which these Regulations come into force.

(2) Every person that, after the day on which these Regulations come into force, manufactures or imports a product set out in column 1 of Schedule 1 that is new to the Canadian market and contains 2-Butoxyethanol in a concentration that exceeds 0.1% shall submit to the Minister the information specified in Schedule 3 within 30 days after the day on which the product is manufactured or imported.

(3) Any change in the information previously submitted shall be submitted no later than 30 days after the change occurs.

TESTING REQUIREMENTS

6. The concentration of 2-Butoxyethanol under these Regulations shall be determined, in accordance with generally accepted standards of scientific practice, by a laboratory that is accredited under the International Organization for Standardization standard ISO/IEC 17025: 1999, entitled *General requirements for the competence of testing and calibration laboratories*, as amended from time to time, or by a laboratory that meets an equivalent standard.

CERTIFICATION

7. Any information required to be submitted to the Minister under these Regulations shall be accompanied by a certification, dated and signed by the person referred to in the applicable provision of these Regulations, or by the person authorized to act on their behalf, that the information is accurate and complete.

RECORD KEEPING

8. (1) Every person that submits information to the Minister under these Regulations shall keep a copy of that information, the certification and any documents supporting the information, for a period of at least five years, beginning on the date of the submission of the information.

(2) The information and supporting documents shall be kept at the civic address in Canada that the person provided to the Minister.

COMING INTO FORCE

9. These Regulations come into force one year after the day on which they are registered.

SCHEDULE 1
(Section 1, subsection 2(1), section 3, subsections 4(1) and 5(1) and (2) and Schedule 3)

CONCENTRATION LIMITS

Item	Column 1 Product	Column 2 Concentration Limit (%)
1.	Cleaner* (pressurized aerosol† product)	5.0
2.	Cleaner* (non-pressurized product)	6.0
3.	Automobile Cleaner‡	10.0
4.	Rug or Carpet Cleaner	10.0
5.	Floor or Baseboard Stripper	2.0
6.	Paint Stripper or Thinner	0.5
7.	Paint or Coating (pressurized aerosol† product)	0.1
8.	Paint or Coating (non-pressurized product)	0.5

* A product to be used to degrease and clean glass, floors and other surfaces, including bathroom and kitchen surfaces, but does not include rug or carpet cleaners, automobile cleaners, automobile degreasers, paint thinners, paint strippers and floor or baseboard strippers.

† Does not include pump sprays.

‡ Does not include automobile degreasers.

SCHEDULE 2
(Subsection 4(2))

INFORMATION TO BE CONTAINED IN AN APPLICATION FOR A PERMIT

1. Information respecting the applicant:

(*a*) their name, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any; and

(*b*) the name, title, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any, of the person authorized to act on behalf of the applicant, if any.

2. Information respecting the product:

(*a*) the name of the product;

(*b*) the concentration of 2-Butoxyethanol in the product;

(*c*) the estimated quantity to be manufactured, sold, offered for sale or imported in a calendar year and the unit of measurement;

(*d*) the identification of each proposed use, if known; and

(*e*) the name, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any, of each person in Canada to whom the manufacturer or importer intends to sell the product, if any.

3. Evidence that there is no technically or economically feasible alternative or substitute available to the applicant for the use of 2-Butoxyethanol.

4. Evidence that explains what measures have been taken to minimize or eliminate any harmful effect of 2-Butoxyethanol on human health.

5. A description of the plan prepared respecting 2-Butoxyethanol identifying the measures to be taken so that the concentration of 2-Butoxyethanol in their product will be within the limit prescribed by these Regulations.

6. Identification of the period within which the plan is to be implemented.

7. Civic and postal addresses of the location where records, certification and supporting documents are kept.

SCHEDULE 3
(Subsections 5(1) and (2))

INFORMATION RELATED TO THE MANUFACTURE OR IMPORT OF PRODUCTS CONTAINING 2-BUTOXYETHANOL

1. Information respecting the manufacturer or importer:

(*a*) their name, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any; and

(*b*) the name, title, civic and postal addresses, e-mail address, if any, telephone number and fax number, if any, of the person authorized to act on behalf of the manufacturer or importer, if any.

2. Information respecting each product containing 2-Butoxyethanol manufactured or imported during a calendar year:

(*a*) the name of the product;

(*b*) the item number of the product named in column 1 of Schedule 1; and

(*c*) a declaration that the concentration of 2-Butoxyethanol in the product is equal to or less than the limit set out in column 2 of Schedule 1 for that product.

3. Indicate if a request for confidentiality is being made under section 313 of the *Canadian Environmental Protection Act, 1999* and the reason for the request.

4. Civic and postal addresses of the location where records, certification and supporting documents are kept.

[28-1-o]

Footnote a

S.C. 2004, c. 15, s. 31

Footnote b

S.C. 1999, c. 33

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.

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Important Notices