Performance Measurement Evaluation for Risk Management of 2-Butanone, oxime - (Butanone oxime)

1. About performance measurement

The Government of Canada is conducting performance measurement on the risk management of toxic substances to ascertain whether actions taken to help protect Canadians and their environment are meaningful and effective over time. The Government of Canada establishes goals in order to help protect Canadians and their environment from risks posed by toxic substances. The Government attempts to achieve these goals by setting human health and/or environmental and risk management objectives, and then developing a strategy to meet those objectives. Performance measurement will help determine how well the risk management actions have reduced or eliminated the risk associated with each toxic substance and identifies any areas of improvement that should be addressed moving forward.

2. Background and risk assessment

The Government of Canada identified butanone oxime as a priority for assessment as it was considered to pose greatest potential for exposure, and its classification by the European Commission as a substance that may cause cancer (Canada 2010a, European Commission 2001). 2-Butanone, oxime (CAS RN: 96-29-7), commonly known as butanone oxime or methyl ethyl ketoxime (MEKO), is a man-made organic compound used widely as an anti-skinning agent, which prevents the drying and formation of a skin on the surface of alkyd paint varnishes, stains and coating products for both industrial and consumer use. It was also found in a number of pesticide products, namely wood preservatives and antifouling marine paints, and in some adhesives, silicone sealants, and printing inks. Butanone oxime was also used as a corrosion inhibitor (used to prevent corrosion) in industrial boilers and water treatment systems, as well as in the manufacturing process of urethane polymers (Canada 2010a).

The Screening Assessment Report under the Chemicals Management Plan in 2010 concluded that butanone oxime may have been entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. It was therefore concluded that butanone oxime meets the criterion in paragraph 64(c) of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 2010a). Subsequently, butanone oxime was added to Schedule 1 of CEPA by order in the *Canada Gazette* on December 21st, 2011 (Canada 2011).

Concerns as a potential carcinogenic substance originally triggered the assessment of butanone oxime; however, there was an increased risk observed only at moderate and

high concentrations, and it was determined based on the available information that existing known levels of exposure to butanone oxime are not likely to be genotoxic (cause genetic mutations that may lead to cancer) (Canada 2010a). In terms of non-cancer health effects, degeneration of the olfactory epithelium (the tissue inside the nasal cavity) following short-term to chronic inhalation exposures, as well as effects in the spleen, liver, kidneys and hematological system after oral exposures were among the health concerns identified in the Screening Assessment Report (Canada 2010a).

The Screening Assessment Report (Canada 2010a) considered the most likely source of human exposure to butanone oxime to occur through use of consumer products. The highest exposure estimate identified in the screening assessment was from inhalation of indoor air during and immediately following application of interior alkyd paints and coating products available to consumers (Canada 2010a, 2010b).

Comparison of levels to which Canadians may be exposed to butanone oxime from products available to consumers in Canada with the levels associated with health effects were determined to pose a risk to human health (Canada 2010a).

A Code of Practice was published in 2014 to control butanone oxime in certain products (detailed below). The Code included a commitment by the Minister of Health to evaluate the progress achieved toward reducing inhalation exposure to butanone oxime five years after the publication. This performance measurement evaluation was undertaken to fulfill this commitment.

3. Risk management

The proposed risk management approach was published in 2010 and outlined the proposed actions to prevent or control the risks posed by exposure to butanone oxime. The risk management and human health objectives were set to minimize human exposure to the extent practicable (Canada 2010a, Canada 2010b). In 2014, a Code of Practice was published to address these objectives.

Code of Practice for 2-Butanone, oxime (Butanone oxime) Associated with the Interior Application of Consumer Alkyd Paint and Coating Products (the Code)

The Code of Practice for butanone oxime was published in 2014 and applies to any person who manufactures, imports or sells interior or dual use (interior/exterior) consumer alkyd paint and coating products containing butanone oxime; and those responsible for labelling these products. The objective of the Code is “to help reduce inhalation exposure to butanone oxime by the general public during and immediately following interior application of consumer alkyd paint and coating products” (Health Canada 2014). The Code identifies three recommended practices to reduce consumer exposure to butanone oxime:

1. to reduce the concentration of butanone oxime in consumer interior alkyd paints and coatings to the lowest level technically and economically feasible;
2. to incorporate the labelling statement, “use only in a well-ventilated area”, on all applicable consumer interior and dual use alkyd paints and coatings; and
3. to implement a consumer education program that will inform consumers on behaviours that will help to achieve well ventilated conditions during and following interior application of all applicable consumer interior and dual use alkyd paints and coatings.

Health Canada committed to review progress of the Code of Practice 5 years after its publication in 2014. Sufficient information on paint and coating products before and after implementation of the Code is available to measure the effectiveness of the Code.

4. Performance measurement indicators

The following section identifies how information was collected and the key performance indicators used to evaluate the risk management performance for butanone oxime.

4.1 Data

Data for each key performance indicator came from both mandatory and voluntary information gathering activities. Several sections of CEPA, such as section 71, allow the Government of Canada to collect information from industry and other individuals regarding their activities with substances. In August 2008, a notice was published in the *Canada Gazette*, Part I: Vol. 142, No. 35 – August 30, 2008 under section 71 of CEPA to gather basic market information on 14 substances included in the first phase of the Chemicals Management Plan, which included butanone oxime. This mandatory survey required market information on manufacturing and import, product types, and quantities of industrial releases containing the substance (Canada 2008). Data from the mandatory survey was used to determine the market status of butanone oxime in 2006.

In addition to the mandatory survey, two voluntary questionnaires were issued to collect market data on products covered by the Code. The questionnaires were each sent to over 400 known and potential stakeholders involved in the paints and coatings sector, including associations, suppliers and formulators. The initial questionnaire was sent out in 2014 to collect baseline data for products sold in the 2013 calendar year, the year before the Code was published. Six responses were received providing information on approximately 1,500 products. The second questionnaire was sent in 2019 for products sold in the 2018 calendar year, and nine responses were received, of which seven were applicable to approximately 550 products covered by the Code.

4.2 Indicators

Each key performance indicator listed below is linked to a recommended practice from the Code of Practice for butanone oxime (see section 3).

4.2.1 Concentrations in products

Voluntary questionnaires asked for data from 2013 and 2018 on the concentration of butanone oxime in consumer interior and dual use alkyd paints and coatings. A reduction in concentration of the substance in products available in Canada in 2018 would indicate adoption of this recommended practice in the Code, and contribute toward reducing human exposure to the substance.

4.2.2 Labelling statement

The recommended practice for labelling was to incorporate a specific statement on consumer interior and dual use alkyd paints and coatings: “use only in a well-ventilated area”. An increase in the percentage of products labelled with this statement between 2013 and 2018 would indicate adoption of this recommended practice in the Code, and would potentially contribute to reducing human exposure to the substance.

4.2.3 Education program

The recommended practice for an education program was to implement a program that would increase consumer awareness of behaviours to reduce exposure to butanone oxime during and after the application of interior and dual use alkyd paints and coatings. Reported efforts to improve public education concerning increased ventilation while using these products would be put in place after publication of the Code. The number of companies that provide information to the public in an obvious and accessible location would be used as an indicator of success of this component of the Code and would contribute to reduced exposure to the substance. These actions would be attributed to the Code, and could contribute toward reducing human exposure to the substance.

5. Key performance indicator data

Performance indicator data was collected and analyzed to evaluate the effectiveness of the Code of Practice for butanone oxime to minimize exposure of Canadians from the harms posed by the substance.

5.1 Section 71 Data

According to the 2006 data obtained from the mandatory survey under section 71 of CEPA, approximately 35 companies in Canada were involved in the import and/or use of butanone oxime, of which approximately 20 were involved with paints and coatings. No companies were involved in the manufacturing of the substance in Canada (Canada 2008). Import quantities of butanone oxime were approximately 500,000 kg, and

quantities used were close to 120,000 kg (Canada 2010a). Information requested in the section 71 survey did not pertain to specific products or concentrations of the substance.

5.2 Voluntary questionnaires

Voluntary questionnaires were sent to stakeholders in 2014 and 2019 to collect data for the calendar years 2013 and 2018, respectively. The voluntary questionnaires requested information on consumer interior and dual use alkyd paint and coating products including:

- product type;
- volume imported or manufactured for sale in Canada;
- concentration of butanone oxime;
- availability of the product beyond 2014 (for the 2013 survey);
- education programs (for the 2018 survey);
- existing ventilation labelling; and,
- information on reformulation, discontinuation or substitution of butanone oxime.

The information provided in each questionnaire can be used to determine if any measurable changes have occurred toward meeting the risk management and human health objectives of reducing exposure to butanone oxime.

5.2.1 Concentrations in products

The following table compares the reported concentrations of butanone oxime on identical consumer interior and dual use alkyd paint and coating products that had information available for both 2013 and 2018. Approximately 300 products were reported in both years.

Total reported changes in concentrations (by ≥ 0.01%) in identical products containing butanone oxime (2013 to 2018)

Reduced	Increased	Unchanged
10.0%	5.7%	84.3%

A concentration of 0.2% or greater was indicated in the Screening Assessment Report as not being adequately protective of human health (Canada 2010a). Of note, 39.3% of the products reported in 2018 indicated concentrations at or above 0.2%, compared with 22% of products in 2013 – an increase of nearly two-fold. While fewer products were reported in 2018, this suggests that many products remaining on the market in 2018 had a concentration of butanone oxime that were not adequately protective of human health. Challenges reported by some companies related to reduction of concentration of the substance in products include anticipated reduced product performance and the potential lack of suitable alternative substances for product re-formulation.

Total reported products with concentrations of butanone oxime ≥ 0.2 w/w%

Percent of products reported ≥0.2 w/w% butanone oxime (2013)	Percent of products reported ≥0.2 w/w% butanone oxime (2018)
22.0%	39.3%

5.2.2 Labelling

In 2013, prior to publication of the Code, three of the six respondents indicated that a low percentage of consumer interior and dual use alkyd paint and coating products were labelled with the recommended statement “Use only in a well-ventilated area”. In 2018, three of the seven respondents had used the recommended statement on 82-100% of their products; in total, 87% of the reported products had the recommended statement.

5.2.3 Education program

Prior to publication of the Code, there were no known education programs informing consumers of how to reduce their exposure to butanone oxime during and immediately following interior paint and coating application. In 2018, four of the seven respondents indicated some type of consumer education at the site of purchase or on a website.

Summary of data reported for 2018 (voluntary questionnaire)

Recommended practice to reduce exposure	Reported efforts as of 2018
a. Reduce concentration of butanone oxime	• 10%[1] products reduced concentration by 0.01% or greater
	• 5.7% products had increased concentrations by 0.01% or greater
	• 84.3% products had the same concentrations reported in 2013
b. Labelling – ventilation statement	• 87% of products labelled per the Code
c. Education for consumers	• 57% companies indicated some form of consumer education

5.2.4 Data gaps

All known and potential members of the paints and coatings industry, including those that indicated an activity with butanone oxime in the section 71 survey, were contacted regarding the Code of Practice. However, some companies opted not to participate in the Code. Therefore, the information from 2013 and 2018 does not represent the whole market in Canada. Nonetheless, it was determined that sufficient information was received to conclude on the success of the Code. Responses to the voluntary questionnaires varied in format and completeness, which meant that some information was not able to be compared.

[1] One company indicated it would reformulate products as of 2019 to avoid the use of butanone oxime.

6. Performance measurement evaluation

6.1 Performance of risk management in place

The Government of Canada took action to address the health risks of butanone oxime by developing a Code of Practice aimed at reducing the exposure of the general public to the substance in consumer interior and dual use alkyd paints and coatings. The Government of Canada has committed to measuring performance of risk management tools to determine whether they have been effective in achieving objectives.

6.1.1 Reduce concentration of butanone oxime in products

A comparison of data from 2013 and 2018 indicates that concentrations of butanone oxime have not been meaningfully reduced, and there are still products on the market with concentrations in the range that are not adequately protective of human health. Therefore, exposure to butanone oxime from inhalation during and directly following the application of interior and dual use paints and coatings has not been reduced by this recommended practice, and remains a concern.

6.1.2 Labelling

In 2018, respondents indicated that 87% of the reported products were labelled with the statement “use only in a well-ventilated area”. While progress has been made, products remain on the market that do not have the recommended label. Therefore, Canadian consumers may be using products in an application of concern with the substance and not be aware of the need for ventilation, which may have reduced their exposure.

6.1.3 Consumer education

Four responses to the 2018 questionnaire indicated that some type of public education program was in place, including fact sheets posted on a website and available at the point of sale. However, it was found for the website content that it would be difficult for consumers who lacked knowledge of butanone oxime to locate the information online.

6.2 Objective outcomes

The human health objective identified in the risk management approach for butanone oxime was to minimize human exposure to the extent possible. The risk management objective was to reduce exposures of the general public to butanone oxime. The main concern was for inhalation exposure to butanone oxime through the interior application of consumer and dual use paints and coatings, and was addressed with a Code of Practice. The objective of the Code was “to help reduce inhalation exposure to butanone oxime by the general public during and immediately following interior application of consumer alkyd paint and coating products” (Health Canada 2014).

Based on the information available to inform this performance measurement evaluation, there has not been significant adoption of the Code, nor significant progress to reduce exposure of the general public to butanone oxime, that can be attributed to the Code. Specifically, concentrations of butanone oxime in consumer interior and dual use alkyd paints and coatings have not decreased, and there were varied degrees of implementation of the labelling and consumer education practices.

It is therefore concluded that the Government of Canada has not achieved its objectives set out to protect Canadians from the risks posed by butanone oxime.

7. Conclusion and next steps

Concentrations of butanone oxime in consumer interior and dual use alkyd paints and coatings were not sufficiently reduced, and increased in some products. Some decreases in concentration were noted as incidental, and some respondents noted challenges such as possible reductions in product performance and the potential lack of suitable alternatives as barriers to Code participation. Some efforts were made to address certain recommended practices in the Code and some respondents have been working on phasing out or reducing concentrations of the substance in their products. Based on the information available and considering the observed increases in concentrations of the substance in products over time, it is concluded that the Code of Practice has not been successful in meeting the risk management objectives for butanone oxime.

To meet the risk management and human health objectives, the feasibility of identification of an adequately protective concentration of butanone oxime in consumer interior and dual use alkyd paints and coatings will be explored. As well, the strategy to manage the human health risks of inhalation exposure to butanone oxime by the general public during and immediately following interior application of consumer alkyd paint and coating products will be revised since the objectives were not met using the existing tool. Stakeholders will be consulted as new proposed approaches to manage risks posed by the substance are considered. Key indicator data collected in 2018 may be used for future tracking as a baseline upon which to measure the performance of risk management tools. In the interim, industry is encouraged to work toward adopting the recommended practices in the Code and any other strategies to reduce consumer exposure to butanone oxime. In addition, Canadians can further protect themselves by ensuring well-ventilated conditions during and immediately following the interior application of alkyd paints and coatings containing butanone oxime.

8 – References

Canada. 2008. Data for Batch 7 substances collected under the Canadian Environmental Protection Act, 1999, Section 71: Notice with respect to Batch 7 Challenge Substances. Data prepared by: Environment and Climate Change Canada.

Canada. 2010a. Screening Assessment for the Challenge 2-Butanone, oxime (Butanone oxime). Environment and Climate Change Canada. Health Canada.

Canada. 2010b. Proposed Risk Management Approach for 2-Butanone, oxime (Butanone oxime). Environment and Climate Change Canada. Health Canada.

Canada. 2011. Order Adding Toxic Substances to Schedule 1 to the *Canadian Environmental Protection Act, 1999*. *Canada Gazette*, Part 2, Vol. 145, No. 26.

European Commission. 2001. 2-Butanone oxime. Commission Directive 2001/59/EC of 6 August 2001. Annex IB. Official Journal of the European Communities. 21.08.2001. L 225/36. European Commission. 28th ATP [Adaptation to Technical Progress].

Health Canada. 2014. Code of Practice for 2-Butanone, oxime (Butanone oxime) Associated with the Interior Application of Consumer Alkyd Paint and Coating Products.