Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Reports for Batch 1 substances on the *Domestic Substances List*

The table below presents a summary of the comments received during the 60-day public comment period from January 19, 2008, to March 19, 2008. Comments summarized below were received by one or more of the stakeholders listed.

Comments on these publications were provided by:

1. Society of the Plastics Industry, Inc.
2. Dow Chemical Canada, Inc.
3. SILON Compounds Ltd.
4. BASF Canada Inc.
5. E.I. du Pont Canada Company
6. PexCor Manufacturing Company Inc.
7. Canadian Vehicle Manufacturers' Association
8. Canadian Environmental Law Association

Substances considered:

- Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl) (DMHBP), CAS RN 78-63-7
- Peroxide, (1,1,4,4-tetramethyl-2-butyne-1,4-diyl)bis[(1,1-dimethylethyl) (DMBP), CAS RN 1068-27-5
- Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl) (DBTMC), CAS RN 6731-36-8

No.	Comment	Response
Bioaccumulation potential		
1	All 3 organoperoxides are metabolized in *in vitro* studies using trout liver extracts (summaries of the studies were included). This limits the bioaccumulation potential of these substances. In at least one study, an expected metabolite and an unidentified 2nd metabolite were detected. Models used to estimate bioaccumulation are not reliable because they do not take metabolism into account and they did not include organoperoxide substances in the training sets used to create the models.	Indicating that a substance is metabolizable is not sufficient to show it is not bioaccumulative. This is very dependent on the *rate* of metabolism. Information about the metabolism of the three substances has been taken into consideration in the revised assessment. Industry has submitted additional information pertaining to persistence and bioaccumulation that has been taken into account in the revised assessment, particularly for modelling bioaccumulation.
2	Draft assessments reported Bioconcentration Factors using the highest BCFs reported in the summary documents from the Japanese NITE database. Industry obtained further	This more detailed information from the NITE database was not available at the time the draft screening assessment report was issued.

	details from the NITE database showing that steady-state BCFs were <5000. The reported BCFs in the NITE database may be overstated if correction for analytical recovery efficiency failed to account for metabolic losses.	Information about the metabolism of the three substances has been taken into consideration in the revised assessment.
3	The reliability of the NITE database is difficult to assess because there is no full access to the primary reports. This database should be used only for comparison purposes.	The NITE database is one line of evidence. In the case of the organoperoxides, industry was able to obtain and submit more detailed information about the results cited in the NITE database, and this information was used in the revised assessment. Studies included in the NITE database were reviewed by government agencies in Japan. This gives credibility to the database.
4	Industry submitted a study showing that 21% of substance 1068-27-5 hydrolysed by 2 hours at 25°C and pH 2.6 (to simulate a fish stomach). The same study showed that the substance was hydrolytically stable after 5 days at 50°C at pH 7 and 9, but 38.2% decomposed at pH 4.	The temperature cited is higher than water temperature in Canada over much of the year and favours hydrolysis. Fish are poikilotherms (ectotherms) and can be expected to have a gut temperature close to the ambient water. The temperature cited is much higher than water temperature in Canada, but the substance is still hydrolytically stable at relevant pH levels.
5	A company commented that "A valid measured BCF should…be used over a predicted BAF to compare to regulatory thresholds."	A predicted BAF is preferred to a BCF for substances with a log K_{ow} > ~4 because, unlike a BAF, BCF does not account for uptake via the diet (which predominates at log K_{ow} > 4). Therefore, a BAF is considered a more "realistic" measure of bioaccumulation potential for hydrophobic substances because biota are exposed to these substances predominantly in food. There are laboratory tests for determining BCFs, but BAFs either are estimated from models or are determined from field studies in which concentrations in biota and in water are measured. Such studies are rare and exist for very few substances.
Persistence		
6	Models used to predict persistence of the 3 substances are not reliable because they did not include organoperoxide substances in the	The model estimates were the only information available during the development of the draft assessment to predict persistence. However, study results

	training sets used to create the models.	submitted by industry during the 60-day public comment period under the Challenge provide an indication that the substances would not persist in the environment.
7	"Evidence of degradation and metabolism of the Substance in two separate studies has been incorrectly dismissed on the basis of possible sorption to the vessel walls."	The draft assessment report stated that there could be sorption to particulate matter and also to vessel walls under the test conditions. Industry subsequently submitted further information stating that likely metabolites were detected in at least one of the studies. This information was considered in revising the assessments. Also, the report has been revised to specify that since the vessels were made of glass, sorption of the substance to vessel walls was probably insignificant.
8	Industry is carrying out tests pertaining to the persistence of these substances and will submit the findings to Environment Canada upon completion.	As of the development of the final assessment draft, Environment Canada had not received the study results.
9	One of the substances was biodegraded in the semi-continuous activate sludge test (SCAS test).	The results of this test are an indication that these substances may disappear under conditions favourable to biodegradation and adsorption (e.g., sewage treatment plant sludges).
Environmental exposure		
10	When calculating environmental exposure values, Environment Canada overestimated the total amounts of the substances used at facilities and the percentage of the substances released. The removal rate at treatment plants was understated and the number of days per year in which the substances are used at facilities was understated. The largest users of these substances are located on large bodies of water with much higher flow rates than those used in the Environment Canada calculations.	Environmental exposure values were recalculated, taking into consideration the accepted information submitted by industry to replace some of the default values. Revised exposure values were used to re-calculate risk quotients. The flow rates used in the calculation are based on a database of river flows, and the flow rates reflect a generic situation that may reasonably exist under low-flow conditions.
11	Parameters used in estimating exposure are skewed on the conservative side, thus propagating conservatism exponentially. It is unrealistic to use the total amount	Stakeholders have the opportunity during public comment periods to submit information that could make exposure estimates more "realistic". In the absence of specific data, conservative estimates are used. Companies submitting data sometimes

	of a substance used in Canada as the maximum amount used at a single facility.	claim the data are confidential. In order to protect this confidentiality, we mask data by presenting them as order-of-magnitude ranges, for example. This can result in an overstatement of releases and therefore of exposure. Information submitted by industry has been considered and release rates have been revised.
	Models and tools used to estimate exposure should be fully disclosed. Is the model [based on OECD release scenarios] valid for Canada?	The release scenarios from the Organisation for Economic Co-operation and Development (OECD) are generic and intended for multi-agency use. When available, information specific to industry handling practices in Canada is used to refine model inputs for assessments of specific substances. If stakeholders believe that estimated release values are incorrect, they have an opportunity during public comment periods to submit information that would be more valid for Canada. Stakeholders are also encouraged to engage during the development of exposure scenario documents relevant to their industrial sector or uses.
	"A casual reader of the Draft Screening Assessment of the substance [78-63-7] could assume from the table of estimated releases that the precision in the percentages is +/- 0.1% which may or may not be supported."	While releases at some stages have been estimated to 0.1% based on available information, as often summarized in exposure scenario documents, it is clearly stated in the draft screening assessment report that there can be significant uncertainty in the overall fraction of a substance released to the environment, particularly at later stages of the life cycle.
12	"The manufacturing process consumes all available peroxide during curing and is completely crosslinked at the end of the line. There is no residual peroxide remaining in the completed product."	Other companies have reported some residual organoperoxides in finished polymers, so a small amount of residual material was assumed in estimating environmental releases.
13	Information on environmental and waste release data collected from user questionnaires should be considered in discussing the uncertainties of the Mass Flow Tool, which is used to estimate environmental releases.	Information from user questionnaires is considered in the use of the Mass Flow Tool in individual assessments. The need to use assumptions and default values is dependent on the amount of specific information that is submitted.
14	"…the assumptions made regarding the potential release of the Substance to the environmental [*sic*] are overly conservative and disregard the handling information provided by industry…	Information submitted by industry has been considered in revising the estimated environmental release rates.

	appropriate practices are in place, regarding the handling of wastes and empty containers, to mitigate the potential of any release to water."	
15	The company provided some information about its handling of shipping containers and claimed that there are no detectable releases of the substance to water.	The submitted information demonstrates that the substances can be handled in a responsible manner to minimize or eliminate environmental releases. Such company-specific information is considered in estimating environmental releases. But that does not mean that all users of these substances have measures in place to minimize or eliminate environmental releases.
16	There are no releases of substance 1068-27-5 to water or the municipal wastewater system. Empty containers are recapped and returned to the supplier for re-use/recycling.	The submitted information demonstrates that the substances can be handled in a responsible manner to minimize or eliminate environmental releases. But that does not mean that all users of these substances have measures in place to minimize or eliminate environmental releases.
17	"Environment Canada may want to consider sending representatives to some sites where the substances are used to develop a more precise understanding of the use of the substance."	Information submitted by industry has been considered and release rates have been revised.
18	In estimating the PEC [predicted environmental concentration], the number of days of operation should be 365, not 150. Flow rates of receiving water and treatment plant effluent appear to be low. Treatment plant removal rate of 81% appears to be low. A proposal was made for a revised PEC.	In the revised assessment, the number of days of operation is 250, as suggested by another stakeholder. The flow rates used in the calculation are based on a database of river flows, and the flow rates reflect a situation that may reasonably exist under low-flow conditions. A higher removal rate is used in the revised assessment. The PEC has been revised, considering information submitted by industry.
19	"DMBP (CAS no. 1068-27-5) and DBTMC (CAS no. 6731-36-8) outline that much of the substances (92.9 % by mass for DMBP and 97% by mass for DBTMC) is transformed during the industrial process and another 5% (DMBP) and 1% (DBTMC) is sent off to	One of the expected transformation products would be tertiary-butanol, CAS No. 75-65-0.

	the waste stream. The assessment report does not elaborate on what the transformation products are for each substance, the toxicity of the transformation products, and whether the amount entering the waste stream breaks down over time and at what rate. The assessment report also does not mention what substances are released into the environment during the incineration of these substances."	The organoperoxide molecules are composed of carbon, hydrogen, and oxygen, so the major incineration products would be carbon dioxide and water.
20	"Other substances identified that exposure routes may be through consumer products or at the end of the product's life as they are sent for final disposal via incineration or landfill, for example CAS Nos. 6731-36-8…In these assessments, no estimates were provided to demonstrate the level of leaching of substances or the type of breakdown products that may be released through incineration."	The percentage of substance remaining in polymeric material would be very small, < 1% of the weight of the polymer. The level of leaching is not known, but this organoperoxide substance has a very high tendency to sorb to particulate matter, so it is likely that it would remain in a landfill. This substance is composed of carbon, hydrogen, and oxygen, so the major incineration products would be carbon dioxide and water.
21	"In assessments that indicated partitioning of substances is favoured in one environmental media over another, limited data or no data was provided to demonstrate the potential impact to other organisms aside from fish, algae or daphnia. For example, CAS No. 78-63-7 would be present in soil and sediment but no data was provided to demonstrate potential impact to air breathing organisms or terrestrial animals that are found in these media."	There is very little environmental release of these substances. The assessment pointed out that the risk quotient for sediments would be similar to that for water. There is no information available about toxicity of the substance to soil organisms. However, the substance is no longer believed to meet the criteria for persistence. It is believed that only small amounts of the substance would be released to air. These small amounts would be very quickly dispersed, so exposure to the substance would be negligible for air-breathing organisms.
Environmental effects		
22	In calculating the Predicted No-Effect Concentrations, clear explanations should be given about why a particular assessment factor was chosen.	In the revised assessments, toxicity information for similar substances is combined. This results in the use of a smaller safety factor than in the draft screening assessment. Assessment reports indicate the types of uncertainties that the assessment factors address.
Risk management		
23	Regarding risk management options, "…if the objective of the CMP	The final assessments conclude that the 3 organoperoxides not be considered to meet

	[Chemicals Management Plan] is to expedite the risk management process, as much a[s] possible, advanced discussion of options should be encouraged."	the definition of "toxic" under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). Risk management options are no longer being considered.
24	The approach required for CEPA 1999 for virtual elimination will be problematic for the peroxides in products. It should be determined if it is necessary to regulate products if the substance is encapsulated or present at low enough concentrations.	The final assessments conclude that the 3 organoperoxides not be considered to meet the definition of "toxic" under CEPA 1999. Virtual elimination is no longer being considered.
25	"It is hoped that any regulation of the substance be as simple as possible… Given that it is likely that no significant environmental releases of the substance are taking place when current industry standard risk management practices are being followed, focus should be on monitoring the existing use of the substances to ensure that users have developed and are using appropriate risk management practices."	The final assessments conclude that the 3 organoperoxides not be considered to meet the definition of "toxic" under CEPA 1999. Risk management options are no longer being considered.
26	"If these substances must be regulated, keep in mind that the objective of regulation is to ensure the elimination of the risk of environmental release…so give the users the responsibility to develop and implement effective ways to eliminate the risk."	The final assessments conclude that the 3 organoperoxides not be considered to meet the definition of "toxic" under CEPA 1999. Risk management options are no longer being considered.
27	In the assessments, exposure estimates come from modelling. Risk management options should consider actual activities in the regulated community, including pre-existing and widely accepted protocols, guidelines, product stewardship practices, etc.	Stakeholders have the opportunity during public comment periods to submit information that can be used to revise exposure estimates. The final assessments conclude that the 3 organoperoxides not be considered to meet the definition of "toxic" under CEPA 1999. Risk management options are no longer being considered.
28	"The removal of [the substance] would mean complete shut down of our facility as there are <u>no alternatives for crosslinking on line</u>."	
29	It would be difficult or impossible to replace substance 6731-36-8 as a curing agent in sealers. The substance is present in very small quantities which react during the curing process. No	The proposal is that the 3 organoperoxides not be considered to meet the definition of "toxic" under CEPA 1999.

	direct releases to water occur. If any substance remains unreacted in the finished product it would likely be in the parts per million range and would be contained with minimal potential release to the environment.	
General comments		
30	The assessments did not seem to be peer reviewed. Assessments would gain credibility and transparency if a peer review was undertaken.	The assessments were peer reviewed by internal and external experts.
31	Almost all physical and chemical properties were generated by models and these estimates were then used as input for other models to estimate persistence, bioaccumulation, toxicity and fate. Quantitative sensitivity analyses should be used on the final results.	Uncertainties in the use of models are recognized, but when empirical data are lacking, the best available estimation methods are used. Stakeholders have the opportunity to submit information during public comment periods that can be used to revise assessments.
32	"It was hoped that…better data would have been collected about the substance in question…some of the basic expectations for presentation of scientific research had been ignored. These include providing complete citations of the sources used and statements of the uncertainties in the conclusions reached.	Laboratory and field data are extremely sparse for many substances on the Domestic Substances List; therefore, the best available estimation methods (models, quantitative structure-activity relationships (QSARs), etc.) have been used to fill data gaps. Public comment periods provide stakeholders with the opportunity to submit unpublished information, etc., to reduce uncertainties. Many stakeholders have taken advantage of these opportunities. More complete citations have been given in the assessment report for some statements or to explain assumptions used in models. Uncertainties about overall conclusions are discussed in the assessment report, but not necessarily for each individual study or model result.
33	Regarding weight of evidence, the applicability of each model needs to be assessed and weighted individually, before weighing the results themselves.	To some extent at least, the uncertainties about the various lines of evidence were discussed qualitatively in the draft screening assessment reports. Industry has submitted the results of laboratory tests relating to the persistence and bioaccumulation potential of the 3 organoperoxides, and this information has been used in the revised version of the assessment.
34	Regarding application of the Precautionary Principle, the certainty level in the ecological effects and ecological exposures should be much	When reliable empirical data are lacking, assessments are based on the best available estimation approaches and tools. There are a number of opportunities under

	higher than what is was demonstrated in the published draft assessment report for the 3 organoperoxides.	the Challenge for stakeholders to submit additional data. As presented above in this table, industry has submitted a considerable amount of new information that has been used in the revised assessment report.

Summary of Public Comments Received on the Government of Canada's Risk Management Scope document on the Organoperoxides for Batch 1 Substances on the *Domestic Substances List*

The table below presents a summary of the comments received during the 60-day public comment period from January 19, 2008, to March 19, 2008. Comments summarized below were received by one or more of the stakeholders listed.

Comments on these publications were provided by

Dow Chemical Canada Inc.
SILON Compounds
Canadian Environmental Law Association

Substances considered:

- Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl) (DMHBP), CAS RN 78-63-7
- Peroxide, (1,1,4,4-tetramethyl-2-butyne-1,4-diyl)bis[(1,1-dimethylethyl) (DMBP), CAS RN 1068-27-5
- Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl) (DBTMC), CAS RN 6731-36-8

Comment	Response
The document [RM Scope] does not suggest a specific potential action or instrument. If the government can suggest a single or a list of potential instruments, stakeholder feedback can be solicited earlier. […] if the objective of the CMP [Chemicals Management Plan] is to expedite the risk management process, as much as possible, advanced discussion of options should be encouraged. With the explicit understanding that discussion and consultation will occur pertaining to the option(s).	Under the Chemicals Management Plan Challenge, the Government of Canada has committed from the outset to engaging stakeholders on proposed approaches for managing the risks associated with substances in the Challenge. When a draft screening assessment report is published and proposes a conclusion that the substance is "toxic", an accompanying risk management scope will be made available to the public for a 60-day comment period. The risk management scope is a preliminary outline of the options being examined for the management of a substance based on the proposed conclusions of the draft screening assessment report. Industry and other interested stakeholders are invited to submit comments on the content of the risk management scope or to provide other information that would help inform decision making. The risk management approach document will be a more detailed document building on the risk management scope and will outline the proposed risk management actions, including the proposed choice of instrument. The release of the risk management approach will coincide with the publication of the final screening assessment report, approximately six months after the release of the risk management scope.

Comment	Response
While we agree and support the use of CEPA 1999 processes for virtual elimination; the act is very specific. The objective of eliminating the release of the substance requires establishing a level of quantification and then a "release rate". […] The approach required by the Act will be problematic for the peroxides in products, but it should be noted that this has been overcome with the first substance subject to virtual elimination – hexachlorobutadiene. To address peroxides in products, a process similar to that which was conducted for hexachlorobutadiene should be considered. In a parallel analysis there should be a determination if it is necessary to regulate products. If products encapsulate or consume to a residual point or the peroxides are present at low enough concentrations; there will not be a need to act under the virtual elimination provisions as there is no risk.	In the Response to the Recommendations of the Standing Committee on Environment and Sustainable Development in Its Report The Canadian Environmental Protection Act, 1999—Five-Year Review: Closing the Gaps, the government recognizes that the current CEPA 1999 provisions have caused implementation challenges with respect to the requirement for a level of quantification. The government also recognizes that the instruments available to attain virtual elimination should not be limited to release-limit regulations and that other instruments could be useful. The government will review options for amending CEPA 1999 to enable it to appropriately address the virtual elimination of releases of persistent, bioaccumulative, anthropogenic, and non-naturally occurring (radionuclide or inorganic) toxic substances.
In sections 1.3 Releases to the Environment and 1.4 Exposure Sources /risks it is apparent the exposure(s) originates from modeling. This conclusion is not consistent with Dow experiences and may be an artifact of modeling.	A mass flow tool, in which various assumptions were made, was used to estimate the quantities of these substances released and the proportions of those releases to the various environmental media. The tool is based on a life-cycle analysis and on emission scenario documents published by the Organisation for Economic Co-operation and Development (OECD 2004, 2006). The goal of this tool is to quantify the mass of a substance released to the environment during its life cycle.
In considering risk management options; actual activities in the regulated community should be considered.	The Ministers of Health and the Environment have given stakeholders that manufacture, import, or use the substance the opportunity to supply new information via the Challenge questionnaire, including information on the use patterns, existing management practices, release and exposure pathways, and potential substitution options. The intent is to use this information to identify industrial best practices in order to set benchmarks for risk management and product stewardship.

Comment	Response
If the substances are going to be targeted for virtual elimination, Environment Canada needs to communicate more clearly as to what virtual elimination will entail. It is hoped by industry that users of the substance will be able to easily demonstrate that their individual use of the substance poses no risk of ecological harm, and so that they should be allowed to continue using the substances.	In the Response to the Recommendations of the Standing Committee on Environment and Sustainable Development in Its Report The Canadian Environmental Protection Act, 1999—Five-Year Review: Closing the Gaps, the government recognizes that the current CEPA 1999 provisions have caused implementation challenges with respect to the requirement for a level of quantification. The government also recognizes that the instruments available to attain virtual elimination should not be limited to release-limit regulations and that other instruments could be useful. The government will review options for amending CEPA 1999 to enable it to appropriately address the virtual elimination of releases of persistent, bioaccumulative, anthropogenic, and non-naturally occurring (radionuclide or inorganic) toxic substances.
There is no evidence that the three substances [DMHBP (1,1,4,4-tetramethyl-1,4-butanediyl) bis[(1,1-dimethylethyl)peroxide], DBTMC (3,3,5-trimethylcyclohexylidene) bis[(1,1-dimethylethyl)peroxide], and DMBP (1,1,4,4-tetramethyl-2-butyne-1,4-diyl) bis[(1,1-dimethylethyl)peroxide]] are at detectable levels in the Canadian environment at this time as presented in the Draft Screening Assessments. The Draft Screening Assessments only establish that it is possible that the substances have been released to the environment. Given that it is likely that no significant environmental releases of the substances are taking place when current industry standard risk management practices are being followed, focus should be on monitoring the existing use of the substances to ensure that users have developed and are using appropriate risk management practices.	A mass flow tool, in which various assumptions were made, was used to estimate the quantities of DMHBP, DBTMC, and DMBP released and the proportions of those releases to the various environmental media. The tool is based on a life-cycle analysis and on emission scenario documents published by the Organisation for Economic Co-operation and Development (OECD 2004, 2006). The goal of this tool is to quantify the mass of a substance released to the environment during its life cycle. The tool results indicate that more than 90% of DMHBP, DBTMC, and DMBP is lost by transformation, mostly during the processing phase at polymer manufacturing facilities. Between 2 and 7% of these peroxides may end up in waste disposal sites as a result of handling and cleaning processes, manufacture, and disposal of off-spec product. The calculations assume that there is no release of any of the substance from these sites, although long-term releases may be possible. It is estimated that between 1 and 2% may be released to water. OECD] Organisation for Economic Co-

Comment	Response
	operation and Development. 2004a. Emission Scenario Document on Plastics Additives [Internet]. Paris (FR): OECD Environmental Directorate, Environmental Health and Safety Division. Available from: http://oecd.org/ehs/ [OECD] Organisation for Economic Co-operation and Development. 2004b. Emission Scenario Document, "Additives in Rubber Industry", JT00166668, ENV/JM/MONO(2004)11, June 24, 2004, Paris, France. [OECD] Organisation for Economic Co-operation and Development. 2006. Draft Emission Scenario Document on Transport and Storage of Chemicals. Prepared by the Environment Agency (UK). Available on request from: Environment Canada, Existing Substances Division, Ottawa, K1A 0H3.
Given the relative small number of users of the substances and the relatively wide spectrum of uses of the substances, specific prescriptive regulations may be of little value. If these substances must be regulated, keep in mind that the objective of regulation is to ensure the elimination of the risk of environmental releases. This result is important, not the way it is reached so give the users the responsibility to develop and implement effective ways to eliminate any risk.	The three final screening assessment reports will provide conclusions as to whether or not DMHBP, DBTMC, or DMBP meets the virtual elimination criteria set out in subsection 77(4) of CEPA 1999. If the following criteria are met, virtual elimination will be implemented: • the substance meets the criteria under section 64 of CEPA 1999; • the substance meets the criteria for "persistence" and "bioaccumulation" as defined by the *Persistence and Bioaccumulation Regulations* made under CEPA 1999; • the presence of the substance in the environment results primarily from human activity; and • the substance is not a naturally occurring radionuclide or a naturally occurring inorganic substance. In this case, the risk management will be based on the objective of eliminating the releases of the peroxide to the environment.
Supports a regulation that aims to phase out the use of DMHBP, DBTMC, and DMBP. Furthermore, the regulation should ensure that incineration is not selected as an option to address end of life products, due to the	The Government of Canada is aware that the three organo-peroxides are used quite extensively to produce a wide variety of articles. The Government of Canada is committed to protecting and advancing the

Comment	Response
toxicity of by-products released from such an approach.	public interest by working with all Canadians and other governments to ensure that its regulatory activities result in the greatest overall benefit to current and future generations of Canadians. This entails that before regulations are put in place, the Government of Canada must first consider risks to the environment and human health as well as social, economic and technical factors.