Health Canada Santé Canada

# Guidance for industry on safety monitoring and reporting requirements for marketed biocides

June 19, 2024

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
*Lignes directrices à l'intention de l'industrie sur les exigences en matière de surveillance de la sécurité et de rapports pour les biocides commercialisés*

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# Foreword

Guidance documents provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As appropriate, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy or quality of a therapeutic product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the relevant sections of the *Regulations* and other applicable guidance documents.

Market authorization holders (MAHs) should refer to the most up-to-date versions of the guidance documents. The links to these other guidance documents are a starting point to help applicants/MAHs. They are not an exhaustive list.

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# Overview

## Purpose and policy objective

This guidance document will help regulated parties understand and comply with the *Biocides Regulations* (regulations) as it relates to information requirements for your marketed biocide. This includes your post-market safety monitoring and reporting obligations. These obligations under the regulations include:

- safety monitoring under section 40
- serious incident reporting under section 39
- issue-related reports under section 41
- information retention under section 40

These requirements include responsibilities for you, the holder of a biocide market authorization, to continue to review new information on the benefits, risks and uncertainties of your own product after it's authorized for sale in Canada.

You must also notify us of any significant safety issues related to the risks or benefits associated with your biocide.

## Compliance and enforcement

All regulated activities conducted with biocides are subject to compliance and enforcement tools and actions as outlined in our Compliance and enforcement policy for health products (POL-0001). If we identify non-compliance, we will apply the provisions of the *Food and Drugs Act* and the *Biocides Regulations* using a risk-based approach.

For example, under the regulations, the Minister may suspend the market authorization or take other compliance and enforcement actions, as appropriate, if you:

- fail to comply with your safety monitoring and reporting obligations or
- do not respond to a request for information or analysis

# Safety monitoring

## Overview

Safety monitoring, outlined under section 40 of the *Biocides Regulations* (regulations), refers to the requirement for you to:

- monitor the safety of your marketed biocide in a manner that reliably allows you to detect significant safety issues that emerge as a result of real-world use
- notify us, without delay, of any significant safety issues that have been detected

## Effective and timely detection of issues

The regulations specify that you must compile and review information that you become aware of involving your biocide in a manner that ensures the effective and timely detection of significant safety issues. This means that you must have systems and procedures in place to ensure that this can be done.

### Systems and procedures

Safety monitoring includes an expectation that you have systems and procedures in place to compile and review the information collected. The design of the systems and procedures, their form, execution and maintenance are at your discretion. However, you must ensure that your systems and procedures are adequate so you can consistently meet your obligations under the regulations.

You should:

- ensure that your systems and procedures are implemented as designed
- review procedures from time to time to ensure they remain current and reflect the current practices (such as your internal practices, industry standards)
- have independent internal or external personnel audit the systems and procedures to ensure they are followed and are effective
- improve the collection and review of information when and if the systems and procedures fail to detect significant safety issues associated with the biocide

### Documentation

You should document your safety monitoring activities and your systems and procedures. Such documentation should be maintained in a manner that is sufficient to demonstrate compliance with regulatory requirements.

Documentation of safety monitoring systems and procedures can include as applicable:

- written procedures
- contractual agreements
- a description of the system and how it operates
- training standards or programs and their records

You should keep documentation in a format that can be provided to us, upon request. However, the form and manner of the documentation is at your discretion.

## Qualified individual in charge

You are responsible for:

- safety monitoring
- ensuring that individuals undertaking safety monitoring activities are duly trained to conduct these activities as described in your systems and procedures

Safety monitoring activities should be conducted under the supervision of a qualified individual. The person should be qualified through a combination of relevant factors such as:

- education, such as a recognized university degree in a relevant field of study
- training relevant to their assigned responsibilities **or**
- practical experience related to their assigned responsibilities

This individual should also have knowledge of all applicable sections of the regulations related to safety monitoring and serious incident reporting requirements. They should also understand the key activities that are performed as part of your safety monitoring systems and procedures.

The qualified individual in charge should be responsible for:

- creating and maintaining the safety monitoring systems and procedures
- ensuring that safety monitoring activities are in accordance with those systems and procedures
- training and supervising additional qualified individuals undertaking safety monitoring activities, if applicable

## Information to compile

You must:

- compile information to detect significant safety issues associated with your biocide
- document the information compiled
- document the source of the information

### What to compile

You must compile, review and document safety information relating to incidents, both domestic and foreign, relevant to your biocide, including:

- notable incidents
- serious incidents, including those that are unexpected

For foreign incidents, you should monitor information concerning your own foreign equivalent products that are also marketed in Canada with the same combination of active ingredients, regardless of variations in the:

- physical form
- conditions of use
- method of application
- formulation, including variations in formulants

You must also compile, review and document relevant information about actions that have been taken outside of Canada to address significant safety issues.

Find more information on the review of safety information and incidents in the following sub-sections.

### Notable incidents

The *Biocides Regulations* (regulations) define notable incidents to include both:

- a response to a biocide that adversely affects human health **or**
- failures in effectiveness that could have resulted in serious harm to a person

Health Canada interprets a response that adversely affects human health to be very wide in scope. It can include any minor response that a person may experience associated with the use of the biocide, such as:

- burns
- rashes
- coughing
- feeling faint
- burning eyes
- difficulty breathing

You must compile and document all notable incidents that you become aware of as part of your safety monitoring activities.

## Serious incidents and serious unexpected incidents

Serious incidents and serious unexpected incidents are defined in the regulations.

A serious incident includes a response to a biocide, or a failure in the effectiveness of a biocide, that results in one of the following:

- in-patient hospitalization or prolonged hospitalization
- chronic or significant disability or incapacity
- congenital malformation
- a life-threatening event
- death

A serious **unexpected** incident includes serious incidents that have not been identified in nature, severity or frequency in the risk information set out on the Canadian label of the biocide.

You must compile, review and document all serious (expected and unexpected) domestic incidents and serious unexpected foreign incidents that you become aware of as part of your safety monitoring activities. You must also report any serious incident that occurs in Canada and any serious unexpected incident that occurs outside Canada under the serious incident reporting requirements.

## User error, misuse, accidental exposure and occupational exposure

A serious or notable incident is not limited in scope to incidents that occur in accordance with the directions of use. You must compile both notable and serious incidents resulting from user error and misuse of a biocide, and accidental exposure and occupational exposure to a biocide, where the response to a biocide adversely affects human health.

User error and misuse include instances where:

- multiple products were mixed
- safety statements on the label were not followed
- directions for use on the label were not read, properly understood or purposely not followed
- the product was used improperly, unforeseeably or not as intended despite the presence of proper use instructions or warnings

Accidental exposure includes instances where there is an unintentional and unexpected outcome resulting from the use of the biocide. Examples of accidental exposure include:

- spills
- splashes
- inhalation

Occupational exposure includes the chronic, acute or accidental exposure to a biocide product during the normal course of one's occupation and results in serious risk to human health.

## Failure in effectiveness

A failure in effectiveness has occurred when the expected performance of the biocide has substantially failed. In other words, the anticipated effect of the biocide on the targeted microorganism:

- did not occur **or**
- did not meet the threshold established to obtain the labelled claim per the market authorization

Failure in effectiveness is included in the definitions of both notable incidents and serious incidents:

- A failure in effectiveness is a serious incident when serious harm to a person occurred as a result of the failure.
- A failure in effectiveness is a notable incident when serious harm to a person could have occurred or could occur if the failure were to recur.

You are responsible for validating the information received and its relationship to the reported outcome of the failure in effectiveness. If you cannot confirm the validity of the information immediately, you should collect information, where possible, to determine if there has been a:

- substantial failure
- plausible causal link between the substantial failure and the illness or disease:
    - contracted for a serious incident or
    - that could have been contracted for a notable incident

If you do not suspect the information is linked to the harm, it may not be reasonable to conclude that a failure in effectiveness has occurred. However, you should retain this information for potential review should similar information become available in the future.

For example, in order to validate the information received, you may consider:

- evidence of effectiveness of a suspected lot or batch
- the performance of the biocide, such as through laboratory testing under approved conditions of use or through chemical analysis
- whether other similar reports have been received for the product, relative to the amount of product sold
- the seriousness of the harm or potential harm
- how the product was used

## Foreign regulatory measures

You must compile and review information on measures taken in foreign jurisdictions to mitigate a significant safety issue for all your biocide products authorized for sale in Canada that are sold in foreign jurisdictions. These can be measures taken by foreign regulatory authorities or measures taken by manufacturers, importers or authorization holders in the foreign jurisdiction for the purpose of mitigating a serious injury to human health.

Note: For products authorized under the Use of Foreign Decisions pathway, paragraph 27(1)(e) of the *Biocides Regulations* requires that you notify us without delay if the foreign biocide has been recalled or the authorization to sell the foreign biocide has been suspended or revoked. Paragraph 27(1)(f) requires that you provide us with a description and, if known, the reasons for a change required by a foreign regulatory authority with respect to the foreign biocide.

## How to compile

You may receive information directly or become aware of relevant safety information or incidents from a variety of sources. For example:

- consumer complaints
- studies conducted by you or the manufacturer
- health professional communications, Health Canada-issued public advisories or public communications
- problems reported directly to you, such as from hospitals, health care professionals or poison control centres

However, to ensure the effective and timely detection of significant safety issues regarding the safety of your biocide, you should scan additional sources for further information on the safety of your biocide. Reliable sources may include:

- local and international media reports, including social media
- actions or measures taken by other market authorization holders (MAHs) or manufacturers regarding similar products or products with the same active ingredients
- scientific or medical literature, including studies conducted by groups or persons not associated with you
- reports or communications from specific groups, such as poison control centres or patient support or disease management groups
- regulatory authority sources, such as measures taken by foreign regulators, expedited reporting databases of foreign jurisdictions and Health Canada's Canada Vigilance Database

Note: When searching the Canada Vigilance Database, you must search for all reported adverse events, including voluntary reports and reports submitted by hospitals. Serious adverse drug reaction reports from hospitals are considered serious incidents.

If you suspect that information for a product could be related to your biocide, but the information does not specify the product source, brand or trade name of the biocide, you should assume it was your own product. You should document that the specific brand was not identified.

You may also become aware of other safety information relating to the use of your biocide or its failure in effectiveness, such as:

- results of tests and studies conducted using laboratory animals
- trends in information on serious harms to animals that could result in serious unexpected harm or signal potential harm to humans

You should review and document all safety information compiled as part of your safety monitoring activities.

## Scanning of safety information and incidents

You should conduct scanning activities to detect significant safety issues in a timely manner. Your qualified individual should use their professional judgment to determine the appropriate timing, frequency, scope and method of any scanning activities based on factors such as:

- the safety profile of your product
- any known or specific emergent issues

Sources of information that may provide a higher potential for identifying relevant safety information or incidents for your biocide should be scanned more frequently. These include:

- poison control centres
- the Canada Vigilance Database
- information published by foreign regulatory authorities and other international and intergovernmental agencies

The sources and types of information sought should reflect the approved conditions of use of the biocide, which include:

- its intended uses or purposes
- the settings in which it is intended to be used
- its risk information
- the directions for use
- the directions for storage

For example, when monitoring for failure in effectiveness, you should prioritize higher-risk settings such as hospital or long-term care settings or commercial food premises for which your biocide has been approved. In these settings there may be an increased risk in the spread of microorganisms or a substantial failure of the biocide that could lead to serious harm.

Your rationale for the timing, frequency, scope and method of the scanning activities should be based on a logical link with the risks and uncertainties of your product and should consider:

- frequency of environmental scanning and whether any new safety information has been identified
- the length of time the frequency for scanning has been in place without new safety information
- the sources consulted (such as databases, websites) and the search parameters
- how you propose to identify any significant safety issue if one arises

## Review of safety information and incidents

The systems and procedures that you have in place must include provisions for reviewing compiled information. Such a review would be used to identify, in a timely manner, significant safety issues that you may not already know.

The review of safety information and incidents should occur after or concurrently with the compilation of information. This is to ensure that all the safety information and incidents related to significant safety issues are considered together.

Your qualified individual should use their professional judgment to determine the appropriate timing, frequency and method for reviewing compiled safety information to adequately detect significant safety issues in a timely manner.

Your rationale for the timing, frequency and method of the safety review should be based on a logical link with the risks and uncertainties of your product and should consider:

- your product's safety profile
- known or specific emergent issues
- shifts in consumer use patterns
- timing and frequency of previous review activities
- timing and frequency of scanning activities for safety information and incidents
- new safety information identified in previous reviews
- indication for a need to increase frequency of review of safety information based on results of previous reviews
- whether follow-up reviews are required based on previous findings

## Significant safety issues

A significant safety issue is one that you have detected through your safety monitoring activities. The significant safety issue can be detected as a result of a single piece of information that has come to your attention. It could also be an accumulation of information, from various sources, that when examined together, result in the detection of the significant safety issue.

## How to determine a significant safety issue

A significant safety issue is more than just a possible issue. You must evaluate the safety issue detected and examine how it relates to the risks and benefits of your biocide.

Issues related to the failed effectiveness of the biocide are considered significant safety issues when serious harm to a person or serious injury to human health has occurred or could occur as a result.

The **significance** of the safety issue relates to whether the safety issue detected reveals new information that could have bearing on the terms of the market authorization, and therefore may warrant further consideration.

You should validate the safety issue detected. Your qualified individual should:

- review the safety issue that's been detected using objective evidence
- apply their professional judgment to review, evaluate and validate the information to determine if a significant safety issue exists

You should document your review activities, including your findings and any decisions made regarding the significance and validation of potential safety issues.

## Trends and accumulation of information

You may detect a significant safety issue related to your biocide following a review of trends noted in a range of safety information. Or, you may decide there is a significant safety issue after evaluating an accumulation of information.

During your review, you may also detect a series of similar incidents. On their own, these do not constitute a safety issue, but together they suggest there may be a significant safety issue.

## Safety information that inherently represents a significant safety issue

In the course of your safety monitoring activities, you may become aware of information that itself represents a significant safety issue. In these instances, a significant safety issue can be determined based on 1 piece of information or 1 incident.

For the purposes of your safety monitoring, you should consider the following types of safety issues to be significant:

- foreign regulatory measures in response to a safety signal or issue
- notable incidents of validated failure in effectiveness

## Foreign regulatory actions in response to a safety signal or issue

You should consider regulatory measures by foreign regulatory authorities, manufacturers, importers or market authorization holders to mitigate a serious injury to human health as significant. Examples include:

- recalls
- public risk communications
- reassessments of an authorization
- suspensions or revocations of an authorization
- labelling changes that have been communicated to or requested by a relevant foreign regulatory authority

These regulatory measures are only significant and notifiable if they:

- relate to a safety issue associated with a biocide authorized for sale in Canada **and**
- are taken to mitigate a serious risk of injury to human health

For information on determining whether a product presents a serious risk of injury to human health, refer to:

- annex A of the Guide to authorities under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)

## Notable incidents of validated failure in effectiveness

Some notable incidents of failure in effectiveness that originate from a credible source (where the data has been validated) can be significant safety issues. Such incidents include situations where a substantial failure in the performance of the biocide against a microorganism has occurred.

Credible sources may include studies or reports from:

- hospitals
- commercial settings
- regulatory authorities
- peer-reviewed scientific journals
- results of testing in laboratory or university settings

For example, results from a study by a credible source that examined the performance of the biocide concluded:

- there was a substantial failure in respect of the claims made **or**
- the possible development of antimicrobial resistance would be a significant safety issue

## Examples of a significant safety issue

The following are examples of potential notifiable significant safety issues that could be detected by safety monitoring under section 40 of the *Biocides Regulations* (regulations):

- You have received several reports from consumers who have developed a rash after using your biocide product. After reviewing the compiled information, you determine that the number of reports received is much higher than what could have been anticipated. Together, this large number of reports of rashes could indicate a significant safety issue.

- A foreign regulatory authority reassesses the authorization for an equivalent biocide to the one you are marketing in Canada after a finding that the biocide poses a potential new or increased risk of injury to human health.

- A foreign manufacturer or regulatory authority issues a risk communication to the public stating that persons with certain pre-existing health issues shouldn't use biocides containing a certain active ingredient. There may be an increased risk of injury to health associated with its use in that population.

- A series of swab tests for listeria at a food processing plant indicates that your biocide, with an approved claim against listeria, did not perform as intended against the bacteria despite its use according to the label directions. There were no cases recorded of employees or consumers of the food product(s) contracting listeria. However, serious injury to human health could have occurred if an employee or consumer had contracted the bacteria.

- A study by a foreign regulatory authority on the effectiveness of biocides concludes that the active ingredient of your biocide performed below expectations. It was only effective against a specific claim 73% of the time.

- While reviewing the compiled information, you notice a new trend in reports from consumers feeling faint or fainting and having difficulty breathing after mixing your biocide with a specific type of cleaning product.

- Your biocide is for commercial use. Several reports of miscarriages have been reported over a number of years following daily use through occupational exposure of your biocide product in a commercial setting.

Examples of serious incidents reportable under section 39 of the regulations can be found under serious incident reporting.

## Notifying Health Canada of significant safety issues

When you identify a significant safety issue, you must notify us, without delay. This means that you should notify us **immediately** after you have validated that the safety issue is significant.

You should include in your notification (using the non-eCTD format):

- your contact information
- your biocide's identification number
- the brand name of your product in Canada
- the brand name of the foreign product, if applicable
- a detailed description of the safety issue
- why it is considered significant
- information on the steps you took, or plan to take, in response to the safety issue, if applicable

If you have questions about how or when to notify us of a significant safety issue, please contact the Regulatory Project Management Office at the Marketed Health Products Directorate (MHPD).

Regulatory Project Management Office
Bureau of Strategic Engagement and Integrated Management Services
Health Canada
Address Locator 0702L
200 Tunney's Pasture Driveway
Ottawa ON  K1A 0K9
Email: bbrs.rpm-gpr.bbra@hc-sc.gc.ca

## Requests for information

We may request that you provide information compiled relevant to the risks and benefits of your biocide. The information you compile could include documentation of:

- notable incidents, serious incidents, serious unexpected incidents and other safety information that you gathered as part of your safety monitoring activities
- measures that have been taken outside of Canada to address significant safety issues
- your review activities, including your findings
- your safety monitoring systems and procedures

We may ask for this information at any time, if we become aware of new information concerning the risks and benefits associated with your biocide.

You must provide the information to us within the timeframe outlined in our request letter. Our letter will specify a reasonable timeframe in which you must submit the information. This timeframe is typically a 30-day period. However, the timeframe we specify may be longer as needed or shorter than 30 days if the information is needed quickly for us to determine if your biocide poses a serious and imminent risk of injury to human health.

All information provided to us must be in either English or French.

# Serious incident reporting

## What is a reportable incident

Serious incident reporting is required under section 39 of the *Biocides Regulations* (regulations). You must report to us the following incidents within 15 calendar days of becoming aware of the incident:

- any serious (expected or unexpected) incident related to your biocide that occurs in Canada
- any serious unexpected incident related to your biocide that occurs outside of Canada

An incident is reportable when the:

- threshold established in the definition of serious incident for incidents that occurred in Canada is met **or**
- threshold established in the definition of serious unexpected incident for incidents that occurred outside of Canada is met **and**
- minimum information for reporting is available

Serious incidents include those where user error and misuse, accidental exposure or occupational exposure have occurred and have led to a response that is either life-threatening or results in serious injury harm or death.

You should also consider important medical events as serious incidents. These are events that may not be immediately life-threatening or result in death or hospitalization, but that may:

- jeopardize the patient, in the clinician's judgment, **or**
- require intervention to prevent any of the outcomes noted in the serious incident definition

You should consider incidents that occur outside of Canada and that involve a fatal outcome as unexpected and reportable under serious incident reporting. The fatal outcome can only be considered expected if your Canadian label specifically states that using the product may be associated with a fatal outcome.

### Failure in effectiveness

The definition of a serious incident includes a failure in effectiveness of the biocide that results in a serious injury to human health, a life-threatening event or death. For a serious incident related to a failure in effectiveness to be reportable, the following must occur:

- a substantial failure of the expected performance of the biocide product, contrary to the claims made by the product in its conditions of use
- a person has been exposed to and contracted an illness or disease from a microorganism that the biocide failed to destroy, inactivate, reduce or control
- the illness or disease that the biocide failed to prevent caused the patient to be hospitalized, prolonged hospitalization, led to chronic or significant disability or incapacity, caused congenital malformation, was life-threatening or resulted in death

You are responsible for validating the failure in effectiveness information before you report to us under serious incident reporting. You should investigate first to determine if there has been a substantial failure and if there is a plausible link between the failure and the illness or disease contracted.

### Source of information

During the course of compiling information as part of your safety monitoring activities, if you become aware of an incident that meets the threshold of a serious incident, you must report the incident through serious incident reporting.

You may become aware of serious incidents through a variety of sources, for example:

- consumer complaints
- poison control centres
- Canada Vigilance Database

If you identify a serious incident when searching the Canada Vigilance Database **and** you have a report from another source on the same incident, you should submit the report from the new source to the Canada Vigilance program. Only reports from the additional source should be submitted to the Canada Vigilance program. Do not resubmit a report that you retrieved from the Canada Vigilance database.

## Notable incident not reportable

Notable incidents do not meet the threshold established in the definitions for serious incident or serious unexpected incident required for reporting. As such, notable incidents are not reportable under the serious incident reporting provisions of the regulations. However, they are to be compiled and considered as part of your safety monitoring activities.

## Examples of reportable incidents

The following are examples of serious incidents, which must be reported to us under serious incident reporting:

- While using a product in accordance with the directions of use indicated on the label, a user accidentally drops the open container and the biocide splashes onto the user's face. The user had a reaction to the biocide and required hospitalization.

- A young patient is hospitalized with rotavirus that was linked back to a daycare centre outbreak. The daycare centre had strict cleaning and disinfection procedures and used your biocide, which had an approved disinfection claim against the virus, on all touch surfaces according to the label directions. You investigated the situation and determined that your biocide failed to perform as indicated against the virus.

- A user in Canada failed to read the directions of use and warnings on the label of your biocide and mixed your biocide with a cleaning product. Toxic fumes were produced as a result of the mixture and were inhaled by the user. The user had a pre-existing lung condition and died from inhaling the toxic fumes.

- A user intentionally drank your biocide as part of a challenge and died as a result.

The following are examples of incidents that are **not** reportable under serious incident reporting:

- A user accidentally poured your biocide on their skin and received a minor burn. The user went to an urgent care clinic and was treated by the attending physician and released without needing further treatment. You should only consider the incident as part of your safety monitoring activities.

- A user outside of Canada failed to read the directions of use on the label of your biocide and mixed your biocide with a cleaning product. The Canadian label of your biocide contained a warning that mixing the product with certain other products may result in a fatal outcome. The user inhaled the toxic fumes that were produced as a result of the mixture. The user had a pre-existing lung condition and died from inhaling the toxic fumes. You should consider the incident as part of your safety monitoring activities, as this was a serious **expected** incident that **occurred outside of Canada**.

# Reporting serious incidents

You must submit a report to us of a serious (expected and unexpected) domestic incident or a serious unexpected foreign incident within 15 calendar days after becoming aware of the incident. The time clock starts on the day that you first have all the minimum information for an incident report.

You must report all serious domestic incidents and serious unexpected foreign incidents that you become aware of. This applies even if the biocide product in question is not currently being sold or has not been sold in Canada for some time. To facilitate the processing of incident reports, the reporter should indicate if the report is domestic or foreign by clearly indicating the country where the reaction occurred.

If you become aware of a serious incident or a serious unexpected incident after your market authorization has been permanently discontinued and revoked, you should still continue to report such incidents.

## What information to include

The minimum information required to submit a serious incident report are:

- an incident
- a biocide product
- an identifiable reporter **and**
- an identifiable person who experienced the harm

You should include all information that is available and relevant in your incident report. Often, you will need to submit an initial report to us with at least the minimum information in order to meet the reporting timelines. You should actively seek follow-up information and provide significant new information to us as it becomes available by submitting a follow-up report.

Significant new information related to the initial report includes, for example:

- a new suspected incident or response
- an additional or changed suspected biocide product
- a change in the assessment for causality
- any new or updated information on the incident that may impact the narrative of what has occurred
- additional key data elements
    - for the person who experienced the harm, such as age, sex, pre-existing medical conditions
    - for the suspected biocide, such as lot number
    - for the incident, such as additional description of the response or reported signs and symptoms

You should clearly identify follow-up reports to ensure that we can link the follow-up report to the initial report.

## An incident

You should document and report all relevant and available information on the incident. The information about the incident should have sufficient detail to provide a narrative of what has occurred.

You should document and report a full description of the serious incident, including:

- the harm that has occurred, including body site and severity
- the reported signs and symptoms
- the criterion (or criteria) for regarding the incident as serious if reported as such
- specific diagnosis for the harm or reaction, if applicable
- the date on which the person was exposed to the biocide
- the date that the harm or reaction first occurred
- the date that the person's health was restored to its original state before the incident
- any relevant diagnostic test results and laboratory data
- the setting where the incident occurred
    - for example, home, hospital, commercial setting, place of employment
- the outcome
    - recovery and any subsequent health effects
- stated cause of death and relevant autopsy or post-mortem findings for a fatal outcome
- other factors that may have contributed to the serious incident
- how the biocide relates to the harm, reaction or event

## A biocide product

You should document and report all available information on the biocide product known or suspected of being linked to the incident to make it easier to identify the product. Such information would include the:

- lot number
- brand name
- physical form
- identification number
- method of application
- settings in which the product is intended to be used

## An identifiable reporter

To avoid duplicate reports and to facilitate follow-up, an identifiable reporter is required for an incident report. An identifiable reporter is the source of the information. You should document and report the source of the information, including the:

- date on which you first received the incident information
- reporter qualification, if applicable, for example:
    - a user or another person on behalf of the user
    - a health professional and their specialty

If the source of the information is not an identifiable person (for example, a literature search, regulatory authority), you should clearly identify the source and the date you documented the report.

Include in the report your name and contact information (such as an email address or phone number) as the sender of the information.

## An identifiable person

To avoid duplicate reports, an identifiable person is also required for an incident report. The identifiable person is the one who experienced harm from the serious incident or serious unexpected incident. This could be, for example, a user of the product or a bystander close to where the product was used.

You should document and report key details of the person, including:

- the person's height and weight
- the person's sex and/or gender
- the person’s age or age category
- whether the person had any pre-existing medical conditions
- whether there were contributing factors associated with the person’s use of the biocide
    - for example, occupational exposure
- whether the person is considered part of a vulnerable population
    - for example, pregnant or lactating, psychiatric, pediatric, geriatric

## How to submit

You should submit serious (expected or unexpected) incident reports and serious unexpected incident reports to us using the form available online and submitted by fax **or** by mail.

Canada Vigilance Program
Health Products Surveillance and Epidemiology Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Address Locator 1908C
Ottawa ON  K1A 0K9
Telephone: 613-957-0337
Facsimile: 613-957-0335

For information about serious incident reporting, please email us with your request: canada.vigilance@hc-sc.gc.ca. Do **not** send reports by email.

# Issue-related reports

## What is an issue-related report

A request for an issue-related report will come from Health Canada. This report contains:

- a concise critical analysis of the issue specified in the request
- the information on which the analysis is based **and**
- any additional information specified and that is accessible to you

We may request, in writing, that you submit an issue-related report when we become aware of an issue that could have significant implications for benefits or risks associated with a biocide.

For example, we may request an issue-related report in response to:

- a notification from you of a significant safety issue under subsection 40(2) of the *Biocides Regulations* (regulations)
- a safety signal identified by us through the Canada Vigilance Program
- new information from a foreign jurisdiction on a similar or equivalent biocide product
- emerging trends or safety information on the benefits or risks of an active ingredient of your biocide

## Information to include in an issue-related report

An issue-related report should contain relevant information, such as:

- a description of the health issues relating to the subject of the report
- a description of the strategy used to collect the relevant information
- a summary analysis of the cases relevant to the issue, such as:
    - a tabulation of notable incidents and serious incidents
    - your comments on the incidents
    - analysis of the relationship between exposure to the biocide and the incidents
    - summary analysis of possible risk factors and confounding circumstances
- data about Canadian and international exposure
    - for example, how much product used
- reference information that reflects Canadian market entry requirements
    - for example, marketed labels and approved labelling information
- your conclusion on the safety of the product as it relates to the events in question and, if applicable, any risk mitigating actions you plan to take
    - for example, making changes to the product or the labelling

In certain instances, we may ask for specific information that is relevant to the analysis. We will specify this in our request letter.

It may be necessary for you to conduct an additional targeted search of available information in order to address our questions. You should include all the information we request that is accessible to you in your issue-related report.

Information is accessible to you if it can be obtained by you. For example:

- public information available through web access
- information that can be gathered by contacting poison control centres or other public bodies

## Submitting an issue-related report

You must submit an issue-related report when requested, within the timeline outlined in our request letter.

### How to submit

You should provide the issue-related report to us in electronic-only format, in either English or French, using the non e-CTD format. You should include a cover letter, with your identification number, and the reason for your submission (for example, response to issue-related report request letter dated YYYY-MM-DD).

If you have questions about issue-related reports, you may contact the Regulatory Project Management Office at the Marketed Health Products Directorate.

Regulatory Project Management Office
Bureau of Strategic Engagement and Integrated Management Services
Marketed Health Products Directorate
Health Canada
Address Locator 0702L
200 Tunney's Pasture Driveway
Ottawa ON  K1A 0K9
Email: bbrs.rpm-gpr.bbra@hc-sc.gc.ca

### Timelines

When we request an issue-related report, we will specify a reasonable timeframe for submitting the report. This timeframe is typically a 30-day period. However, we may specify different timeframes:

- longer as needed **or**
- shorter than 30 days if the information is needed quickly and we believe your biocide may pose a serious and imminent risk of injury to human health

# Information retention requirements

This section only applies to the information retention requirements in section 40 of the *Biocides Regulations* (regulations). The regulations also contain other record-keeping requirements for recalls and quality assurance.

## What information is required to be kept

You must keep all information compiled in accordance with subsection 40(1) of the regulations.

Subject to further discussions (which follow), you must keep information for at least 10 years after becoming aware of it. You cannot destroy or dispose of this information (including any documentation) before the end of the 10-year retention period.

### Incidents and foreign actions

You must keep all information that you become aware of relating to notable incidents, serious incidents and serious unexpected incidents regarding your biocide.

Examples of information that you must keep, if available, include:

- details of the biocide, such as the brand name, identification number, lot number, physical form, method of application, settings
- details of the person who experienced the harm, such as age or age category, sex or gender, height and weight, pre-existing conditions
- details of the incident, such as a description of the reaction and event, outcome, if there was user error or accidental exposure, date and time of incident, setting where the incident occurred
- details of the reporter, including the source of the report and date it was reported
- any assessments you've made about the incident
- evidence that the incident was reported to the Canada Vigilance Program, if applicable

You must also keep all information that you become aware of relating to measures that have been taken outside of Canada to address a significant safety issue.

If, in the course of your safety monitoring activities, you discover that a quality issue is related to the failure in effectiveness of your biocide, the quality control records retention period under section 52(3) no longer applies. Rather, the information retention provisions under section 40 of the regulations would apply to all the relevant quality control records related to the failure of effectiveness.

### Safety monitoring documentation

You are expected to keep documentation of your safety monitoring activities. Section 40(1) of the regulations requires you to compile and review information "in a manner that ensures the effective and timely detection of issues." The information that you keep should be sufficient for auditing purposes and to verify compliance.

Examples of information that supports the documentation of safety monitoring activities include:

- a description of your safety monitoring activities, such as written procedures, contractual agreements, training standards and records
- the rationale for the timing, frequency and nature of the safety review and scanning of sources to detect issues
- how and from where you collected the compiled information
- your findings for any detected significant safety issue
- your conclusions following safety monitoring activities, including if no new significant safety information was identified

## The form and manner of information retention

The form and manner in which you keep the information is at your discretion. However, you must ensure that the information:

- is readily accessible
- includes all relevant and required information
- could be submitted to us within the requested timeframe

You must preserve the integrity of the data. Based on how documents are preserved, you should consider having processes to:

- restrict file access to relevant personnel
- validate computerized systems and audit trails
- make periodic backups for electronic documents
- ensure documents are preserved in disaster situations

We also recommend that the information be easily searchable to ensure that a request can be addressed in a timely manner.

Information must be kept "at the ready." This means it must either be kept on-site or be easily accessible and, when requested, be submitted to us within the specified timelines.

## Who is required to keep the information

You are responsible for keeping the information for the applicable retention period. If you decide to store documents outside of your facility (for example, at a third-party facility), you are still responsible for ensuring the documents are preserved and accessible.

If your market authorization is revoked or suspended, you continue to be responsible for keeping the information for the remainder of the retention period. The requirement to keep information does not stop when a market authorization is revoked or suspended.

If a new MAH substitutes you, you must transfer all information to the new holder. You are responsible for keeping the information until its transfer. Once you have transferred the information, the new MAH is then responsible for keeping the information for the remainder of the retention period.

Examples of a new MAH stepping in as a substitute include a:

- transfer of the market authorization
- takeover by a new corporation or legal entity
- sale of the product and its market authorization

# Definitions

**Adverse event:** A notable incident, a serious incident, a serious unexpected incident or a serious adverse drug reaction.

**Biocide:** A drug that is manufactured, sold or represented for use in destroying or inactivating micro-organisms, or in reducing or controlling their number, on a non-living and non-liquid surface. However, it does not include a drug that:

a) is manufactured, sold or represented for use exclusively on the surface of food
b) is manufactured, sold or represented for use on the surface of a contact lens
c) meets the following conditions:
    i. is manufactured, sold or represented for use on the surface of
        A. an invasive device or
        B. a medical device that is not an invasive device but is intended to channel or store gases, liquids, tissues or body fluids, for the purpose of being introduced into the body by infusion or other means of administration and
    ii. is capable of destroying or irreversibly inactivating either
        A. all types of pathogenic micro-organisms, but not necessarily large numbers of pathogenic bacterial spores or
        B. all types of micro-organisms

**Foreign regulatory action:** An action taken by a foreign regulatory authority relating to the benefits or risks associated with the biocide for the purpose of mitigating or eliminating a serious risk of injury to human health. Action includes risk communications, recalls, label changes, reassessments of market authorization and suspensions or revocations of market authorization.

**Foreign regulatory authority:** A government agency or other entity outside Canada that controls the manufacture, sale or use of biocides within its jurisdiction and that may take enforcement action to ensure that biocides marketed within its jurisdiction comply with the applicable legal requirements.

**Market authorization holder (MAH):** The person who holds the market authorization for a biocide issued under the *Biocides Regulations.*

**Notable incident:** Means a:

a) response to a biocide that adversely affects human health or
b) failure in the effectiveness of a biocide that, in respect to human health,
    i. could have resulted in in-patient hospitalization, prolongation of existing hospitalization, congenital malformation or chronic or significant disability or incapacity, or
    ii. could have been life-threatening or resulted in death

**Qualified individual:** An individual qualified by a combination of education, training and experience relevant to their assigned responsibilities.

**Safety monitoring:** The MAH's obligations under section 40 of the *Biocides Regulations.*

**Serious adverse drug reaction:** Applies to hospital reporting requirements and means a response to a biocide that, in respect of human health:

a) results in in-patient hospitalization, prolongation of existing hospitalization, congenital malformation or chronic or significant disability or incapacity, or
b) is life-threatening or results in death

**Serious incident:** A response to or a failure in the effectiveness of a biocide that, in respect of human health:

a) results in in-patient hospitalization, prolongation of existing hospitalization, congenital malformation or chronic or significant disability or incapacity, or
b) is life-threatening or results in death

**Serious incident reporting:** The MAH's obligations under section 39 of the *Biocides Regulations.*

**Serious unexpected incident:** A serious incident that is not identified in nature, severity or frequency in the risk information that is set out on the Canadian label of the biocide.