

Public Health and Wellbeing Regulations Sunset Review regulatory impact statement

Chapter 5: Legionella risks in certain premises (water delivery systems)

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The following chapter is an extract of the regulatory impact statement for the proposed Public Health and Wellbeing Regulations (2019).

Information on infringements, consultation, implementation, evaluation and the exposure draft regulations are contained in the full regulatory impact statement available on the [Engage Victoria website](https://engage.vic.gov.au) <<https://engage.vic.gov.au>>.

This extract was prepared to assist stakeholders who access the report by accessing a specific category on the Engage website.

Introduction (and invitation to comment)

Overview

The Public Health and Wellbeing Regulations 2009 (the current regulations) were made under the *Public Health and Wellbeing Act 2008* (the Act) and are due to sunset on 15 December 2019. New regulations are needed to replace them.

The remaking process provides an opportunity to revisit whether regulations are still needed and, if so, whether there are ways to improve them.

Public health regulations provide a framework for businesses, councils and individuals to protect the health and wellbeing of Victorians. Understanding how these regulations, and any proposed changes, will impact on Victorian business and the Victorian community is critical to the effective operation of the regulatory framework.

The current regulations include several regulatory areas, and the subject matter varies widely. In some ways these regulatory areas are distinct in their nature; however, their overall objective gives effect to the Public Health and Wellbeing Act.

To the extent that the regulatory areas are different, the department consulted key stakeholders to ensure any issues were understood and the impact of proposed solutions would be acceptable. This preliminary consultation has informed the proposed regulations and a summary is provided in the 'Consultation' chapter.

Purpose and objective

Victorians enjoy one of the highest standards of health and wellbeing in the developed world. This could not be achieved without laws and regulations that protect and promote public health and wellbeing.

The Act

The current regulations were made under the Public Health and Wellbeing Act. The purpose of the Act is to provide a legislative framework that promotes and protects public health and wellbeing in Victoria.

The state has a significant role in promoting and protecting the public health and wellbeing of Victorians.

Public health and wellbeing includes the absence of disease, illness, injury, disability or premature death and the collective state of public health and wellbeing. Public health interventions are one of the ways in which the public health and wellbeing can be improved and inequalities reduced.

The regulations

As set out in the Public Health and Wellbeing Act, the aim of the regulations is to achieve the highest attainable standard of public health and to prevent disease and illness while minimising costs for regulated industries.

Public health regulations provide a framework for businesses, councils and individuals in the practical application of the Act.

The regulatory impact statement

The purpose of this regulatory impact statement is to provide information and analysis to review how these regulations, and any proposed changes, will affect Victorian business and the Victorian community and contribute to the effective operation of the regulatory framework for public health.

The current regulations are due to expire on 15 December 2019. New regulations are needed to replace them.

Preparation of the new regulations

Before new regulations are made, the *Subordinate Legislation Act 1994* requires completion of the following four steps shown in Figure 1.

Figure 1: The four steps of making new regulations



Preliminary consultation

The department undertook preliminary consultation with key stakeholders to inform development of the proposed regulations. The proposed regulations address a range of matters for giving effect to the Act and therefore different stakeholders were engaged on different matters.

A summary of the preliminary consultation that has occurred is provided in the ‘Consultation’ chapter of this regulatory impact statement.

Public consultation: regulatory impact statement, evaluation and implementation

This regulatory impact statement has been prepared to meet the requirements of the Subordinate Legislation Act, enabling public consultation on the proposed regulations. The regulatory impact statement presents the range of matters addressed in the proposed regulations in separate chapters. Each chapter includes the regulatory objective for the matters addressed in the chapter, an assessment of the costs and benefits of the proposed regulations and possible alternatives.

In most cases the regulatory impact statement considered and analysed three regulatory options: to remove all regulation, to remake the current regulations without change, or to strengthen the requirements set out in the current regulations. The extent of the analysis of the regulatory options varies but is consistent with the need for regulatory change. In most cases the recommended option for each regulatory area is to strengthen the current regulations.

Each of the regulatory areas included within the regulatory impact statement has a specific implementation plan that will support awareness and understanding of any changes, preparedness and compliance. Information about implementing the proposed regulations can be found in the ‘Implementation’ chapter.

The proposed regulations will operate for up to 10 years. Evaluation has a key role in ensuring the intended improvements of the proposed regulations (appropriately effective and proportionate) are borne out and align with government objectives on an ongoing basis. Each of the regulatory areas included within the regulatory impact statement has a specific evaluation plan. Information about the evaluation, including public consultation, can be found at the end of the regulatory impact statement.

The proposed regulations are included as an attachment to this document.

Consideration of submissions

Public comments and submissions will be considered before the new regulations are made.

Final decision

The decision to make or not to make the proposed regulations will be informed by the public comments and submissions received. Notice of the decision will be published as soon as practicable after the decision has been made.

Small business impact and competition assessment

Small businesses may disproportionately experience the impacts from regulatory requirements for a range of reasons, including relatively limited resources to interpret compliance requirements or to keep pace with regulatory changes, and the cumulative effect of different requirements.

Most of the proposed regulations propose simplified and streamlined regulatory definitions and requirements compared with the current regulations, particularly where stakeholder feedback has raised issues about ambiguity of the intention of regulations. Any regulatory proposal needs to be scrutinised carefully to assess whether it is having an adverse impact on the ability of firms or individuals to enter and participate in the market. In line with the *Victorian guide to regulation*, new legislation (both primary and subordinate) needs to demonstrate that it will not restrict competition, unless benefits of the restriction outweigh the costs and the objectives of the legislation can only be achieved by restricting competition.

In instances where restrictions on competition have been identified, the benefits of the restriction outweigh the costs and the objectives of the legislation can only be achieved by restricting competition. For example, the registration of a premises by local government for the purposes of infection control standards creates an additional cost for starting a health and beauty service business. However, this cost is offset by the reduced risk of disease in the community and the reduced risk of an infectious disease outbreak.

Structure of the regulatory impact statement and the proposed regulations

This regulatory impact statement and the proposed regulations have grouped the regulations according to either how the regulations are administered or the regulation's purpose in the Act. These are broadly grouped into:

- regulations administered by councils
- regulations administered by the department
- regulations related to managing and controlling infectious diseases, micro-organisms and medical conditions
- other regulations.

Regulations administered by councils

- Vector-borne infectious disease control
- Registered premises – infection control
- Aquatic facilities

Regulations administered by the Secretary to the Department of Health and Human Services

- Cooling tower systems

- Legionella risks in certain premises (water delivery systems)
- Pest control

Management and control of infectious diseases, micro-organisms and medical conditions

- Notifications of infectious diseases, micro-organisms and medical conditions
- Closed court orders for prescribed diseases
- Immunisation and exclusions – schools and childcare
- Escort agencies providing information to sex workers and clients

Other regulatory provisions

- Prescribed senior officers (Chief Health Officer delegations)
- Tissue donations
- Consultative councils.

What isn't included in this regulatory impact statement

The Public Health and Wellbeing Act

The Public Health and Wellbeing Act is the legislation under which these regulations are made. The matters that can be set out in the regulations are confined to what is required under the Act. The requirements under the Act are not the subject of this review, only the details set out in the regulations. During the process of the review and consultation it is likely that potential improvements to the Act may be identified, but that is not the focus of this regulatory impact statement.

Public Health and Wellbeing Regulations relating to prescribed accommodation

Regulations relating to prescribed accommodation will not be considered within this regulatory impact statement (rr. 13 to 27). Separate new regulations relating to prescribed accommodation will be made in 2020. In the interim, the operation of the prescribed accommodation regulations will be extended in their current form for 12 months to allow further time for review and consultation.

The extension of the prescribed accommodation regulations provides an opportunity to separate regulations relating to prescribed accommodation from the other regulations made under the *Public Health and Wellbeing Act 2008*. It is intended that the extended prescribed accommodation provisions will be contained in the renamed 'Public Health and Wellbeing (Prescribed Accommodation) Regulations 2009' and will operate separately from the proposed Public Health and Wellbeing Regulations 2019.

Public Health and Wellbeing Regulations relating to HIV testing

The Public Health and Wellbeing Act prescribes special requirements for HIV testing and these requirements are included in the 2009 regulations. The need to review and modernise these requirements is an issue that a range of sector stakeholders have been raising for some years. Overwhelmingly, the sector has supported a repeal of relevant sections of the Act relating to pre and post HIV testing. The Victorian Parliament recently passed the Public Health and Wellbeing Bill 2019 to repeal the HIV testing specific provisions (ss. 131 and 132) on the basis that they stigmatise people with HIV and are outdated. As a result, the prescribed regulations will not need to be made.

Invitation to comment

In accordance with the *Victorian guide to regulation*, the Victorian Government seeks to ensure that proposed regulations are well-targeted, effective and appropriate, and impose the lowest possible burden on Victorian businesses and the community.

The regulatory impact statement process involves assessing regulatory proposals and allows members of the community to comment on proposed regulations before they are finalised. Such public input provides valuable information and perspectives and improves the overall quality of regulations.

The Public Health and Wellbeing Regulations 2019 (the proposed regulations) will replace the Public Health and Wellbeing Regulations 2009 (the current regulations). A copy of the proposed regulations is published with this regulatory impact statement.

Public comment is invited on the regulatory impact statement and the proposed regulations.

The consultation period is 60 days. Please note that all comments and submissions received will be treated as public documents.

Submission deadline

Comments and submissions should be received by the Department of Health and Human Services no later than 5.00 pm, Monday 30 September 2019.

How to make a submission

Preferred method

The [Engage Victoria website](https://engage.vic.gov.au) <https://engage.vic.gov.au> is the preferred method for receiving submissions. The website includes specific questions for each regulatory area and allows for additional feedback to be provided.

Email

If you are unable to use the preferred method above, submissions can be received by [emailing the department](mailto:phwa.enquiries@dhhs.vic.gov.au) <phwa.enquiries@dhhs.vic.gov.au>.

Post

If you are unable to use the preferred method above, submissions can be received by post marked 'Submission to the Review of the Public Health and Wellbeing Regulations 2009' and addressed to:

Chief Health Officer
Regulation, Health Protection & Emergency Management
Department of Health and Human Services
GPO Box 4057
Melbourne VIC 3001

Where can I obtain copies of this regulatory impact statement and the proposed regulations?

Copies of this regulatory impact statement and the proposed regulations can be obtained from the [Engage Victoria website](https://engage.vic.gov.au) <https://engage.vic.gov.au>.

How can I be updated on the progress of the review?

The [Engage Victoria website](https://engage.vic.gov.au) <https://engage.vic.gov.au> enables you to register to receive updates on the progress of the review of the current regulations.

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This extract was prepared to assist stakeholders who access the report by accessing a specific category on the Engage website. This is not intended to limit the scope of submissions; the department welcomes submissions from all interested parties.

Chapter 5: Legionella risks in certain premises (water delivery systems)

Problem analysis

Victoria regulates water delivery systems to protect our most vulnerable community members from legionellosis – a serious disease caused by a bacterium that can breed in warm, wet places such as pipes and showers.

Water delivery systems can provide a breeding ground for Legionella bacteria. If inhaled by a human, the bacteria can cause legionellosis (also known as legionnaires' disease) – a serious and sometimes fatal form of pneumonia.

Victoria regulates water delivery systems supplying aged care facilities, health services, health service establishments, registered funded agencies, correctional services and commercial vehicle washes in Victoria to prevent and control outbreaks of legionellosis.

Hazard

Water delivery systems (pipes, showers and sundry plumbing that provide temperature-controlled water for use by people in buildings) can be a potential source for Legionella bacteria. While Legionella bacteria is commonly associated with cooling tower systems, it can also exist in any type of water system where the conditions (for example, temperature and water quality) are favourable to Legionella bacteria to grow. Legionella has been detected in water delivery systems associated with showers and ice dispensers in hospitals and aged care facilities in Victoria. Cases of legionellosis have also been linked to warm water in commercial car wash facilities.

Exposure

Water delivery systems are present in most homes and buildings in Victoria. It would be highly unlikely that a person living in Victoria would pass a single day without using a water delivery system. Requirements for manufacturing and installing water delivery systems are in place, with the objective of ensuring water is safe for humans to use. This includes requirements designed to prevent or limit the growth of Legionella bacteria. Exposure is an unavoidable consequence of inhabiting the built environment with operating water delivery systems.

Vulnerability

Most people exposed to Legionella bacteria do not get sick. However, of those who do become ill, 93 per cent end up in hospital.¹ These are usually people who are at increased risk of illness, such as the elderly, smokers and people with weak immune systems or underlying chronic illnesses.

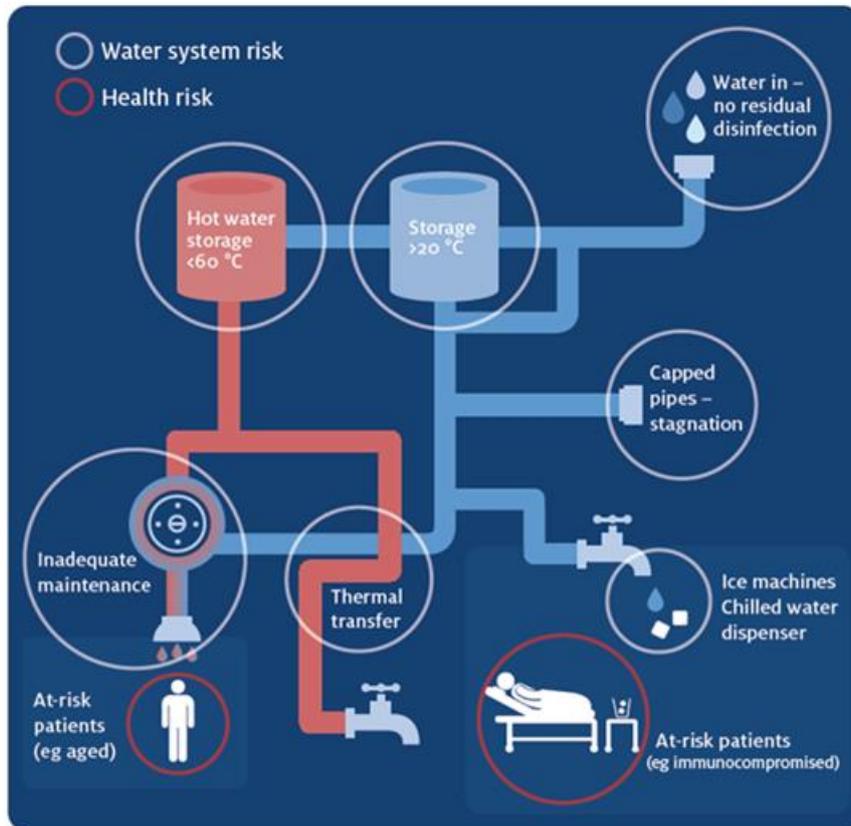
Exposure to Legionella bacteria in places with high concentrations of people with an increased risk of illness, such as hospitals and aged care facilities, have higher infection rates and a significantly higher case-fatality rate (up to 40 per cent) compared with the 3.3 per cent case-fatality rate for legionellosis in Victoria since 2009.²

¹ Department of Health and Human Services (Victoria). Interactive infectious disease surveillance reports

² Ibid.

Figure 5.1 provides a broad overview of the risks in water delivery systems and associated health risks.

Figure 5.1: Water system and health risks in water delivery systems



Source: enHealth 2015³

History of regulation

Water delivery systems were first regulated in Victoria in 1990 by the Health (Infectious Diseases) Regulations 1990, in recognition of the risk of legionellosis with water delivery systems as the source. These regulations required that the owner or the person who manages or controls any building that is served by a warm water system must maintain that system in a manner set out in the *Guidelines for the control of Legionnaires' disease* published by Health Department Victoria in May 1989.

New regulations were made in 2001 as part of the comprehensive Legionella risk management reforms following the outbreak of legionellosis associated with the Melbourne Aquarium. While the focus of the reforms was on improving the management of cooling tower systems, a second component regulated all warm water systems except those in single dwellings. Those regulations required the use of either a prescribed form of disinfection or a method approved by the Secretary to the department. The regulations also required Legionella testing under some circumstances, record keeping and a mandatory response to advice from the Secretary that a site had been associated with a case of legionellosis.

While Legionella bacteria has been detected in Victorian water delivery systems in a wide variety of premises over the period since the original regulations were first made, there have been very few cases of legionellosis attributed to exposure to Legionella bacteria from water delivery systems in Victoria over the past 20 years.

³ enHealth 2015, *Guidelines for Legionella control in the operation and maintenance of water distribution systems in health and aged care facilities*, Australian Government, Canberra

In recognition of the low number of cases attributable to water delivery systems, in 2009 the regulations relating to Legionella and water delivery systems were altered to be less prescriptive and more targeted. Removing these prescriptive requirements saw the onus placed on the responsible person to manage the risk associated with the operation and use of the water delivery system. In place since 2009, the current regulations do not require a documented risk management plan and do not specify any maintenance, regular water sampling, disinfection or record-keeping requirements.

The current regulations also confine the application of the regulations to those premises understood to be at highest risk of a legionellosis outbreak due to the vulnerability of the patients or residents, except for commercial vehicle washes, which were specifically included after the 2008 outbreak of legionellosis at a Hoppers Crossing car wash facility.

The most well-known Australian outbreak related to a water delivery system occurred at the Wesley Hospital in Brisbane, Queensland in late May and early June 2013. Two patients were diagnosed with legionellosis, one of whom subsequently died as a result of the infection.

Objective of the regulations

The objective of the regulations is to reduce the risk of Legionella bacteria in water delivery systems in premises where vulnerable populations are concentrated or where Legionella is known to have occurred.

The regulations contribute to minimising the impact of legionellosis on the Victorian community by reducing illness at car washes and within vulnerable populations in health and aged care facilities and reducing service disruption at these premises.

Requirements of the current regulations

The regulations are made pursuant to ss. 232, 234(b) and 238(2) of the *Public Health and Wellbeing Act 2008*, which allow for certain requirements such as preventing, controlling and minimising public health risks to be prescribed.

The current regulations place the onus on a 'responsible person' to manage the risk of Legionella and set out the general risk management requirements to address the risk of Legionella being present in water delivery systems within aged care facilities, health services, health service establishments, registered funded agencies, correctional services and commercial vehicle washes (see Table 5.1).

The regulations set out the general risk management requirements to address the risk of Legionella being present in water delivery systems within certain types of premises.

The responsible person must:

- take reasonable steps to manage the risk of Legionella
- disinfect the system within 24 hours after receiving a report that Legionella has been detected in a water sample
- ensure that a water sample is promptly taken for testing and reporting if informed by the Secretary that a system is suspected or implicated in a case or outbreak of legionellosis
- disinfect the system in accordance with any reasonable direction of the Secretary.

The 'responsible person' is defined as the person who owns, manages or controls the water delivery system.

Table 5.1: Water delivery systems regulations

Service	Description
Aged care services	The Commonwealth Department of Health's 2016 aged care services list identifies 1,326 aged care facilities located in Victoria. Aged care services are generally regulated by the Commonwealth under the <i>Aged Care Act 1997</i> and related instruments.
Health services, health service establishments and registered funded agencies	These organisations are structured and governed in accordance with the Victorian <i>Health Services Act 1988</i> , which is administered by the department. They include public hospitals, private hospitals, denominational hospitals, day procedure centres and state-funded residential care services. They are required to adhere to various standards developed by the department, such as cleaning standards.
Correctional services	According to Corrections Victoria, the state has 11 publicly operated prisons, three privately operated prisons and one transition centre. Under the Victorian <i>Corrections Act 1986</i> , the term 'correctional services' also encompasses a range of non-prison services, including facilities that administer community-based corrections orders.
Commercial vehicle washes	According to IbisWorld's May 2017 report on car washing and detailing services in Australia, Victoria has around 825 car washes. Car wash usage is expected to increase due to the environmental benefits (compared with car washing at home) and busier lifestyles. There is a trend away from manual car wash services (where either the user or a staff member washes the car) to more automated solutions. However, the department understands that most car wash operators have moved away from warm water car washing due to the risk of legionellosis.

Options

- Option 1: Retain the current regulations without changes
- Option 2a: Amend the current regulations
 - Option 2b: Amend the current regulations and remove the mandatory disinfection requirement
- Option 3: Remove or reduce the current regulations

Option 1: Retain the current regulations without changes

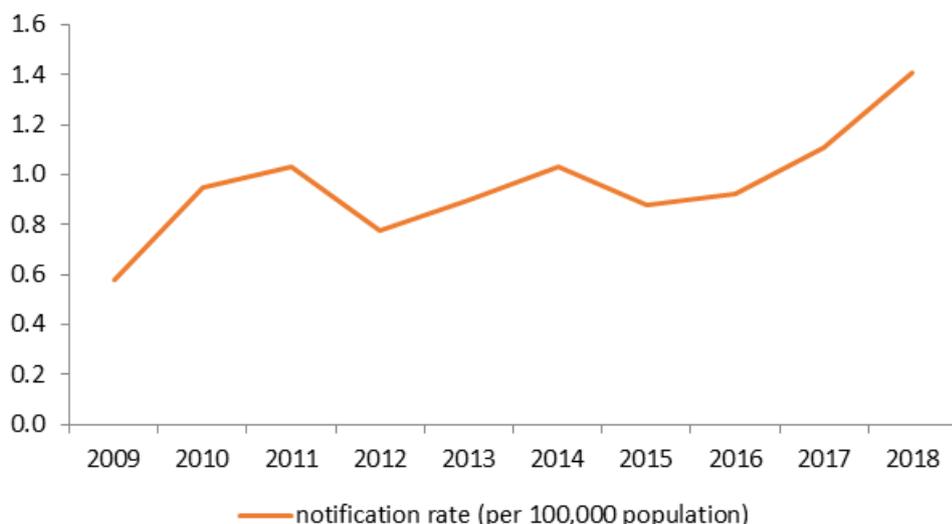
By reviewing whether the current regulations have reduced the risk of *Legionella* from water delivery systems in places of highest exposure or infection, an assessment can be made regarding the viability of remaking the current regulations without changes.

The number of cases of legionellosis in Victoria is rising

Exposure to *Legionella* via water delivery systems generally involves a specific type of *Legionella* bacteria – *Legionella pneumophila*. By reviewing the incidence of *Legionella pneumophila* (Figure 5.2), a sense of the number of cases from cooling towers (see Chapter 4) and warm water delivery systems can be gained.

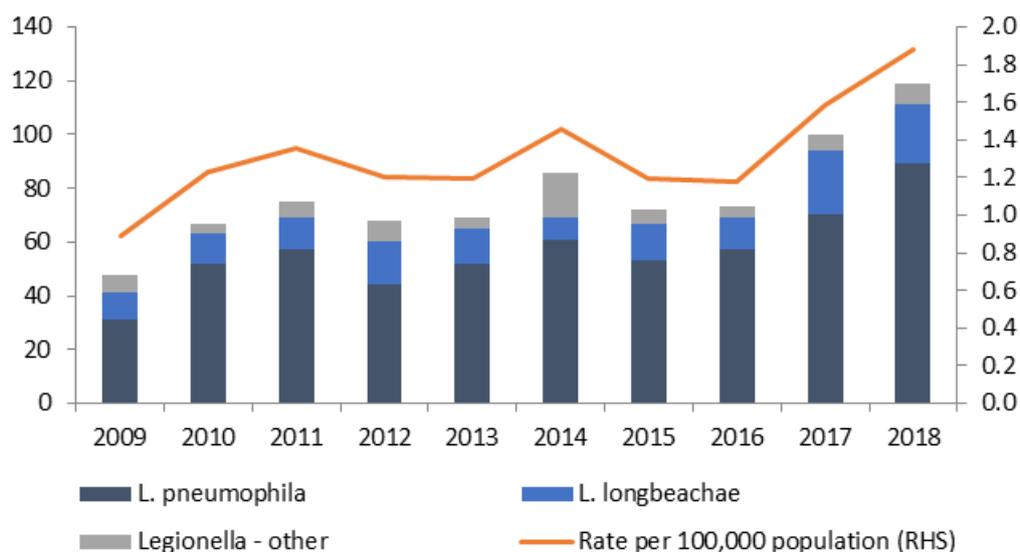
There has been a steady increase in the number of cases of legionellosis (including cases attributed to *Legionella pneumophila* bacteria; see Figure 5.3) in Victoria over the past 10 years; however, as outlined in Chapter 4 there are demographic trends that are likely to contribute to this gradual increase, and this increase is still lower than the rate per 100,000 experienced between 2002 and 2008. There is also an as-yet unexplained global increase in cases of legionellosis due to *Legionella pneumophila*.

Figure 5.2: Legionella pneumophila notified cases per 100,000 population, Victoria, 2009–2018



Source: The Department of Human Services, Victorian Government

Figure 5.3: Notifications of Legionella by type, Victoria, 2009–2018



Source: The Department of Human Services, Victorian Government

The graphs above shows that, while other types of Legionella bacteria are also on the rise, the majority of cases remain *Legionella pneumophila* – of which the suspected sources are cooling towers, water delivery systems or other sources in the environment.

Cases of Legionella arising from exposure to a water delivery system

There is limited available information that identifies legionellosis infections based on the potential setting acquired, such as exposure via water delivery systems, either in Australia or abroad. This is partially attributable to the difficulty in assigning a specific source responsible for an infection. During the infection period a person is likely to have been exposed to multiple sources capable of producing aerosols containing Legionella.

While Legionella has been detected in Victorian water delivery systems in many different types of premises over the period since the current regulations were made, there have been few cases of

legionellosis, possibly as low as two to three cases, attributed to exposure to water delivery systems as defined in the current regulations over the past 20 years in Victoria.

Given the absence of outbreaks (multiple cases linked in time and location) attributed to water delivery systems over the past 20 years and particularly over the life of the current regulations, it could be argued that the regulations have been successful; however, whether this is specifically due to the regulations is impossible to say. In any case, the department considers the scope to be appropriate due to experiences of other regulators globally.

Similar international jurisdictions have had numerous outbreaks in comparable water delivery system settings (with vulnerable populations) and have acted to regulate these settings rather than regulating settings frequented by lower risk populations such as showers in gymnasiums and residential homes.

Legionellosis infections attributed to water delivery systems overseas have seen infections occur gradually over a long period. For example, an aged care facility in the United States had 13 cases over four months, and this was considered an outbreak. Other outbreaks have occurred over multiple years. This slow infection rate is contrasted with the 'explosive' rate of infection observed from a cooling tower, such as the Melbourne Aquarium outbreak in 2000, which resulted in three deaths and more than 100 cases in a short period.

Possible explanation for the increase in reported cases of Legionella

While an examination of the notifications data could be seen to indicate an emerging issue with legionellosis in Victoria, the department believes several influencing factors have contributed to this increase that cannot be impacted by changes to the Public Health and Wellbeing Regulations. Legionellosis remains comparatively less prevalent in the nine years since 2009 (1.32 per 100,000 population) compared with the 2000–2009 period (1.98 per 100,000 population) and below the Australia-wide five-year average (1.6 per 100,000 population, 2013–2017). Contributing factors to the increase in reported cases in Victoria most likely include:

- improved reporting of cases by medical practitioners and laboratories resulting from improved awareness
- demographic and population behaviour changes including:
 - an ageing population contributing to a larger number of more vulnerable Victorians in the community
 - increased density of the urban population resulting in more people living in and around areas with cooling towers
 - increased travel between countries resulting in Legionella acquired overseas being notified in Victoria.

For further analysis of these factors please see the 'Cooling tower systems' chapter.

While the number of reported cases of legionellosis has increased beyond what would be expected relative to population growth, the likely contributing factors to this increase (population changes, changes to notification behaviour, overseas travel patterns and global increases from unknown sources) are beyond the scope of the Public Health and Wellbeing Regulations, which pertain to managing Legionella. The number of reported cases remains low overall, with fewer than two cases per 100,000 Victorians each year. This does not preclude the possibility that improved regulation could lead to a decrease in cases.

Advantages and disadvantages of this option

The advantages of this option are that it provides continuity. That is, no change for stakeholders to adapt to. The disadvantages of this option are that the regulations would still:

- apply to some classes of premises that the department considers represent low risk (options 2a and 2b would propose to limit the scope of the regulations slightly to address this problem)
- require the responsible person to disinfect the entire water delivery system following the detection of Legionella. This requirement has been problematic for large facilities with extremely large water delivery systems (the detection of Legionella in one outlet triggers the requirement to disinfect many hundreds of outlets). This issue is discussed further in options 2a and 2b.

Option 2a: Amend some aspects of the current regulations

Consultation with stakeholders, including public hospitals and health services with regulated water delivery systems and maintenance contractors, was undertaken in early 2018 to inform the review of these regulations. Written submissions were invited in response to circulating regulatory options with targeted stakeholders. Supplementary information was gleaned from face-to-face meetings conducted by departmental staff. A consistent theme of the consultation was the need to recognise the variation in size, type and operation of water delivery systems as well as the degree to which they pose a risk to public health.

The department subsequently analysed the consultation results and determined that certain clarifications and additions could improve the regulations to better meet regulatory objectives, specifically:

- more clearly defining the places where the regulations apply to better reflect the risk profile of Legionella
- adding a new offence to falsify a laboratory report or tamper with a sample taken from a water delivery system.

In this option, the proposed regulations reflect these findings.

Clearer definition of where regulations apply based on duration of stay

As Legionella risk relates to warm water distributed by water delivery systems used in large facilities and the exposure to aerosols created (for example, by shower heads), the risk exists where such exposure is most likely and those exposed may be more vulnerable to infection. Likelihood of exposure in a health service will relate to the patient's duration of stay (use of shower facilities over the course of several days). Current regulations are applicable to water delivery systems used in day procedure centres (as health service establishments) where no appreciable risk of exposure exists (for example, length of stay is less than one day). In this option, this requirement would be removed to allow the regulations to focus on areas and facilities considered to be of high risk to vulnerable people.

More clearly defining the premises where the regulations apply will allow more targeted communications from the department and reduce unnecessary compliance efforts in premises where the Legionella risk is low. It will enable the department to allocate resources to the more tailored prevention activities outlined below.

Adding a new offence to falsify a laboratory report or tamper with a sample

Consultation suggested that there is a need to address the potential that water samples may not reflect the real state of the water due to tampering or swapping of the source water. A specific offence is proposed to be added to deal with this issue.

Option 2b: Amend some aspects of the current regulations and remove the mandatory disinfection requirement

This option contains the same measures above to option 2a with one key exception – removing the requirement to disinfect the entire water delivery system following the detection of Legionella in the system.

As described earlier, there has been an increasing problem observed where extremely large facilities with hundreds of water outlets have found it highly disruptive to comply with the current regulations requirement for system-wide disinfection following the detection of Legionella in any part of the system. Facility managers of large facilities have long argued that the specific circumstances of the Legionella detection and the design of each water delivery system needs to be considered in the decision on whether to perform a system-wide disinfection.

For example, a very large facility may have a hot water loop circulating at a temperature at which Legionella will not survive. The system may feed, for example, 200 TMVs, which then feed a total of, for example, 500 outlets. A sampling program may take, for example, 10 samples and Legionella may be detected in one of those samples. The current regulations would dictate that the entire system be disinfected following that detection. Facility managers have argued that this is a disproportionate response and that they are better placed to work with clinicians on developing a tailored response that considers the risks and benefits of responding in a different way. Given the extremely low numbers of cases in Victoria over the past 20 years, in this option it is proposed that the regulations be silent on the issue of disinfecting the system and to leave the issue with facility managers to resolve, taking into account the overall risk profile of the facility and the people who may be exposed to the water delivery system.

Advantages and disadvantages of option 2b

The advantages of this option are that it responds to the increasing difficulty experienced by some sites to comply with the current requirement to disinfect the entire water delivery system following detection of Legionella at low levels in one outlet.

The disadvantages of this option are that the regulations would no longer require mandatory disinfection of the water delivery system following detection of Legionella. Stakeholders have proposed a position that full disinfection is not required given there is already a requirement for the responsible person to manage the risks of Legionella in the water delivery system, and that mandatory disinfection does not mitigate risks and comes with a high cost.

For operators of less complex or smaller water delivery systems it is expected that disinfection is likely to be the best approach for mitigating the risk of Legionella in the system, and that these operators would continue to undertake this action.

Option 3: Remove or reduce the current regulations

No regulation is a potential option and would be supported by information and awareness campaigns produced by the department. The regulations could be removed in favour of relying on reputational effects and post-infection legal action brought by those affected to control the risk of legionellosis from water delivery systems. However, these controls are relatively weak and their effect is significantly delayed.

A lack of regulation would not be sufficiently replaced by market forces and would reduce the prevention of Legionella bacteria in water delivery systems, impede the ability for the department to detect Legionella bacteria, and impede remedial action following a detection.

Lack of prevention

The absence of regulations means that any action taken to protect people from Legionella bacteria in water delivery systems could only occur following illness, rather than preventing illness, as is currently the case. Building operators would have existing liabilities under general consumer protections; however, this recourse would only be possible after an outbreak of legionellosis.

The lack of regulations may contribute to a perception that the risk of Legionella within water delivery systems is not serious. This would most likely lead to reduced preventative action taken by the person

responsible for the water delivery system to manage the risk of Legionella bacteria. Water delivery systems can be expensive to maintain, and adequate maintenance incurs a cost that the building operator may not prioritise with competing fiscal demands.

Reduced or removed preventative action would lead to more outbreaks of legionellosis.

Impeded ability to detect Legionella bacteria

Without regulation, the department would no longer have the specific power to require a water sample to be taken from the water delivery system if it is suspected or implicated as the source of a legionellosis infection.

The department would continue to investigate cases of legionellosis associated with stays in aged care facilities, hospitals, correctional services and car washes; however, this would rely on an authorised officer using their power to enter a public place or, with consent of the occupier, any other premises to investigate whether there is a risk to public health.

It may be necessary for the department's authorised officers to obtain consent to enter a particular place to take water samples, and this may lead to refusal or delays because of the time required to obtain that consent.

The Chief Health Officer could consider authorising authorised officers to exercise any of the public health risk powers in the Act. This is a relatively cumbersome method and its use, if required, on a frequent basis would place a significant administrative burden on the department.

Impeded or ineffective remedial action following detection

In the absence of regulations, there would be no requirement for remedial action to prevent further infection if Legionella bacteria was detected in a sample taken from a water delivery system. The department would continue to provide best practice guidelines to owners/operators of water delivery systems to provide guidance about appropriate measures to control the risk of Legionella bacteria.

In the absence of regulations, thorough disinfection of the entire water delivery system may not be undertaken or may not be undertaken within the 24-hour period currently specified, which puts users of or those exposed to the system at greater risk of exposure to Legionella bacteria.

Further reducing regulatory requirements based on historical evidence

Regulatory requirements could be further reduced from the current requirements by reducing the types of premises required to comply with water delivery systems regulation. This could be done by reducing the scope of the regulations to apply only to premises with a history of outbreaks of legionellosis or detections of Legionella bacteria. This is not considered a viable option because past performance has not proven to be a reliable predictor of future performance in relation to Legionella outbreaks. There has been no substantial change to the risk profile of the disease, and an ageing population and increased population density means there are most likely larger numbers of people vulnerable to infection.

Public expectation

The final consideration is whether removing Legionella regulation would meet the expectations of the public that the government manages this public health risk. Outbreaks of Legionella have been associated with significant media attention and public demands for intervention and action by government. In responding to potential outbreaks, the department considers there is a heightened reaction (relative to the number of people identified as contracting legionellosis) to the real or potential health impacts of an outbreak of legionellosis. Academic literature theorises that this is because the risk cannot be assessed by the public and the hazard is invisible. It is likely that shifting the regulations to

focus solely on the most vulnerable populations or the highest risk cooling towers would not be enough to address the expectations of the public in the event of an outbreak.

Impact analysis

Burden of disease

The burden of disease is similar to the discussion in chapter 4 relating to Cooling tower systems. The same dollar value for a case of legionellosis would be expected to be applicable to a case of legionellosis – \$14,663.66 for a case involving hospitalisation and \$5,163.66 for a case not requiring hospitalisation.

Avoided economic burden of an outbreak of legionellosis from water delivery systems

While the number of cases attributed to water delivery systems in Victoria has been low, the economic costs of an outbreak would be high.

An Australian example of the impact is the response to legionellosis cases at the Wesley Hospital in Brisbane, Queensland in 2013. After detecting a number of cases, the hospital was closed, and no showers were allowed to be used. The hospital recalled 1,400 recently discharged patients, and more than 2,000 surgical procedures had to be rescheduled to other facilities. In the 2014–15 financial year, remediation costs (on top of the impacts listed above) were estimated to be \$2.6 million and included immediate plumbing remediation, water remediation, filters, advertising and other media costs. These actions not only had an impact on the operation of the Wesley Hospital, but also affected the workload of south-east Queensland's whole health system.

This example demonstrates that there can be sizeable economic costs in the event of an outbreak.

Cost for industry to implement the regulations

The regulations apply to water delivery systems in aged care facilities, health services, health service establishments, registered funded agencies, correctional services and commercial vehicle washes.

The number of water delivery systems to which the regulations apply is estimated to be at least 2,478.

Number and complexity of water delivery systems

Aged care facilities

There are 1,326 aged care facilities in Victoria. Based on the department's inspections of this type of facility, these water delivery systems tend to be located in facilities where there is no on-site engineering expertise to manage the operation of the water delivery system. The size of the facilities varies but appears to be increasing.

Health services, health service establishments and registered funded agencies

As a lower estimate, there are 279 hospitals in Victoria (includes hospitals classified as a bush nursing hospital, day procedure centre, denominational hospital, multi-purpose service, private hospital, privately operated hospital, or public hospital).

The department does not have an accurate estimate of the number of 'smaller' water delivery systems that are within Victorian hospitals but notes that changes proposed in option 2 would improve the clarity of systems that are included in the regulations and reduce the number of facilities captured by the regulations. These water delivery systems can range from extremely large and complex for major hospitals, to small for a day procedure centre.

Correctional service centres and prisons

There are approximately 33 correctional service centres in Victoria, 11 publicly operated prisons, three privately operated prisons and one transition centre. The water delivery systems in these facilities vary from extremely large and complex to small in the case of smaller regional facilities.

Car washes

Victoria has around 825 car washes. The water delivery systems are understood to be of moderate risk due to the occasional practice of heating water used in the car wash process.

Costs and benefits

Option 1: Retain the current regulations with no changes

Table 5.2 lists the expected impacts on operators of water delivery systems if the current regulations are retained, relative to a base case of no regulations.

Table 5.2: Retain the current regulations with no changes

Current regulation (option 1)	Benefit	Cost
Scope of regulation water delivery systems	Outlines the scope of the regulations based on the risk of these systems containing Legionella. This makes it easier for regulated parties to comply with regulations and reduces risks to the community through better compliance.	At least 2,478 water delivery systems covered by regulations.
Person responsible for the water delivery system	This regulation creates a liability for a responsible person to manage the risk of Legionella. This is likely to increase compliance with regulations and reduces risks to community.	Minor. This does not create any regulatory burden apart from those not complying with the regulations.
Reasonable steps to manage the risks of Legionella	Obligation for the person responsible to take 'reasonable steps' to manage the risks of Legionella in any water delivery system located in a specified premises.	Nil. These actions depend on the type and setting of the water delivery system, and consequently minimal actions are specified in the regulations. For some operators, these costs would be quantifiable due to outsourcing of maintenance to a third party; however, these operations are likely to address Legionella risk as a part of broader maintenance, disinfection and record-keeping requirements.
Legionella testing (routine testing)	Provides an obligation to test if directed by the department. Frequency of testing specified in guidelines not regulations. The operator makes an assessment of the testing required to manage the risk.	Nil. Frequency of testing specified in guidelines not regulations.

Current regulation (option 1)	Benefit	Cost
Testing requirements	Provides an obligation where a water delivery system is suspected or implicated as the source of legionellosis. A water sample is promptly delivered to a laboratory for testing and reporting on for Legionella.	Unquantifiable. Unable to estimate expected frequency. In practice, there is often no cost for industry because the department undertakes these tests upon notification of a suspected or implicated source of legionellosis in a water delivery system.
Reporting upon detection of Legionella	Awareness of detection of Legionella by the department.	Negligible.
Response upon detection of Legionella	Provides an obligation to respond to the detection of Legionella.	Unquantifiable. No process prescribed by the regulations. These actions depend on the type and setting of the particular water delivery system, and consequently minimal actions are specified in the regulations.
Disinfection of water delivery system	Proactive response to the risk of Legionella.	Unable to estimate the number of detections and subsequent disinfections systems per year. Cost can range from \$1,250 to 3,500 for a small system, up to more than \$10,000 for a major water delivery system in a hospital.

Option 2: Amend current regulations (both options 2a and 2b)

Table 5.3 shows that the proposed amendments to improve regulation efficacy would be expected to have the following impacts on the requirements above:

- reduced scope
- new offences to ensure integrity of water sampling and reporting of test results.

Table 5.3: Impacts of amending current regulations (options 2a and 2b), compared with option 1

Proposed amendments (option 2)	Benefit	Cost
Scope of regulation water delivery systems	More clearly defining the places where the regulations apply to better reflect the risk profile of Legionella. The department estimates that, based on a more refined definition, the number of facilities in scope would decrease by 20 per cent to at least 1,982 systems in scope.	Number of systems covered to fall from the current 2,478 systems.
New offences to ensure integrity of water sampling and reporting of test results	Ensure integrity of testing regime.	Unquantifiable. Unable to estimate expected frequency.

The main difference between options 2a and 2b is the removal of the requirement for mandatory disinfection. Option 2b would be expected to have a reduced impact (decreased cost) on water delivery system operators because disinfection would no longer be mandatory.

Proposed approach

Adopting option 3 (the base case – removing or reducing the regulations for water delivery systems) will potentially:

- negatively impact on the health of the Victorian population by increasing the likelihood of legionellosis in the community due to water delivery systems
- negatively impact the Victorian economy in the event of an outbreak in a facility with a vulnerable population due to the possible closure or reduction in facility operations to prevent further infections
- positively impact on the operations of water delivery system operators in the short term by providing greater flexibility to reduce servicing and maintenance standards.

Options 1 and 2 are expected to positively impact the health outcomes of the Victorian population, relative to having no regulations, by reducing the likelihood of legionellosis in the community due to poorly maintained water delivery systems and the associated impacts of an outbreak of legionellosis.

By reducing ambiguity of the definition of water delivery system, option 2 (both 2a and 2b) are expected to improve health outcomes more significantly than option 1.

Both options 1 and 2 would positively impact by reducing the economic impacts of an outbreak of legionellosis and assist in reducing the stigmatisation of exposure sites in the event of an outbreak.

Option 2 (both 2a and 2b) would be expected to improve health outcomes; however, there is a limited evidence base for the number of infections from water delivery systems in both options 1 and 2. Both options impact the operations of water delivery system operators, who may opt for less rigorous servicing and maintenance programs in the absence of regulations. Option 2 (both 2a and 2b) is expected to increase costs for water delivery system operators relative to option 1 by confirming the obligations relate to specific facilities with the associated burden. However, it will also reduce impacts on other low-risk premises that were inadvertently covered by the current definition. Option 2b would have less of an impact on operators than 2a through removing the mandatory requirement to disinfect.

These qualitative criteria have been scored in absolute terms below, with a score between –10 and +10.

Given the focus on the public benefits of the regulations and the Act, the health impacts have weighted equally important (0.2) alongside the potential economic impacts of an outbreak (0.3) (Table 5.4). The impacts on water delivery system operators is included as the key sector with regulatory burden (0.5). Multiplying the scores (–10 to +10) by the weightings gives a total possible score between –10 and +10 for each option.

Table 5.4: Analysis of options regarding the regulation of water delivery systems

Option	Health impacts Score/weight	Potential economic impacts Score/weight	Impact on water delivery system operators Score/weight	Total (range: –10 to +10)
1. Retain the current regulations without changes	+4 / 0.4	+5.5 / 0.1	–2 / 0.5	1.15 (1.6 + 0.55 + -1)

Option	Health impacts Score/weight	Potential economic impacts Score/weight	Impact on water delivery system operators Score/weight	Total (range: -10 to +10)
2a. Amend some aspects of the current regulations	+5.5 / 0.4	+5.5 / 0.1	-1.5 / 0.5	2 (2.2 + 0.55 + -0.75)
2b. Amend some aspects of the current regulations and remove the mandatory disinfection requirement	+5 / 0.4	+5 / 0.1	-1 / 0.5	2 (2 + 0.5 + -0.5)
3. Base case – remove or reduce regulations	0 / 0.4	0 / 0.1	0 / 0.5	0

Based on the above impact analysis the preferred option is option 2a: Amend some aspects of the current regulations.

The department considers option 2a – to amend the current regulatory system, with improvements to increase the clarity of scope and requirements – is the best option to address the public health risk and in recognition of the precautionary principle to maintaining public health in the Act. This approach would also maintain a reasonable level of confidence in the management the risks in these facilities.

Removing the mandatory disinfection requirement would reduce the impact on water delivery system operators in certain circumstances and provide flexibility for operators to manage the risks based on their individual circumstances; however, this is expected to have a potential subsequent impact on health outcomes across Victoria. Disinfection of the water delivery system is still expected to be the most effective approach to reduce public health risks (and subsequent health and economic impacts) for most operators of water delivery systems.

The public health risks of Legionella are high in the event of an outbreak, as observed overseas; however, the number of observed cases from water delivery systems in Victoria is believed to be low compared with other sources (such as cooling tower systems).

Stakeholder consultation was undertaken on these changes. Industry was broadly supportive of the current regime with amendments similar to those proposed in option 2a.

Accessing the full regulatory impact statement

Information on infringements, consultation, implementation, evaluation and the exposure draft regulations are contained in the full regulatory impact statement available on the [Engage Victoria website](https://engage.vic.gov.au) <https://engage.vic.gov.au>.

This extract was prepared to assist stakeholders who access the report by accessing a specific category on the Engage website. This is not intended to limit the scope of submissions; the department welcomes submissions from all interested parties.

Making a submission to the review

Public comment is invited on the proposed regulations and RIS. Please note that all comments and submissions received will be treated as public documents.

Comments and submissions should be received by the Department of Health and Human Services no later than **5.00 pm, Monday 30 September 2019**.

The Engage Victoria website is the preferred method for receiving submissions. Submissions can also be received by [emailing the department](mailto:phwa.enquiries@dhhs.vic.gov.au) <phwa.enquiries@dhhs.vic.gov.au>, or post, marked 'Submission to the Review of the Public Health and Wellbeing Regulations 2009' and addressed to:

Chief Health Officer
Regulation, Health Protection & Emergency Management
Department of Health and Human Services
GPO Box 4057
Melbourne VIC 3001

Copies of the RIS and proposed regulations can also be obtained from the [Engage Victoria website](https://engage.vic.gov.au) <https://engage.vic.gov.au/>.