Public Health and Wellbeing Regulations Sunset Review regulatory impact statement

Chapter 7: Notifications of infectious diseases, micro-organisms and medical conditions

VICTORIA State Government | Health and Human Services

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Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

ISBN/ISSN 978-1-925947-82-3

Available from the Engage Victoria website <https://engage.vic.gov.au/>.

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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>.

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> 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 <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>.

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

The Engage Victoria website <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 7: Notifications of infectious diseases, micro-organisms and medical conditions

Problem analysis

Victoria regulates to require medical practitioners and pathology services to notify the Department of Health and Human Services if they suspect or detect certain diseases or conditions. This enables monitoring and response to prevent further illness. As diseases, testing methods and technologies change, how does regulation need to change?

The requirement to notify a central health authority when particular diseases or micro-organisms are detected is a common feature of public health surveillance systems around the world. Mandatory reporting of certain diseases was established with the first Victorian Public Health Act in 1854. The 'listed' or notifiable conditions in Victoria have changed over time with improvements in sanitation, as well as the introduction of new vaccines or other measures that have effectively controlled, or even eradicated, some diseases.

Notification of diseases and conditions prescribed in the regulations:

- provides a crucial early warning of a potential threat to public health
- enables the department to respond to prevent or control the spread of disease and prevent further illness
- allows emerging trends to be identified and appropriate policy responses and public health interventions to be implemented.

In the decade since the 2009 Public Health and Wellbeing Regulations came into effect, a range of developments and challenges have arisen in relation to the surveillance and management of notifiable conditions and micro-organisms. These include policy challenges posed by:

- changing disease patterns
- a significant increase in reporting of notifiable conditions and subsequent resourcing issues (for more information see the appendix: *Increasing notification of prescribed notifiable conditions*)
- new-generation treatments and associated health outcomes
- the rising threat of antimicrobial resistance
- technological advances in diagnostic methods
- changes to current practice that are not reflected in the regulations.

For a history of regulation requiring notification of diseases and conditions, see the appendix: *History of regulation*.

Objectives of the regulations

The objectives of the regulations are to enable the Department of Health and Human Services to:

- respond rapidly to serious or severe cases of disease to protect others
- detect environmental hazards and disease outbreaks in a timely manner and prevent further cases

- monitor disease epidemiology, including monitoring the burden of disease for priority conditions in certain 'at-risk' populations such as Aboriginal and Torres Strait Islander people
- inform public health interventions and policy such as immunisation, legislation or education programs.

These objectives contribute to reducing the spread of notifiable communicable diseases through timely notification of high-quality data that enables an appropriate and robust public health response.

Without these regulations, the department's disease surveillance system would not function.

Requirement of the regulations

The regulations relate to:

- Division 3, Part 8 of the *Public Health and Wellbeing Act 2008*, which establishes the framework for Victoria's notifiable conditions scheme
- s. 238 of the Public Health and Wellbeing Act, which allows certain matters in respect of the management and control of infectious disease, micro-organisms and medical conditions to be prescribed.

The regulations currently prescribe 62 conditions that must be notified by medical practitioners and 71 that must be notified by laboratories. The regulations provide legal authority for medical practitioners and laboratories to provide information to the Department of Health and Human Services that might otherwise be considered confidential. All, except anaphylaxis and elevated blood lead levels, are infectious diseases or complications of infectious diseases.

The specific conditions prescribed in the regulations are informed by Victorian health priorities, the National Notifiable Diseases List and the national *Biosecurity Act 2015*.

Twenty-four of the prescribed notifiable conditions are classified as 'urgent' and must be notified to the department by telephone immediately on initial diagnosis, whether presumptive (suspected) or confirmed. Diseases requiring immediate notification are those that pose the greatest threat to public health, allowing for immediate actions to be taken.

The remainder of the conditions, classified as 'routine', must be notified in writing within five days of initial diagnosis.

Schedules 4 and 6 of the current regulations list the prescribed notifiable conditions and the requirements for notification (how and when to notify and what information needs to be included in the notification).

Notification regulations apply to medical practitioners (of which the majority are general practitioners – approximately 8,500 in Victoria) and pathology laboratories (of which there are around 170). The impact of the current regulations is outlined in the appendix: *Impact of the current regulations on industry*.

The conditions have been prescribed both because of their potential to affect public health in Victoria and because the Victorian Government is bound to uphold the regulation of disease notification by federal and international laws and agreements.

Options

The options explored are:

- Option 1: Retain the current regulations without changes
- Option 2: Amend some aspects of the current regulations
- Option 3: Remove or reduce the current regulations.

Option 1: Retain the current regulations without changes

Retain the requirements for notifying micro-organisms in food

The notification of micro-organisms in food often results in a recall of contaminated food products as an essential measure to protect public health. To make decisions about risks and responses in the quickest possible timeframe, the department needs all the information regarding the case, the contaminant and the risks as soon as is practicable.

The current regulations do not require written notice of a notifiable micro-organism within the desired timeframe (micro-organisms in food)

The Public Health and Wellbeing Regulations currently require that a notification of a prescribed micro-organism detected in food supplies is made to the department immediately by telephone, followed by a written notice within five days. This time period reflects the time taken by the postal system to deliver written notice.

The written notification can provide important information for determining the appropriate public health response. To make decisions about risks and responses in the quickest possible timeframe, the department needs all the information regarding the risks as soon as is practicable. In practice, most laboratories provide the written notification immediately after or coinciding with the telephone notification. The majority of these notifications are provided electronically.

Retaining the regulation that requires written notification within five days does not reflect the need and current practice of most laboratories of providing immediate written notification to enable the quickest response from the department.

The current regulations do not require the written notice of a notifiable micro-organism (micro-organisms in food) to include all the details required to determine a response

The Public Health and Wellbeing Regulations currently require that the written notice of a notifiable micro-organism detected in food or water must specify the:

- micro-organism isolated or detected
- date of isolation or detection
- source – food or water
- type – batch identification (if appropriate)
- name and contact number of notifying laboratory.

In practice, these requirements do not ensure enough information is always provided with the notification to ensure that the department can assess the scale of the risk and respond rapidly. Nor do the requirements reflect current practice by the notifying laboratories, which is to provide additional required details such as:

- details of the food sample, including type of food, product and brand name (if known)
- name and contact details (including phone number) of the person or company that submitted the sample.

Continuing with the current system would mean notifying laboratories would continue to provide the additional information needed by the department for public health risk assessment and response, either voluntarily through the written notification process or via follow-up contact initiated by departmental officers. This is not transparent or efficient, it may lead to delays in time-sensitive cases and does not reflect current practice.

The current regulations do not ensure enough information is always provided with the notification to ensure the department can respond rapidly – for example, in undertaking a full risk assessment. Nor do the requirements reflect current practice by the notifying laboratories. Further, the current regulations do

not compel primary laboratories to forward clinical specimens or isolates at the request of the Secretary to the department to obtain the crucial isolate typing information needed to definitively attribute the source of the pathogen and therefore determine the most appropriate public health response.

Maintain the current compliance tools for notifiable conditions

Compliance tools within the current regulatory framework for notifiable conditions and micro-organisms allow for a departmental response at the highest and lowest levels of intervention:

- **Guidance and support:** the department's primary response is education, used to encourage compliance.
- **Prosecution:** potential to use the existing failure-to-notify penalties that may be applied to medical practitioners (s. 127) and pathology services (s. 128) in relation to notifiable conditions, and for laboratory services in relation to food (s. 130). This reflects the importance of notifications to controlling infectious diseases, and the Act specifies maximum penalties of 60 penalty units (equivalent to $9,671.40 in 2018–19).

Education programs have been used to improve medical practitioner compliance with the notification requirements, with limited success.

An analysis of 2017–18 notification data revealed that 47.9 per cent of laboratory notifications had a corresponding notification from a medical practitioner. This contrasts with high compliance with notification requirements by pathology services, potentially attributable to pathology services' consistent use of highly automated systems for providing notifications.

Maintaining the current regulations without change carries the risk that many will continue to fail to notify.

Experience demonstrates that the current regulatory option (prosecution) does not serve as a sufficient deterrent. While many contextual issues underpin noncompliance with legislative penalties for administrative processes (such as notification requirements), general perceptions that prosecutions 'never happen' often nullify deterrent effects. In the absence of an intermediate-level intervention, such as official warnings or infringement notices, these perceptions may not change.

Maintain the current list of prescribed notifiable conditions and microorganisms without change

The conditions that must be notified to the department by medical practitioners and laboratories have been prescribed both because of their potential to affect public health in Victoria and because the Victorian Government is bound to uphold the regulation of disease notification by federal and international laws and agreements.

The specific conditions prescribed in the regulations are informed by Victorian health priorities, the National Notifiable Diseases List and the national *Biosecurity Act 2015*. As diseases, testing methods and technologies change, the prescribed notifiable conditions need to change. Maintaining the current list of prescribed notifiable conditions and microorganisms without change presents challenges in addressing antimicrobial resistant organisms, clarity regarding the nomenclature for Shiga toxin and verotoxin-producing *Escherichia coli* and does not reflect significant advances in the diagnostic testing for Hepatitis B and C.

The current regulations do not prescribe specific antimicrobial-resistant (AMR) organisms or test results to be notified by pathology services

AMR is the process whereby micro-organisms become resistant to antimicrobial medicines such as antibiotics. AMR is increasing dramatically worldwide due to our reliance on and, in many cases, misuse of antibiotics.

Studies have confirmed that an increasing number of infections in healthcare facilities and the community are caused by resistant pathogens. Figures from 2014 suggest that about 700,000 people die each year, worldwide, from antimicrobial-resistant varieties of common bacterial infections – though this is probably an underestimate due to poor reporting and surveillance.

The current Victorian notification scheme does not include notifications for AMR. While pathology services may test for AMR and susceptibility to provide doctors with clinical information about patient treatment options, under the current regulatory requirements these results do not need to be reported to the department for broader public health responses.

Retaining the list of prescribed conditions without change will not provide the information needed to determine an appropriate public health response.

The key shortfall of this current regulations is that they are designed for surveillance and not response, and while the department is able to access the data, this is not reported in a timeframe or manner that allows for an immediate and rapid response to an instance of critical AMR.

The current regulations do not prescribe Shiga toxin-producing *Escherichia coli* as a notifiable micro-organism in food or drinking water

Shiga toxin and verotoxin-producing *Escherichia coli* (STEC/VTEC) are not prescribed as notifiable micro-organism. STEC/VTEC are generally accepted as alternative names for the same strain of *Escherichia coli* and are often used interchangeably.

Retaining the list of prescribed conditions without change will perpetuate the lack of transparency and reliance on assumed knowledge around this condition.

Without specifying both names the reporting requirements are not transparent, and this assumes a common understanding across all involved in the notifications scheme about the interchangeable nature of the terminology.

The current regulations do not require reporting of results of any nucleic acid tests performed at the time of a hepatitis B virus (HBV) and hepatitis C virus (HCV) diagnosis and subsequent notification.

The increasing use of nucleic acid testing (NAT) test results for HBV and HCV allows for the measurement of the activity of the virus in a patient and can indicate the stage of an infection, in particular whether the diagnosis is an acute infection. However, there is no requirements to notify the department when a NAT test is done in combination with a primary diagnostic test, such as serology for HBV or HCV.

Maintain the current specifications for case information required to be notified to the department

The Public Health and Wellbeing Regulations specify what details must be supplied as part of a condition notification to the department, including information specific to the individual, not just the condition. Retaining the current requirements without change would negate the opportunity to improve information that could better inform public health action.

The current regulations do not include 'Aboriginal or Torres Strait Islander status' as a notification detail that must be provided by pathology services

The 18 priority conditions identified by the Communicable Diseases Network Australia for Indigenous status are currently notified in Victoria by both medical practitioners and laboratories. The current regulations require that written notifications from medical practitioners include the Aboriginal or Torres Strait Islander status of the case.

However, medical practitioner noncompliance with the notification requirements is widespread. An analysis of 2013 notification data identified that only 51 per cent of laboratory notifications had an accompanying medical practitioner notification. The completeness of medical practitioner notifications is also an area of concern for the department. These challenges contributed to the Australian Institute of Health and Welfare's recommendations that Aboriginal and Torres Strait Islander status be included on pathology forms.

The department is currently investigating opportunities to link existing health datasets, and this may provide some intelligence on the prevalence of priority conditions among Aboriginal and Torres Strait Islander people. This approach also has significant limitations because it will produce only a partial picture due to incomplete datasets.

The current regulations do not require reporting of individual health identifier number and/or Medicare number as a component of the notification process

This information is currently obtained on an as-needs basis by the department making follow-up contact with the relevant medical practitioner or laboratory.

Without the regulated – and therefore consistent – collection of this data, the possibility of inappropriate direction of resources to 'new' disease events or a misrepresentation of disease burden in the community exists. Gathering additional information that impacts on the public health response, such as immunisation status, would remain a manual process that relies on personal interviews undertaken by departmental staff.

Option 2: Amend some aspects of the current regulations

Proposed changes, based on consultation findings, aim to improve the accuracy or timeliness of data that notifications provide or to clarify ambiguities in the regulations, enabling an improved public health response. Some changes involve formalising and standardising current practices.

Table 7.1 lists the proposed regulatory amendments and classifies them according to their regulatory objective.

Table 7.1: Proposed regulatory amendments classified by regulatory objective

Respond rapidly to serious or severe cases of disease to protect others

Proposed amendment	The purpose of the proposed amendment is...
1. Change the timing of the written notice for a notifiable micro-organism from five days to one day (micro-organisms in food)	... to support a rapid response to food-and waterborne illness, reflecting the current informal practice of notification within one day and the common use of electronic means of written notification, such as web notification, rather than post for written notification.

Detect disease outbreaks in a timely manner and prevent further cases

Proposed amendment	The purpose of the proposed amendment is...
2. Expand the information required in the written notice of a notifiable micro-organism to provide additional details about the food sample and the submitter (micro-organisms in food)	... to reflect current practice and formalise the requirement for the contextual information needed to determine the scale of the public health risk and what action is required to prevent further cases.

Monitor disease epidemiology

Proposed amendment	The purpose of the proposed amendment is...
3. Introduce infringements for failure to notify	… to enable the department to address noncompliance by medical practitioners and pathology labs in a proportionate, adaptable and expedient way, resulting in improved notification practices and more complete data on disease epidemiology.
4. Prescribe specific antimicrobial-resistant organisms or test results to be notified by pathology services	... to provide data that will contribute significantly to a Victorian, national and global response to the significant threat that antimicrobial resistance poses to public health.
5. Prescribe Shiga toxin-producing *Escherichia coli* as a notifiable micro-organism in food or drinking water	... to remove ambiguity in the regulations regarding which conditions need to be notified, potentially caused by the interchangeable use of two terms for the same condition.
6. Require reporting of results of any nucleic acid tests performed at the time of a hepatitis B virus (HBV) and hepatitis C virus (HCV) diagnosis and subsequent notification.	… to allow the department to collect information to inform better management of the disease as well as interventions designed to support HBV and HCV strategies.

Inform public health interventions and policy

Proposed amendment	The purpose of the proposed amendment is...
7. Include 'Aboriginal or Torres Strait Islander status' as a notification detail that must be provided by pathology services	… to reflect the national recognised need for accurate identification of Aboriginal and Torres Strait Islander people to understand trends and disparities in health status and inform the design of health interventions and policy.
8. Require reporting of individual health identifier number and/or Medicare number as a component of the notification process.	… to ensure the right health information is associated with the right individual, assisting with surveillance and control activities.

1. Change the timing of the written notice for a notifiable micro-organism from five days to one day (micro-organisms in food)

Proposed change to the regulations

The Public Health and Wellbeing Regulations currently require that a notification of a prescribed micro-organism detected in food or drinking water supplies is made to the department immediately by telephone, followed by a written notice within five days.

It is proposed that the regulations be amended to reflect current practice and require that a written notice is provided within one day of obtaining test results.

The requirement for immediate telephone notification will remain.

Rationale

The notification of micro-organisms often results in a recall of contaminated food products as an essential measure to protect public health. To make decisions about risks and responses in the quickest possible timeframe, the department needs all the information regarding the risks as soon as is practicable.

Notifying laboratories should have all the details needed for the written notice at the point at which they notify the department by telephone, and so forwarding through written confirmation in a very short

timeframe is practicable and reasonable, particularly since most laboratories now have databases set up to automatically notify the department by fax.

Formalising current practice in regulation transparently articulates the department's expectations and needs for all regulated entities and is not expected to significantly increase the burden on laboratories.

The Public Health and Wellbeing Regulations currently require that a notification of a prescribed micro-organism detected in food or drinking water supplies is made to the department immediately by telephone, followed by a written notice within five days.

The five-day timeframe was based on the time required for a written notice to be received through the postal system.

Current practice involves written notices being routinely provided by email, and so it is reasonable to expect the timeframe could be substantially reduced. Reducing the timeframe to one day would ensure there is a swift response to assessing and managing any potential public health risks posed by the food or drinking water in question, including the rapid recall of contaminated food or water from the market if required.

There is an informal expectation that this 24-hour timeframe is currently met – this position has been previously communicated to notifying laboratories in writing. Laboratories typically comply with the reduced timeframe and have not demonstrated or articulated any obstacles to meeting the requirement.

The requirement for immediate telephone notification should remain, as this ensures that early attention is drawn to detections of notifiable micro-organisms in food and water, and that immediate actions can be taken for high public health risk cases.

2. Expand the information required in the written notice of a notifiable micro-organism to provide additional details about the food sample and the submitter (micro-organisms in food)

Proposed change to the regulations

It is proposed that the regulations be updated to reflect the current practice that enables the department to respond to potential risks with minimum delay. This would require that a written notice includes:

- details of the food sample, including type of food, product and brand name (if known)
- name and contact details (including phone number) of the person or company that submitted the sample.

Including these additional details in the written notice would not represent a significant, if any, additional burden on notifying laboratories. This information would be close at hand, and the requirement reflects the information that is already typically provided by notifying laboratories either directly or through follow-up by the department.

Rationale

The Public Health and Wellbeing Regulations currently require that the written notice of a notifiable micro-organism detected in food or water must specify the:

- micro-organism isolated or detected
- date of isolation or detection
- source – food or water
- type – batch identification (if appropriate)
- name and contact number of notifying laboratory.

In practice, these requirements do not ensure enough information is always provided with the notification to ensure that the department can assess the scale of the risk and respond rapidly. Nor do the

requirements reflect current practice by the notifying laboratories, which is to provide the additional required details.

Food sample details

Limiting the source to 'food or water' does not enable the department to determine if there is a significant public health risk. For example, the detection of *Salmonella* in raw chicken is common and does not pose a particular public health risk, given that chicken is typically well-cooked before consumption. However, detection of *Salmonella* in a ready-to-eat chicken product would warrant further investigation and present a potential risk to health.

Current practice by laboratories is to describe, in detail, the type of food associated with the notification – for example, a description such as 'egg and lettuce sandwich' followed by the brand of the product if known. This provides the department with the contextual information required to assess the risk posed by the notifiable micro-organism.

Details of the food sample submitter

A laboratory notification is not currently required to provide the contact details of the person or company that submitted the sample to the laboratory (for example, the manufacturer of the product). Current practice by laboratories is that written notices are routinely provided with submitter details to allow the supplier of the food or water to be identified. This practice helps the department to obtain further information about the sample from the submitter for the purpose of investigations and risk assessment.

3. Introduce infringements for failure to notify

Proposed change to the regulations

It is proposed to introduce a failure to notify infringement notice within the regulations for pathology services and medical practitioners who fail to notify under r. 71. This measure is intended as a more moderate mechanism to address poor notification compliance by medical practitioners. The penalties that apply to infringement notices are lower than those that would apply if the same offence were prosecuted. This provides the incentive for the person against whom the notice was served to expiate the offence by paying the infringement, which finalises the offence without the matter going to court or a conviction being recorded. This makes an infringement notice an appropriate tool to deal with the kind of noncompliance that may not lend itself well to prosecution, owing to the time, cost and resources involved, or because it is not serious enough to warrant prosecution.

It is proposed that the infringements should be set at 4 penalty units, equivalent to $661 in 2019–20.

An infringements scheme would be applicable to both medical practitioners and pathology services. However, based on current compliance, it is envisaged that infringements among pathology services would be extremely unusual.

Rationale

An analysis of 2017–18 notification data revealed that 47.9 per cent of laboratory notifications had a corresponding notification from a medical practitioner. The department reviewed the list of conditions medical practitioners were required to notify and the reduced the number of conditions required to be reported.[1]

This contrasts with high compliance with notification requirements by pathology services, potentially attributable to pathology services' consistent use of highly automated systems for providing notifications.

[1] Further details of this reduction in regulatory burden is outlined in option 3: Remove or reduce the current regulations.

Compliance tools within the current regulatory framework for notifiable conditions and micro-organisms only allow for a departmental response at the highest and lowest levels of intervention:

- **Guidance and support:** the department's primary response is education, used to encourage compliance.
- **Prosecution:** potential to use the existing failure-to-notify penalties that may be applied to medical practitioners (s. 127) and pathology services (s. 128) in relation to notifiable conditions, and for laboratory services in relation to food (s. 130). This reflects the importance of notifications to controlling infectious diseases, and the Act specifies maximum penalties of 60 penalty units (equivalent to $9,671.40 in 2018–19).

At present, the regulatory framework does not provide for an intermediate response and the department is unable to respond to noncompliance in a graduated and proportionate way. For example, in a case where a medical practitioner *repeatedly* fails to notify, providing further guidance and support is an insufficient response; however, prosecution may also be a disproportionate response depending on the circumstances.

The need to modernise enforcement options under the Act by introducing an intermediate-level response to address noncompliance by a medical practitioner in a more proportionate, adaptable and expedient way has become increasingly evident.

Section 209 of the Act provides for infringements for prescribed offences within the regulations, enabling this approach.

4. Prescribe specific antimicrobial-resistant organisms or test results to be notified by pathology services

Proposed change to the regulations

It is proposed that the Public Health and Wellbeing Regulations are amended to:

- prescribe additional notifiable conditions for immediate notification: *Candida auris* and Carbapenemase-producing *Enterobacterales* (CPE) infection
- prescribe additional notifiable conditions for notification within five days: Carbapenemase-producing *Pseudomonas,* Carbapenemase-producing *Acinetobacter,* VanA-type Vancomycin-resistant *Enterococcus* (VRE)
- prescribe that the results of any antimicrobial resistance (AMR) testing, where undertaken, including minimum inhibitory concentration (MIC) values, are notified to the department for existing notifiable conditions.

Introducing this reporting at a Victorian level would mean that some laboratories (primarily the Microbiological Diagnostic Unit) would be required to report into two systems. Ultimately laboratory reporting to the department will be streamlined, and of very low burden, through completing the electronic laboratory reporting project (currently being implemented).

Many clinical laboratories currently voluntarily report AMR test results to the department (where relevant) with notifications for prescribed conditions. This proposal would safeguard that practice in regulation but also expand the number of conditions that need to be notified.

Rationale

AMR is the process whereby micro-organisms become resistant to antimicrobial medicines such as antibiotics. AMR is increasing dramatically worldwide due to our reliance on and, in many cases, misuse of antibiotics.

Studies have confirmed that an increasing number of infections in healthcare facilities and the community are caused by resistant pathogens. Figures from 2014 suggest that about 700,000 people die each year,

worldwide, from antimicrobial-resistant varieties of common bacterial infections – though this is probably an underestimate due to poor reporting and surveillance.

Improving surveillance of AMR in infectious diseases has been recognised as a global priority. Collecting data on AMR through the Victorian notifiable conditions framework would contribute significantly to a Victorian, national and global response to the threat of AMR.

The Australian Government departments of Health and Agriculture jointly released the first national AMR strategy, *Responding to the threat of antimicrobial resistance*, in June 2015. Among measures to improve awareness and response to AMR, improve antimicrobial stewardship and promote research and investment in the development of new intervention, the strategy seeks to improve surveillance of AMR and use.

The current Victorian notification scheme does not include notifications for AMR. While pathology services may test for AMR and susceptibility to provide doctors with clinical information about patient treatment options, under the current regulatory requirements these results do not need to be reported to the department for broader public health responses.

Some conditions are of particular concern in Victoria; however, it should be noted that more pathogens may emerge as public health issues over time:

- CPE
- Carbapenemase-producing *Pseudomonas*
- Carbapenemase-producing *Acinetobacter*
- VRE infection
- *Candida auris*.

Identifying and controlling cases of CPE is a priority for Victoria. Its relatively emergent state means it may be possible to control this threat with timely and coordinated responses. The Victorian CPE guidelines were developed with this in mind. Including CPE as a notifiable condition would formalise reporting expectations and strengthen these arrangements.

VRE has relatively high prevalence in Victorian healthcare settings, and as such there is limited value in responding to individual cases.

5. Prescribe Shiga toxin-producing *Escherichia coli* as a notifiable micro-organism in food or drinking water

Proposed change to the regulations

It is proposed that the regulations list Shiga toxin and verotoxin-producing *Escherichia coli* (STEC/VTEC) as notifiable micro-organism. STEC and VTEC are generally accepted as alternative names for the same strain of *Escherichia coli* and are often used interchangeably.

Rationale

Listing both names would ensure transparency in the reporting requirements and remove the possibility of misinterpretation. Given it is likely that laboratories are already reporting STEC under the requirement to report VTEC, this reporting requirement is not expected to increase the burden on laboratories.

6. Require reporting of results of nucleic acid testing when hepatitis B virus and hepatitis C virus is notified

Proposed change to the regulations

Section 238 of the Public Health and Wellbeing Act establishes broad powers to make regulations about collecting information in relation to notifiable conditions that could be used to make a regulation requiring that NAT test results for HBV and HCV be notified in certain circumstances.

It is proposed that the regulations are amended to require pathology services to report positive results of any tests (including NAT) performed at the time of a HBV and HCV diagnosis and subsequent notification to the department.

Rationale

NAT measures the activity of the virus in a patient and can indicate the stage of an infection, in particular whether he diagnosis is an acute infection. However, there is no requirements to notify the department when a NAT test is done in combination with a primary diagnostic test, such as serology for HBV or HCV.

Mandatory reporting of any NAT test results performed upon HBV and HCV diagnosis would allow the department to collect information to inform better management of the disease as well as interventions designed to support HBV and HCV strategies.

7. Include 'Aboriginal or Torres Strait Islander status' as a notification detail that must be provided by pathology services

Proposed change to the regulations

Notification details (the case information that must be provided with a notification) are currently prescribed in the regulations. It is proposed that Aboriginal or Torres Strait Islander status be added to this list for pathology services. This may require pathology services to modify their pathology request forms to collect that information from medical practitioners. Pathology services would only be expected to provide this additional information when it was provided to them by the medical practitioner.

Medical practitioners are currently required to report this information to the department with disease notifications. They would therefore typically be expected to have the information to hand when completing pathology request forms.

Rationale

The Department of Health and Human Services' priorities include implementing strategies across the entire department's business to improve the health of Aboriginal and Torres Strait Islander people. An important aspect is the aim to improve data and evidence.

Accurate identification of Aboriginal and Torres Strait Islander people is vital for understanding trends and disparities in health status and important for planning and improving health services to meet the needs of these groups.

The National Notifiable Disease Surveillance System (NNDSS) collects and publishes data from state and territory health departments (Australian Government 2015), but Aboriginal and Torres Strait Islander status is often not reported for a large proportion of notifications.

At present, when a pathology provider notifies a state registry, they usually cannot provide the Aboriginal and Torres Strait Islander status of the patient because this information is not requested as standard practice. An important source of data for monitoring health status is therefore not available.

Following extensive consultation, the Australian Institute of Health and Welfare developed a business case recommending a focus on improving Aboriginal and Torres Strait Islander identification in national

health registries. This business case noted that including Aboriginal status on pathology request forms is important in improving key health datasets. Including Aboriginal status identification on pathology forms is also a key priority for the National Advisory Group on Aboriginal and Torres Strait Islander Health Information and Data.

New South Wales and Tasmania already require pathology services to report on Aboriginal and Torres Strait Islander status with disease notifications.

Section 238 of the Public Health and Wellbeing Act establishes broad powers to make regulations regarding the collection of information in relation to notifiable conditions. This could be used to meet the objective of a more comprehensive and reliable data regarding health conditions impacting on Aboriginal and Torres Strait Islander communities.

8. Require reporting of individual health identifier number and/or Medicare number as a component of the notification process

Proposed change to the regulations

Notification details (the case information that must be provided with a notification) are currently prescribed in the regulations. It is proposed that the list of details required be amended to include an individual health identifier number and/or Medicare number. This will ensure the right health information is associated with the right individual, assisting with surveillance and control activities.

Rationale

The benefits of including an individual health identifier number and/or Medicare number are as follows:

- It better enables the department to contact the patient (case), their medical practitioner and, when relevant, other individuals as part of a public health investigation – for example, to limit the spread of infection to other members of the community.
- It ensures that each person's notifiable condition is only captured once in the surveillance system and not each time a notification is made, avoiding the possibility of inappropriate direction of resources to 'new' disease events or a misrepresentation of disease burden in the community.
- It enables additional information about the person being notified to be gathered from other databases or surveillance systems – for example, whether the case attended hospital, has been vaccinated or identifies as being Aboriginal and Torres Strait Islander. This information informs an appropriate public health response.

The use of a person's individual health identifier or Medicare number is supported by the *Victorian health priorities framework*, which sets out a plan to deliver a sustainable and productive health system. It is consistent with federal law regarding sharing this information and aligns with the national framework for communicable disease control, which identified that integrating data captured from other datasets should form part of a modernised public health surveillance system.

Option 3: Remove or reduce the current regulations

In a major effort to reduce the regulatory burden of these regulations on medical practitioners, the current regulations were remade on 1 September 2018. This followed a review of the necessity for medical practitioner notifications for certain conditions that found that regulatory burden for medical practitioners could be reduced without adversely impacting on public health. Following consultation with medical practitioners, pathology services, infectious disease experts and other key stakeholders, the Public Health and Wellbeing Regulations 2009, which set out the requirements for both medical practitioners and pathology services to notify the department of specific conditions, was changed to:

- reduce the number of conditions that must be notified by medical practitioners (10 conditions were removed)

- simplify the groupings of notifiable conditions (from four classes requiring different timing and method of notification, to two groups – 'urgent' and 'routine')
- reduce the requirement to notify in writing (medical practitioners are no longer required to follow up telephone notifications with a written notification).

For full detail see the communique provided to medical practitioners in the appendix: *Changes to notifiable conditions from 1 September 2018*.

Given that a reduction in regulation has recently been implemented and the assessment of its effectiveness is ongoing, further reductions have not been considered at this time. Some of the changes to regulations explored in option 1 will result in reduced prescriptive requirements. Where this is the case, it is noted under option 1.

Impact analysis

Benefits and costs of option 1

Effective public health responses to infectious diseases require an efficient and effective system for health professionals to notify relevant authorities as cases occur. This system is designed to monitor and control the occurrence of infectious diseases and other specified conditions and helps to prevent further illness. The aim is to protect the health and safety of the community and improve public health outcomes in Victoria.

The current regulations are intended to reduce the burden of disease in Victoria. It is difficult to quantify with any accuracy the amount of disease prevented and the fiscal impact of less disease. Adding to the complexity, the impact of each disease varies.

The existing system imposes notification requirements on both medical practitioners and pathology laboratories. The notification methods that meet the requirements are outlined below:

How to notify conditions in Victoria

How to notify

Note: Urgent conditions must be notified immediately (24/7) by telephone to 1300 651 160. Written notification does not replace the obligation to telephone urgent conditions.

Notify all other conditions using one of the following methods:

- **online** via the department's website <health.vic.gov.au/notify>
- **post** to Department of Health and Human Services, Reply Paid 65937, Melbourne VIC 8060
- **fax** to 1300 651 170.

Standard notification forms are available for all conditions and contain the minimum mandatory information required. Using the standard form, you can notify securely online (this is the department's preference). Alternatively, you can download a form from the link above and return the form by post or fax.

The department's preference is for notifications to be submitted using the secure online forms where possible. This system is considered secure and provides safeguards that all relevant information is provided.

Enhanced notification forms are available for some conditions from the link above. Enhanced notification forms collect the same mandatory information as the standard form, as well as additional epidemiological data about the case and/or potential public health risks.

Source: Department of Health and Human Services website: <https://www2.health.vic.gov.au/public-health/infectious-diseases/notify-condition-now>

The time of staff to notify, as well as technology and systems to enable efficient and effective notification are costs imposed on industry. The majority of notifications are submitted online through forms with fields to complete. On average the department estimates that a notification submitted through the online form would take between three and five minutes to complete; however, the actual time will depend on the type of condition and the level of detail provided by the medical practitioner (with more detail on the case providing greater context). Based on consultations with laboratories, the majority of this industry's condition notifications are submitted via automatic (or partially automatic process) as part of the testing of samples. There has been a trend of rising numbers of notifications, which is described further in the technical appendix.

The department bears costs and responsibility following from the regulated notification requirement, including the administrative costs of recording and collating the notification and excludes the costs of substantive follow-up activity, which is undertaken to address public health concerns and is not a direct requirement of regulation notification requirements.

Benefits for option 2

The proposed changes are expected to reduce the burden of disease in Victoria. It is difficult to quantify with any accuracy the amount of disease prevented and the fiscal impact of less disease. Adding to the complexity, the impact of each disease varies.

Notification regulations apply to medical practitioners (of which the majority are general practitioners – 8,500 in Victoria) and pathology laboratories (of which there are around 170). The department received more than 115,000 case notifications in 2017 (due to the significant 2017 influenza season) and approximately 74,000 in 2018. Estimating financial benefits from avoided disease is problematic in the context of incremental changes proposed in option 2. The proposed changes address risks to public health by improving the public health surveillance system of Victoria to:

- respond rapidly to serious or severe cases of disease to protect others
- detect disease outbreaks in a timely manner and prevent further cases
- monitor disease epidemiology
- inform public health interventions and policy.

Costs for option 2

The costs associated with the proposed changes are expected to be incurred through minor adjustments to existing systems or small additional costs, such as courier costs to forward samples. These potential costs, when considered relative to the wider operations and complexities of pathology laboratory operations, are anticipated to be small.

The benefits and costs are described qualitatively in Table 7.2.

Table 7.2: Cost/benefit analysis of option 2 – changes to improve regulation efficacy

Respond rapidly to serious or severe cases of disease to protect others

Proposed amendment	Benefit	Cost
1. Change the timing of the written notice for a notifiable micro-organism from five days to one day (micro-organisms in food).	Supports a rapid response to food and waterborne illness, reflecting the current informal practice of notification within 24 hours and the common use of electronic means of written notification, such as web notification, rather than post for written notification.	Negligible processing cost for laboratories. All laboratories already email rather than post notifications.

Detect disease outbreaks in a timely manner and prevent further cases

Proposed amendment	Benefit	Cost
2. Expand the information required in the written notice of a notifiable micro-organism to provide additional details about the food sample and the submitter (micro-organisms in food)	Reflects current practice and formalises the requirement for the contextual information needed to determine the scale of the public health risk and what action is required to prevent further cases.	Negligible. This information would be close to hand and the requirement reflects the information that is already typically provided.

Monitor disease epidemiology

Proposed amendment	Benefit	Cost
3. Introduce infringements for failure to notify	Addresses noncompliance by medical practitioners in a more proportionate, adaptable and practical way, resulting in improved notification practices and a more complete disease epidemiology data.	As a new infringement, it is unclear how many infringements would be issued. Initially, the department would absorb costs to administer the infringements as part of costs to manage the notifications surveillance system.
4. Prescribe specific antimicrobial-resistant organisms or test results to be notified by pathology services	Provides data that will contribute significantly to a Victorian, national and global response to the significant threat AMR poses to public health.	Cost to laboratories to implement change to reporting mechanism to the department. Initial consultation with impacted stakeholders indicated that costs could be absorbed as part of broader IT maintenance and upgrades.
5. Prescribe Shiga toxin-producing *Escherichia coli* as a notifiable micro-organism in food or drinking water	Removes ambiguity in the regulations regarding which conditions need to be notified, potentially caused by the interchangeable use of two terms for the same condition.	Nil.
6. Require reporting of results of any nucleic acid tests performed at the time of a hepatitis B virus (HBV) and hepatitis C virus (HCV) diagnosis and subsequent notification	Allows the department to collect information to inform better management of the disease as well as interventions designed to support HBV and HCV strategies.	Cost to laboratories to implement a change to the reporting mechanism. Initial consultation with impacted stakeholders indicated that costs could be absorbed as part of broader IT maintenance and upgrades.

Inform public health interventions and policy

Proposed amendment	Benefit	Cost
7. Include 'Aboriginal or Torres Strait Islander status' as a notification detail that must be provided by pathology services	Reflects the nationally recognised need for accurate identification of Aboriginal and Torres Strait Islander people to understand trends and disparities in health status and	Cost to pathology services to modify their pathology request forms to collect Aboriginal status from medical practitioners. Initial consultation with impacted stakeholders

Proposed amendment	Benefit	Cost
	inform the design of health interventions and policy.	indicated that costs could be absorbed as part of broader IT maintenance and upgrades.
8. Require reporting of individual health identifier number and/or Medicare number as a as a component of the notification process.	Ensures the right health information is associated with the right individual, assisting with surveillance and control activities.	Cost to laboratories to implement change to the reporting mechanism. Initial consultation with impacted stakeholders indicated that costs could be absorbed as part of broader IT maintenance and upgrades.

Proposed approach

Option 2: Amend some aspects of the current regulations

It is proposed that all elements of the current regulatory framework regarding notifiable conditions are adopted in any replacement regulatory scheme. The public health benefits of a notifications scheme such as this have been demonstrated previously, and the department considers that they continue to apply. The notifications scheme maintains consistency with other Australian jurisdictions and enables agreed reporting and response at the national level.

The notifiable conditions and notification requirements prescribed in the current regulations were reviewed in 2018, with amendments to the scheme coming into effect on 1 September 2018. The objective of the 2018 review was to reduce regulatory burden, modernise the scheme and ensure the lists of notifiable conditions reflected contemporary public health risks and priorities. Extensive stakeholder consultation was undertaken on these recent changes, and for that reason it is not proposed to revisit the issues considered and resolved by that recent review in this sunset review.

However, this sunset review provides an opportunity to identify emerging issues and mechanisms to further improve the recently updated regulatory scheme. Several additional options for regulatory improvement have been canvassed in the previous sections.

It is proposed that the current requirements for notifiable micro-organisms are broadly adopted in any replacement regulations, with minor amendments to modernise the scheme, as detailed in option 2.

Technical appendix

History of regulation

The reporting of certain diseases has been required in Victoria since the first Victorian Public Health Act commenced in 1854.

In the decade since the 2009 regulations were drafted, a range of developments and challenges have arisen in relation to the surveillance and management of notifiable conditions and micro-organisms. These include policy challenges posed by changing disease patterns, new-generation treatments and associated health outcomes, the rising threat of AMR and technological advances in diagnostic methods.

The list of notifiable conditions prescribed in the regulations was reviewed and updated in 2018, with the primary objective of taking a more risk-based approach to notifications and reducing the regulatory burden on medical practitioners. The revised list of notifiable conditions and a reduction on the number of diseases requiring notification by both doctors and laboratories (known as 'dual notification') came into effect on 1 September 2018.

Under the revised public health surveillance system, influenza and nine other conditions no longer require medical practitioners to notify cases to the department. More information about the changes is available from the department's website <https://www2.health.vic.gov.au/about/publications/policiesandguidelines/notifiable-conditions-changes-sep-2018>.

Impact of the current regulations on industry

The requirement to notify the department of certain conditions and micro-organisms has an associated burden on medical practitioners and laboratories to provide the related information. Table 7.3 outlines the department's minimum expectations for industry to fulfil this requirement. Where the method of notification is not prescribed, industry has the flexibility to notify in a method that aligns with their business operating practices. For example, some laboratories have automated several processes and information related to notifications.

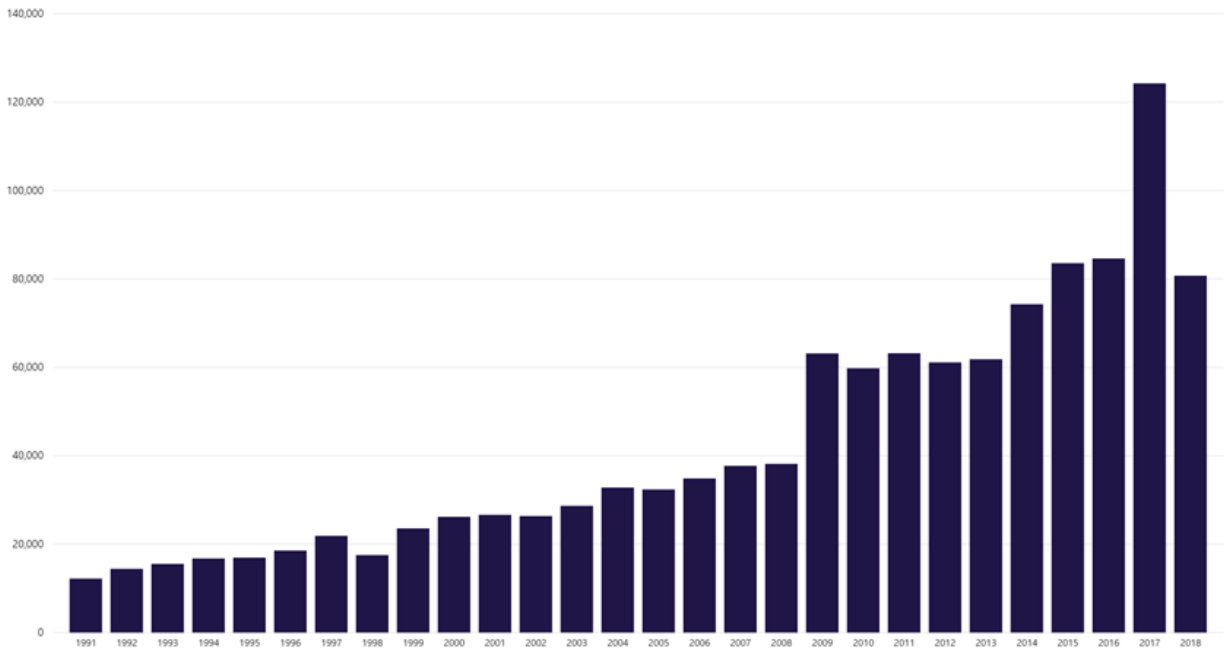
Table 7.3: Minimum notification expectations on industry

Who	Type	Description of impact
Medical practitioner – general	Urgent	Require immediate notification to the department by telephone on 1300 651 160 (24 hours) upon initial diagnosis or clinical suspicion. The process of initial notification takes 5 – 10 minutes.
	Routine	Require written notification within five days of diagnosis by fax, post or on the deaprtment's website <https://www2.health.vic.gov.au/public-health/infectious-diseases/notify-condition-now>. The form takes three to five minutes to complete.
Laboratory	Urgent	The prescribed period is immediate notification by telephone whether presumptive or confirmed, followed by written notification within five days of obtaining the result of the test indicating that the person has or may have any notifiable condition.
	Routine	Complete online form (most information pre-filled)

Increasing notification of prescribed notifiable conditions

The number of cases (patients with a diagnosed notifiable condition) notified to the department is increasing year on year. This is in part due to factors such as population growth, the addition of new notifiable diseases to the regulatory scheme and the increasing sensitivity of testing methods. It is also influenced by disease patterns. For example, in 2015 and 2016 there were 75,000–80,000 notified cases of infectious disease, but in 2017 this jumped to more than 115,000 cases due to the significant 2017 influenza season (Figure 7.1).

Figure 7.1: Notified cases of infectious diseases by year of notification, 1991–2018, Victoria



A single case of a notifiable condition will typically have several notification events associated with it, including a notification from a medical practitioner plus one or more notifications from laboratories (information is progressively provided to the department if/as additional tests results become available).

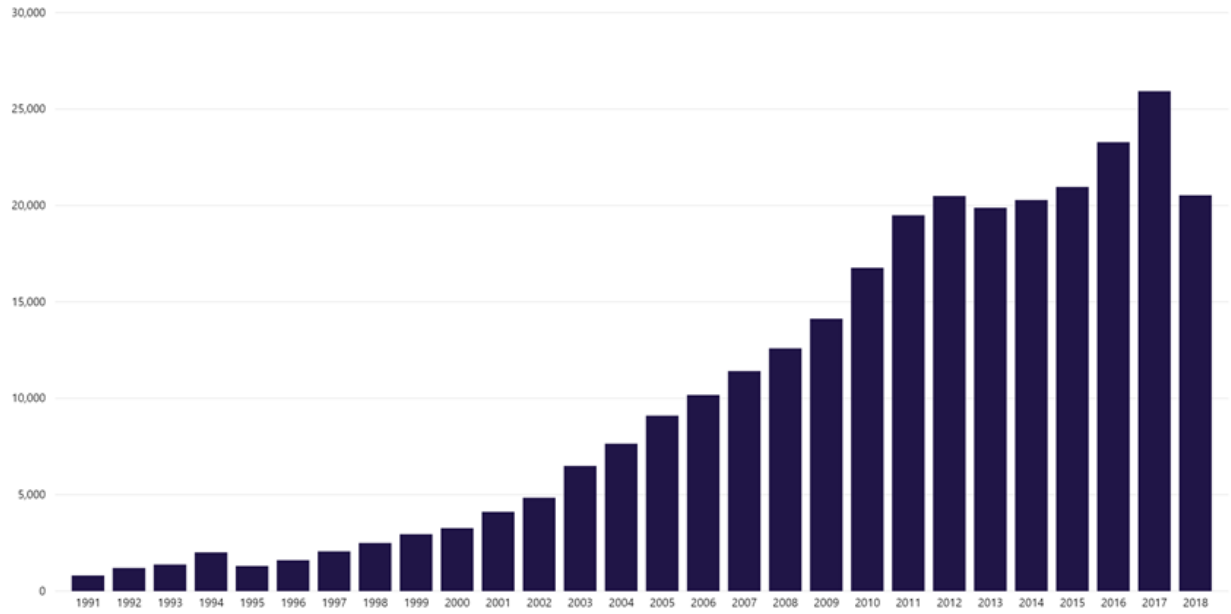
The department's use of notification data varies depending on the specific condition but may involve one or more of the following:

- immediate public health actions to limit the potential spread of a disease – for example, isolating a measles case while infectious or providing antibiotics to close contacts of a case of invasive meningococcal disease
- investigation – for example, interviewing cases affected by an outbreak of foodborne disease to identify and eliminate the cause
- contact tracing to prevent further person-to-person spread of infectious disease – for example, partner notification for certain sexually transmitted infections
- epidemiology and surveillance activities – for example, activities at a population level to identify disease trends and risk factors that can inform population-level prevention policies and programs such as community education, vaccination and research.

Chlamydia notifications, Victoria

Figure 7.2 shows the notified cases of chlamydia in Victoria from 1991 to 2018.

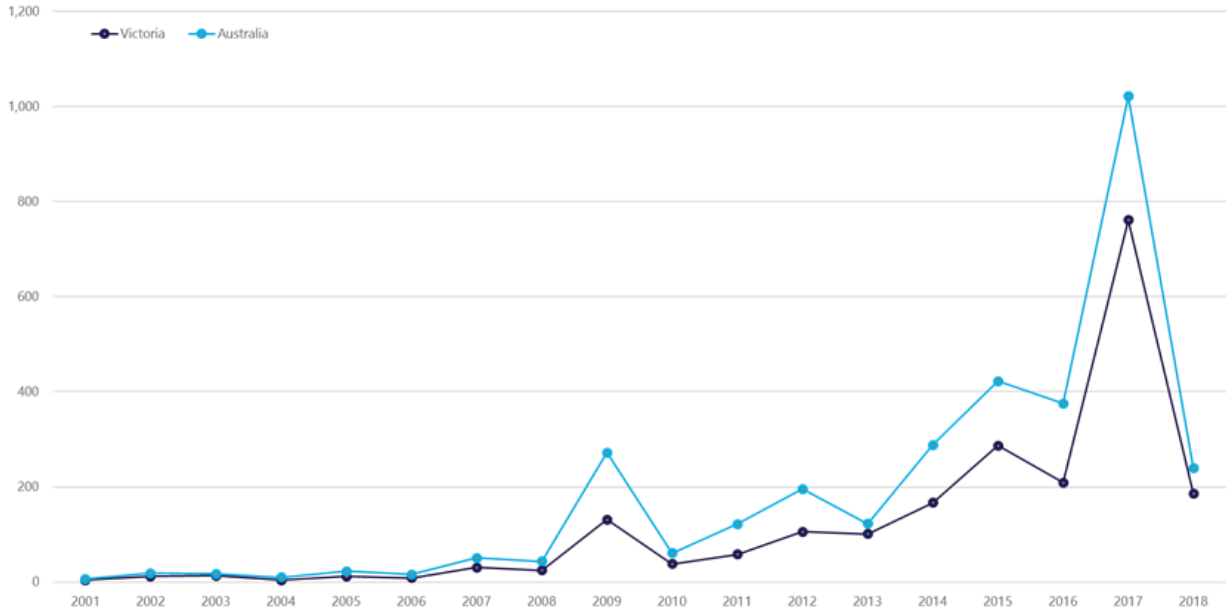
Figure 7.2: Notified cases of chlamydia by year of notification, Victoria, 1991–2018



Notification rates of laboratory-confirmed influenza, Victoria and Australia

Figure 7.3 shows the notification rate per 100,000 population of laboratory-confirmed influenza for Victoria and Australia between 2001 and 2018.

Figure 7.3: Notification rate per 100,000 population of laboratory-confirmed influenza by year of notification, Victoria and Australia, 2001–2018



The Age: 'Victoria's horror flu statistics revealed as stronger vaccine on way'

Victoria's horror flu statistics revealed as stronger vaccine on way

By Aisha Dow

25 January 2018 — 5:31pm

A strengthened flu vaccine could be introduced this year after cases soared by nearly 300 per cent during last year's horror flu season in Victoria.

There were just over 48,000 laboratory-confirmed cases of influenza last year in Victoria, compared to 12,785 the year before.

Source: Dow A 2018, 'Victoria's horror flu statistics revealed as stronger vaccine on way', The Age, 25 January.

Changes to notifiable conditions from 1 September 2018

Visit the department's website for information about changes to notifiable conditions <https://www2.health.vic.gov.au/about/publications/policiesandguidelines/notifiable-conditions-changes-sep-2018> from 1 September 2018.

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>.

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 <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/>.