

# Statement of Reasons

## Public Health and Wellbeing Regulations 2019

### Preamble

The exposure draft Public Health and Wellbeing Regulations and the associated regulatory impact statement were released for formal public consultation between 20 August and 30 September 2019. There were 82 submissions received, as well as 153 survey responses via the Engage platform. Consultation feedback was carefully reviewed and informed the new Public Health and Regulations 2019.

On the whole, the intent and purpose of the exposure draft were positively received, and the recommendations set out in the regulatory impact statement were supported. Many of the comments proposed helpful points of clarification or offered practical suggestions for implementation. The Public Health and Wellbeing Regulations 2019 have been made with several minor amendments to the exposure draft, the purpose of which were to improve the clarity, operation and practicality of the proposed regulations.

The final response takes into consideration a range of stakeholder concerns and viewpoints, often divergent, and seeks to balance the priorities of protecting public health and reducing regulatory burden. The regulations will be complemented by support for implementation, and many of the detailed issues and considerations that were raised in consultation will be encompassed in guidance materials.

**The tables below set out the key issues and responses according to the Parts of the Regulations:**

### Part 4: Vector-borne infectious disease control

#### Possible detrimental effects to the environment using pesticides and scope of the changes

<b>Issue</b>	<p>Concerns relate to:</p> <ul style="list-style-type: none"><li>• the use of pesticides;</li><li>• the strengthening of the regulations; and</li><li>• the Beating Buruli Ulcer project.</li></ul> <p>Primarily, the concerns focus on the detrimental effects of pesticides on the environment and how the strengthened regulations will be implemented. Feedback argues that the strengthening of the existing regulations is not warranted.</p>
<b>Response</b>	<p>The remaking of the Public Health and Wellbeing Regulations is separate from the mosquito research program associated with the Beating Buruli project.</p> <p>In response to concerns, the final regulations replace the terms 'eliminate' and 'eradicate' with 'control' in the directions that relate to mosquito control. Control is consistent with the intent and the title of the Division.</p> <p>These changes provide a more practical and balanced response, having regard to a variety of measures to control mosquitoes and assessing local context and risk.</p>

	<p>The regulations enable a measured response to manage the potential risk posed by mosquitos across their lifecycles and allow action to reduce or control any exotic mosquitoes detected in Victoria that could spread disease such as Dengue or Zika.</p> <p>The <i>Public Health and Wellbeing Act 2008</i> (the Act) sets out principles to inform implementation, such as precaution, primacy of prevention and proportionality. The exercise of any measures must be in keeping with the principles in the Act and would be undertaken in a consultative manner supported by clear communication.</p> <p>It is intended that guidance materials will provide councils with further clarity about the intended application of the proposed regulations, ensuring any actions are reasonable, not arbitrary and consider a range of control practices.</p>
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## Duty to eliminate mosquito breeding grounds and the terms eliminate and eradicate in the directions

<b>Issue</b>	<p>Concerns regarding the duty for owners and occupiers to eliminate mosquito breeding grounds and the terms 'eliminate' and 'eradicate' in directions.</p> <p>The concerns focus on the practicality and application of the draft regulations.</p>
<b>Response</b>	<p>In response to concerns, the final regulations replace the term 'eliminate' with 'control' in the duty that relates to mosquito control. These changes provide a more practical and balanced response.</p> <p>The duty to control breeding grounds and abate conditions on the premises conducive to their establishment is based on 'taking reasonable steps'.</p> <p>Taking reasonable steps would have regard to local context, circumstances and proportionality and is a preventative mechanism. A common-sense approach would guide this approach. Factors such as heavy rainfall may influence reasonable steps in certain environments.</p> <p>To better reflect the context of the duty to control mosquito breeding grounds, the final regulations reduce the maximum court penalty from 20 penalty units to 10 penalty units. This reduction in penalty units reflects that the direction set out in the following regulations are an escalation in response to a failure of that duty. There is no infringement associated with this duty.</p> <p>As described above, to address concerns, the term 'control' will replace 'eliminate' and 'eradicate' in the directions.</p>

## Application of Chief Health Officer disease vector control notice

<b>Issue</b>	<p>Clarification/information about the use and application of a Chief Health Officer disease control vector notice as well as guidance and support for implementation.</p> <p>Concerns raised about the strengthening of the regulations and impact on the environment.</p>
<b>Response</b>	<p>It is intended the Chief Health Officer would use the disease control vector notice in limited circumstances and in incidences where a transmission risk is known to be present from an animal through a vector and transmission of an associated disease is actively occurring in the community.</p> <p>In doing so, the Chief Health Officer would consider a range of evidence and information and collaborate with affected parties. This will help inform the order and any action to reduce the risk to public health.</p> <p>The Department will provide further information to respond to issues raised during consultation. It is intended that information will outline:</p> <ul style="list-style-type: none"> <li>• the circumstances in which the Chief Health Officer will use the disease vector control notice</li> <li>• consultation with affected parties, including councils and community groups</li> <li>• regard for vulnerable persons with respect to the control measure.</li> </ul>

## Part 5 Division 2: Registration of certain business (hairdressing, beauty therapy, colonic irrigation, tattooing and skin penetration)

### Infection control standards

<p><b>Issue</b></p>	<p>Issues and recommendations about hand washing facilities, inclusion of the department's Infection Control Guidelines for hair, beauty and skin penetration industries in the regulations, training for practitioners, notice about the scope of registration, and considerations to inform implementation.</p> <p>It is argued that consideration of issues and recommendations will improve infection control and provide additional clarity around interpretation and enforcement.</p>
<p><b>Response</b></p>	<p>As per the exposure draft, the final regulations require that hand washing facilities be accessible, a departure from the 2009 regulations which require that facilities be easily accessible.</p> <p>The Department notes through the consultation processes that there are varying views and considerations about hand washing facilities and what constitutes accessible. Without consensus, an over-prescription of what constitutes accessible hand washing facilities may have unintended consequences and create an unnecessary regulatory burden for some businesses.</p> <p>The Department recommends a pragmatic interpretation and enforcement approach that focusses on outcomes and the intent of the regulation (effective handwashing by practitioners). Considerations include the layout of the business, the procedures being performed and the Department's <i>Infection Control Guidelines for hair, beauty and skin penetration industries</i>.</p> <p>However, the Department is open to discussion and possible further changes based on a consensus approach that meets intended outcomes.</p> <p>Training requirements were considered for the draft regulations, but appropriate credentialed courses cannot be guaranteed. This would mean compliance with such a regulation may be problematic. Business impact and the application of training requirements on practitioners also requires consideration.</p> <p>The Department acknowledges recommendations to mandate compliance with department's <i>Infection Control Guidelines for hair, beauty and skin penetration industries</i> as a regulation. However, there would need to be a review of the guidelines to ensure they are designed, and appropriate, for inclusion into the regulations. Opportunity would need to be given to industry to comment about this recommendation. However, the Department is open to further discussion about this recommendation.</p> <p>To address certain implementation considerations and feedback, the final regulations:</p> <ul style="list-style-type: none"> <li>• create a class or classes of business as a prescribed particular under the applications for issue, renewal and transfer of regulations. These changes align with the application of section 68 the Act, as well as new regulations 37 and 38, which refers to class of business.</li> <li>• reduce the maximum penalty for failure to display a notice about the scope of registration from 20 penalty units to 10 penalty units. This change ensures a more proportionate response and aligns with the associated infringement penalty.</li> </ul>

### Emerging cosmetic procedures

<p><b>Issue</b></p>	<p>Issues and recommendations to strengthen regulation of certain emerging cosmetic procedures such as those involving blood products, restricted substances and lasers.</p>
<p><b>Response</b></p>	<p>The scope of this review is limited to the Public Health and Wellbeing Regulations and does not extend to the Act.</p> <p>To mitigate some concerns, the final regulations intend to:</p>

	<ul style="list-style-type: none"> <li>• provide clarity about the scope of registration (so registration is not seen to apply to the quality of procedures undertaken or the abilities of individuals undertaking the business)</li> <li>• prevent misleading advertising about registration</li> <li>• ensure businesses provide accurate information about the risks and safeguards of procedures to clients.</li> </ul> <p>Further consideration of other regulatory frameworks and the definitions that determine the scope of registered premises under the <i>Public Health and Wellbeing Act 2008</i> is required to identify the best approach to address this issue. This includes identifying the whether any change applies to the premises, procedure or practitioner.</p>
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## Exemptions for practice of nursing and midwife professions

<b>Issue</b>	Recommendation to clarify that nursing and midwifery are distinct professions.
<b>Response</b>	The final regulations clarify the exemption for these professions, which are regulated by the Australian Health Practitioner Regulation Agency.

## Part 5 Division 3: Aquatic facilities

### General duties and parameters

<b>Issue</b>	Issues and recommendations relating to increased requirements, adherence to existing 4-hour chemical testing and microbiological standards, categorisation of aquatic facilities, compliance exemptions for certain facilities, approval of water quality risk management plans and technical/operational suggestions to improve the regulations.
<b>Response</b>	<p>The final regulations address many of these issues by a range of amendments, including:</p> <ul style="list-style-type: none"> <li>• adding the number and description of aquatic facilities to the applications for issue, transfer and renewal of registration</li> <li>• simplifying the obligation on an aquatic facility operator with respect to the microbiological quality of aquatic facility water and clarifying parameters for the treatment of aquatic facility water</li> <li>• clarifying the procedure for responding to a suspected or implicated source of infection and applying equivalent and consistent penalties</li> <li>• simplifying the procedure for responding to non-compliance with microbiological parameters and aligning the penalty units for failure to notify the council of closure with the infringement penalty.</li> </ul> <p>The Department will continue to develop support materials to assist councils and aquatic facilities understand, interpret and apply the regulations. This includes guidance and templates for local council inspections and aquatic facility record keeping. The new <i>Water quality guidelines for public aquatic facilities- managing public health risks</i> support the regulations and provide practical operational guidance for maintaining water quality.</p> <p>The Department will continue to work with aquatic facility operators, local government and the aquatics industry to promote understanding and compliance.</p> <p>For category 1 aquatic facilities, the new registration requirements will commence on 14 December 2020. This is to allow time needed for both councils and category 1 aquatic facilities to transition to the new requirements.</p> <p>The Department has not created additional categories of aquatic facilities or included additional compliance exemptions from those proposed in the draft regulations that were subject to consultation. Proposals received for exempting types of aquatic facilities or incorporating additional categories have not been accepted as these proposals were not supported with appropriate justification or risk mitigation strategies to demonstrate an equivalent level of public health protection.</p>

## Part 6 Division 1: Cooling tower systems

### Technical and operational matters

<b>Issue</b>	Issues and recommendations that clarify disinfection to the interior of the cooling towers, record keeping, cleaning of drift eliminators, aligning high heterotrophic colony count with other jurisdictions, 5-year retention of records and start-up of a cooling tower system.
<b>Response</b>	<p>The Department notes the issues and recommendations, primarily to improve clarity about the operation of the regulations.</p> <p>The final regulations are unchanged from the draft regulations. The Department will provide further clarity for the interpretation and application of matters raised during consultation in guidelines that will be released to support implementation.</p>

## Part 6 Division 2: Legionella risks in certain premises (water delivery systems)

<b>Issue</b>	<p>Issues raised about:</p> <ul style="list-style-type: none"><li>the difficulty and burden for operators to comply with the requirement to disinfect the entire system within 24 hours in response to Legionella detection.</li><li>expanding the regulations to cover other facilities such hotels and private healthcare facilities and risk management.</li></ul>
<b>Response</b>	<p>The Department acknowledges that the specific circumstances of the Legionella detection and design of each water delivery system needs to be considered in whether or not to disinfect the entire system.</p> <p>The purpose of this regulation was to ensure that the risk of people contracting legionellosis is appropriately managed. The Department recognises there are alternative means of managing this risk that may be more practical, less burdensome and more proportionate to the identified risk. As such, the regulation requiring disinfection of the entire system has been removed. There remains a clear obligation in regulation 82 that a responsible person must take all reasonable steps to manage the risks of Legionella in water delivery systems.</p> <p>The Department will continue to provide guidance on the appropriate risk management plans that should be implemented by the responsible person as part of a response to the detection of Legionella at a premises. This approach is more flexible and responsive than prescribing disinfection of an entire system, which in some instances may be impossible.</p> <p>Expansion of the regulations to other facilities requires broader consultation and risk analysis.</p>

## Part 6 Division 3: Pest control

<b>Issue</b>	<p>Issues and concerns<sup>1</sup> regarding:</p> <ul style="list-style-type: none"><li>incurred costs transitioning to the new national licensing and training requirements</li><li>alignment with certain training requirements agreed in the Agriculture Minister's forum in 2018.</li></ul>
<b>Response</b>	Transitional arrangements until 31 December 2021 will allow time and opportunity for operators to undergo a process of recognition of prior learning or undertake further training as necessary.

<sup>1</sup> Some submissions under Pest Control raised specific concerns about the impacts of pesticides on the environment to control pests. These submissions are reflected in Part 4 Vector-borne disease control as the scope of Part 6, Division 3 is limited to licensing and training requirements of pest control operators.

	<p>The final regulations:</p> <ul style="list-style-type: none"> <li>clarify the training organisations that can issue recognition of current competencies or prior learning</li> <li>remove references to pesticide (including fumigants) to control pest animals and associated units of competency in the Schedule. This change reflects that these activities are likely to only occur in an agricultural or natural resource management situation and therefore meets the exemption requirements under s.100 of the Act.</li> <li>amend a licence category in Schedule 1 from “Pesticides (excluding fumigants) formulated to control pest animals.....” to just “Pesticides formulated to control pest animals to align with national licensing and training agreement.</li> </ul>
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## Part 7 Divisions 1-3 (and Schedules): Management and control of infectious diseases, micro-organisms and medical conditions

### Immediate notification

<b>Issue</b>	Issues regarding interpreting the term immediately to better reflect the intent of notifications and to allow enforcement.
<b>Response</b>	<p>To address this issue, the final regulations clarify immediate notification requirements to ‘as soon as practicable and no later than within 24 hours.’ The relevant regulations have also been redrafted to simplify the requirements and improve consistency.</p> <p>The inclusion purpose for the notification requirements provides greater clarity about their intended operation. A defined parameter also supports appropriate enforcement.</p>

### Transfer of isolates for sub-typing

<b>Issue</b>	<p>Robust evidence to inform a rapid and tailored public health response to outbreaks of food or water borne illness is required in contemporary public health frameworks. The more accurately a micro-organism can be typed, the more rapid and appropriate the public health response. Accurate typing can reduce misattribution of illness to particular sources.</p> <p>Following isolation and notification of a micro-organism from food or drinking water, further isolate typing information may be required to determine the relatedness of isolates to each other and therefore the likelihood of a particular food or water sample being the source of infection. This information can only be obtained by having a reference laboratory (a laboratory equipped to undertake testing to determine the sub-type of a pathogen, such as microbial genomic sequencing) analyse the isolate(s).</p> <p>Current practice of primary laboratories forwarding food and water isolates to reference laboratories for the purposes of sub-typing and reporting is based on voluntary practice. This may lead to delays in identifying the source of food or water-borne illness.</p>
<b>Response</b>	<p>To address this issue, the final regulations create two regulations about:</p> <ul style="list-style-type: none"> <li>the transfer of samples and isolates for sub-typing to prescribed public health laboratories upon request from the Secretary</li> <li>the provision of sub-typing information to the Secretary, which will complement the above regulation.</li> </ul> <p>The regulations are intended to apply if the person in charge of a laboratory service has notified the Secretary of details of a notifiable micro-organism in food or drinking water in accordance with section 130(2) of the Act and the Secretary is of the view further sub-typing is necessary.</p> <p>There may be some small costs to laboratories in forwarding samples, however it reinforces current voluntary practice and ensures rapid and accurate evidence can be obtained in response to food and water-borne illness.</p>

## Reporting of positive nucleic acid testing for HBV and HCV

<b>Issue</b>	Only reporting positive nucleic acid testing for hepatitis B virus (HBV) and hepatitis C virus (HCV) for those previously diagnosed and notified with HBV and HCV will not enable comprehensive data collection about undetectable or cured cases. This data could provide an important evidence base for interventions designed to support and advance hepatitis B and hepatitis C strategies and management.
<b>Response</b>	The Department acknowledges this consideration and its relevance to effective hepatitis B and C management and strategies. However, this cannot be achieved under this regulation review; changes to the Act would be needed to enable this data collection.

## Notification of *E. coli*

<b>Issue</b>	Notification of all strains of <i>E. coli</i> would cause administrative and operational costs that are not proportionate to risk
<b>Response</b>	The final regulations better reflect the policy intent by prescribing that only Shiga toxin and verotoxin producing <i>Escherichia coli</i> (STEC or VTEC) are required to be notified under Schedule 5.

## Notification of Carbapenamase-producing *Enterobacterales*

<b>Issue</b>	Carbapenamase-producing <i>Enterobacterales</i> no longer requires urgent notification. Notification within 5 days is considered more consistent, appropriate and practical.
<b>Response</b>	To address this issue, the final regulation removes Carbapenamase-producing <i>Enterobacterales</i> from Schedule 4 Part 1 – Notifiable conditions requiring immediate notification and inserts it in Schedule 4 Part 2 – Notifiable conditions requiring written notification within 5 days.

## Part 7 Division 5 (and Schedule): Immunisation

### Exclusion

<b>Issue</b>	<p>Current regulations enable the Secretary to direct a school principal or person in charge of a child care centre to exclude an unimmunised child during an outbreak of infectious disease when there is a risk of transmission.</p> <p>The relates only to a child who is not immunised against a specified vaccine-preventable disease and does not consider factors such as a child's immunity and immunisation status, the risk of the child contracting the vaccine-preventable disease, and the severity of illness if the child were to contract a vaccine-preventable disease.</p>
<b>Response</b>	<p>To improve the policy intent and application, the final regulations empower the Chief Health Officer, rather than the Secretary, to direct a primary school principal or person in charge of a child care centre to exclude a child based on a material risk of a child contracting a vaccine-preventable disease.</p> <p>The exercise of the power by the Chief Health Officer brings an appropriate level of technical expertise to the determination. The power will allow the Department to continue to take necessary action to protect vulnerable children during outbreaks of infectious diseases in high-risk settings.</p>

## Exclusion (Schedule)

<b>Issue</b>	<p>Schedule 7 requires clarification that a child should not be excluded if they have latent tuberculosis. This is on the basis that tuberculosis and latent tuberculosis infection should be treated separately.</p> <p>Schedule 7 requires clarification so that the exclusion of <i>Haemophilus influenzae</i> type b (Hib) aligns with the National Health and Medical Research Council guidelines.</p>
<b>Response</b>	<p>To improve the policy intent and application, the final regulations make minor adjustments to Schedule 7 to:</p> <ul style="list-style-type: none"><li>• clarify latent tuberculosis does not need exclusion</li><li>• align exclusion for <i>Haemophilus influenzae</i> type b (Hib) with the National Health and Medical Research Council guidelines 'Exclude until 48 hours after initiation of effective therapy'.</li></ul>

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