



Food Unit Notice

Requirements for Pathogen Notification – Regulation 15.

Notice number 24.1

July 2024

Distribution of Notice

All laboratories and analysts approved by the Chief Executive Officer in accordance with Part 7 of the *Food Act 2008*.

Food businesses undertaking internal microbial analysis of their own food products, premises or anything associated with their food business.

Purpose

1. To provide clarification on when notification of pathogen isolation is required under Regulation 15 of the *Food Regulations 2009* with respect to:
 - Laboratory methods where the viability of the pathogen is confirmed, and
 - Presumptive results from culture-independent methods (including PCR and ELISA).
2. To provide written directions from the CEO under Regulation 16 as to procedures that must be followed by a person in charge of a laboratory, following notification of Salmonella genus.
3. To detail best practice responses to:
 - presumptive pathogen detections using culture-independent methods, and
 - Listeria genus detection

Pathogen Notification Requirements

The following section details when pathogen notification requirements are applicable under Regulation 15:

Notification required:

Persons in charge of laboratories within Western Australia or their delegate, must notify the CEO, or a delegate of the CEO, of all suspected and confirmed isolations of pathogens from laboratory methods that substantiate the viability of the organisms. This includes pathogen isolations in or upon growth media.

Owners of food businesses operating within Western Australia have the responsibility of notifying suspected and confirmed isolations of pathogens, from laboratory methods that substantiate the viability of the organisms, if the laboratory analyses are undertaken outside of Western Australia.

Notification not required:

Notification requirements are not applicable to presumptive results of culture independent methods that do not substantiate the viability of the pathogen. This includes PCR and ELISA pathogen detection results. Refer to [best practice responses](#) for presumptive pathogen detections.

Directions

CEO directions – Regulation 16:

Regulation 16 enables the CEO to give directions as to the procedures to be followed subsequent to a pathogen notification under Regulation 15.

Direction to determine the species of Salmonella

In accordance with Regulation 16 the CEO directs that all notifications of Salmonella genus must be further analysed to confirm the Salmonella species.

Direction to provide the CEO with results

In accordance with Regulation 16 the CEO directs that further to notification, any subsequent identification of species, molecular typing or enumeration results of isolated pathogens must be provided to the CEO in writing within 24 hours of finalisation.

Direction to forward isolates for molecular typing

In accordance with Regulation 16 the CEO may direct bacterial isolates of pathogens listed in Regulation 14 to undergo further molecular typing. Instructions will be provided following the notification by a laboratory or food business.

Best practice responses

Presumptive pathogen detections

When a culture independent laboratory process detects the presence of a pathogen prescribed under the Regulations, the person in charge of the laboratory, or their delegate, should:

- Advise the client as soon as practicable
- Proceed to culture-based laboratory methods to confirm the presence and viability of the pathogenic organism.

Listeria genus detection

Where a laboratory process detects the genus Listeria in a sample submission from food, a person, premises, a vehicle or anything else associated with a food business, the food business has the duty of care to confirm the absence of viable Listeria monocytogenes.

For the purposes of the *Food Act 2008*, food is considered 'unsafe' if it would be **likely** to cause physical harm to a person who might later consume it. While not all Listeria species are pathogenic, and not all presumptive pathogen detections correlate to a public health threat, the known presence of the Listeria genus, or a positive presumptive detection, indicates a higher probability that a food product is unsafe. In these circumstances food businesses should initiate their pathogen detection protocol, while undertaking further laboratory analysis to determine what response is appropriate.

Background

Regulation 15 of the Food Regulations 2009 requires that a person in charge of a laboratory must give the CEO of the Department notice of the isolation, or suspected isolation of a pathogen from food, a person, premises, vehicle, or anything else associated with a food business.

The regulations do not specifically define the terms 'isolation' or 'suspected isolation'. In microbiology the accepted interpretation of the term 'isolation' is the process of developing a pure culture by separating one species of microbe from a mixture of many other species. Generally, this is performed by culturing bacteria on growth media. 'Suspected isolation' refers to the growth on the initial differential media prior to isolates being transferred onto selective media for confirmation. Isolation of pathogens using these methodologies confirms the viability of the pathogenic organisms.

Other commonly used methods of pathogen detection include polymerase chain reaction (PCR) and enzyme-linked immunosorbent assay (ELISA). These are culture-independent tests because they do not involve culturing the targeted pathogen on growth media. Culture independent tests provide rapid detection results of pathogen components, but they do not distinguish viable (live), inactivated, or lysed/destroyed cells within the sample. For these reasons, the positive detection of a pathogen using a culture independent methodology does not indicate the same public health risk presented by isolation of a cultured pathogenic bacteria.

The Department is of the position that references to pathogen isolation, or suspected isolation within Regulation 15, refer to methodologies that include culturing pathogens and/or confirming microbe viability. Notification of pathogen isolation using this type of laboratory method is a regulatory responsibility of persons in charge of approved laboratories.

There has been speculation and uncertainty amongst approved laboratories regarding the application of notification requirements of Regulation 15 to presumptive pathogen detections resulting from culture independent analysis. The Department clarifies that laboratories are not required to notify pathogen detections resulting from culture independent analysis.

Terms and definitions

Term	Definition
Regulation	A reference to the <i>Food Regulations 2009</i>
Notify	Notification of isolation, or suspected isolation of a pathogen, in the approved form, in accordance with Regulation 16 of the Food Regulations 2009
Department	Western Australian Department of Health
CEO	Mean the CEO of the Western Australian Department of Health or a member of staff principally assisting with administration of the <i>Food Act 2008</i>
Culture-independent method	A method of detecting the presence of a pathogen that does not involve culturing the target pathogen on, or in growth media. Culture-independent methods includes PCR and ELISA
PCR	polymerase chain reaction
ELISA	enzyme-linked immunosorbent assay

Resources and websites

- WA Department of Health ww2.health.wa.gov.au
- Food Standards Australia <http://www.foodstandards.gov.au/code/Pages/default.aspx>

More information

Contact the Environmental Health Directorate Food safety team

Email: foodsafety@health.wa.gov.au

Phone: (08) 9222 2000

Website: ww2.health.wa.gov.au

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