



August 14, 2024

## Notice

### **Health Canada is Rescinding Recommendations for Measures to Address the Potential Risk of Zika Virus Transmission through Human Cells, Tissues and Organs**

This notice is to inform you that Health Canada is rescinding the recommendations outlined in the notice entitled “*Revised Measures to Address the Potential Risk of Zika Virus Transmission through Human Cells, Tissues and Organs*” that was distributed to stakeholders on May 5, 2016 and is replicated under the heading “Addressing risk of transmitting Zika virus” at the end of the *Guidance on the Safety of Human Cells, Tissues and Organs for Transplantation Regulations*.

The purpose of this action is to decrease barriers to donation and move towards harmonization of donor screening measures for donors of cells, tissues and organs in Canada and the United States.

#### **Background:**

Since the emergence of Zika virus in the Americas in 2015, the Public Health Agency of Canada has been conducting surveillance in order to inform public health actions. The outbreaks that occurred in 2016 have subsided and the incidence of Zika in Canada has dropped significantly. The Public Health Agency of Canada is now focusing on monitoring for indicators of any change in the risk of Canadians acquiring Zika (e.g., due to new outbreak activity).

The available evidence in Canada and the United States demonstrates that Zika virus no longer has sufficient incidence and/or prevalence to affect donors of cells, tissues and organs. Zika virus is not endemic to Canada and no travel related cases of Zika virus infection have been documented in Canada since 2019. Furthermore, there have been fewer than six travel related cases of Zika virus infection in the United States per year since 2020 and there is currently no local transmission of Zika virus in the continental United States.

#### **Next Steps:**

The CAN/CSA-Z900.2.4:22 “Ocular tissues for transplantation” standard and the CAN/CSA-Z900.2.2:22 “Tissues for transplantation” standard exclude donation from



persons with an active Zika virus infection in the past 6 months. These exclusion criteria are contained within sections of the standards that are incorporated by reference in the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* (CTO Regulations). On July 10, 2024 the CSA Group launched a 30 day public review to give stakeholders the opportunity to comment on a proposed amendment to these two standards. The proposed amendment would remove the following two clauses:

**Z900.2.2:**            *13.1.2 h) persons with an active zika virus infection in the past 6 months.*

**Z900.2.4:**            *13.1.3 m) persons with an active zika virus infection in the past 6 months.*

The amended versions of these two standards will be published in the coming months, at which time these clauses will cease to be regulatory requirements. It should be noted that until the new CSA standards are published, the requirement to screen donors for Zika virus remains in effect.

Please note that if there is a change in epidemiology that leads Health Canada to determine that Zika virus may again have sufficient incidence and/or prevalence to affect donors of cells, tissues and organs then we may re-issue guidance with recommendations to reduce the risk of transmission of Zika virus through transplanted cells, tissues or organs.

Questions or comments may be submitted to Health Canada's Centre for Policy, Pediatrics and International Collaboration.

Sincerely,

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