



Application of the GST/HST to Supplies of In Vitro Diagnostic Test Kits

It has been the Canada Revenue Agency's (CRA) position that supplies of *in vitro* diagnostic test kits designed for laboratory use are subject to the goods and services tax/harmonized sales tax (GST/HST). However, the Tax Court of Canada (TCC) decided in *Centre Hospitalier Le Gardeur et al v The Queen* 2007 TCC 425 that certain *in vitro* diagnostic test kits are zero-rated pursuant to paragraph 2(a) of Part I of Schedule VI to the *Excise Tax Act* (ETA).

The CRA is currently reviewing the impact of the TCC decision, which is dated July 20, 2007. In the interim, the CRA has adopted an administrative position which is in keeping with the TCC decision. This position applies from the date of the TCC decision until such time as the CRA review in this matter is completed.

Pursuant to the CRA's interim administrative position, the supply of an *in vitro* diagnostic test kit will be zero-rated pursuant to paragraph 2(a) of Part I of Schedule VI to the ETA if it is for use in the diagnosis of a disease in humans and it contains one or more of the following substances, which were listed in the TCC decision:

- monoclonal and polyclonal antibodies;
- blood and blood derivatives;
- snake venom; and
- micro-organisms that are not antibiotics.

Suppliers of *in vitro* diagnostic test kits containing one or more of the four above-listed substances may sell such products on a zero-rated basis. Conversely, *in vitro* diagnostic test kits which do not contain one or more of these substances will be subject to the GST/HST at 5% or 13%.

If a supplier collected and remitted the GST/HST on supplies that qualify for zero-rating under this administrative position, it may refund or credit the amounts collected as GST/HST to its customers in accordance with the requirements set out in section 232 of the ETA. Alternatively, customers may apply for a rebate from the CRA for tax paid in error under section 261 of the ETA.

Persons who file tax paid in error rebate claims with the CRA for tax paid on *in vitro* diagnostic test kits must provide sufficient documentation with the rebate claim to enable the CRA to verify that the test kits that are the subject of the claim contain one or more of the above-listed substances. No rebate will be payable for the GST/HST paid on *in vitro* diagnostic test kits that do not contain one or more of these four substances.

In addition, customers who intend to file tax paid in error claims may only claim for the difference between any amount they have obtained as part of a public service body rebate and the total amount paid as tax. If a customer claims and receives the amount under the public service body rebate and also claims the total amount as tax paid in error under section 261, the CRA will reassess the public service body rebate with respect to the amount paid as such and charge any applicable interest. As well, the CRA may apply penalties. Finally, the rebate claim must comply with the time limit in subsection 261(3) of the ETA. The customer must file the application for the rebate within two years after the day the amount was paid.

La version française de la présente publication est intitulée *Application de la TPS/TVH aux fournitures de trousse de diagnostic in vitro*.



The CRA will announce its final decision on this issue once its review is completed. Please note that any change to the CRA's position, should one occur, will be effective on a prospective basis.

Enquiries by telephone

Technical enquiries on the GST/HST: 1-800-959-8287

General enquiries on the GST/HST: 1-800-959-5525 (Business Enquiries)

If you are located in Quebec: 1-800-567-4692 (Revenu Québec)

All technical publications on GST/HST are available on the CRA Web site at www.cra.gc.ca/gsthstech.