

PORCINE EPIDEMIC DIARRHOEA

CURRENT GLOBAL SITUATION AND POSSIBLE THREAT FOR EUROPE

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Summary

The purpose of this report is to present Canada's experience so far with the emergence of porcine epidemic diarrhea (PED) using a pro-active risk management approach. This approach is reflected in the actions the Canadian Food Inspection Agency took in collaboration with other stakeholders starting from the period the disease was first confirmed in United States to the time after it was confirmed within Canada and covering the feed investigations. This report provides the details about these actions and an overview of the Swine National Biosecurity Standard.

This report also highlights the efforts the Canadian Food Inspection Agency made, under the leadership of the Chief Veterinary Officer's office, to engage with the provinces, industry, producers and other important stakeholders.

It is also intended to focus on the current global PED situation, an update on the disease situation in Canada and the success Canada has achieved in its efforts to contain the spread of the disease. This includes steps Canada has taken to mitigate any possible threat to the European Union from the trade in live swine from Canada.

Keywords

Canada – emerging disease – Europe – porcine epidemic diarrhoea (PED) – risk management

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1. Introduction

Porcine epidemic diarrhea (PED) is a viral disease of swine caused by porcine epidemic diarrhea virus (PEDV), which is a member of the family Coronaviridae. PEDV is not a risk to human health or to other species of animals, nor is it a food safety risk. It is not an OIE-listed disease or federally reportable in Canada. The current PED situation is globally described as a disease which is emerging/re-emerging in swine populations otherwise considered naive. The situation in some of the countries in North America as well as in South America is worth noting where PEDV has been recently reported for the first time. This warrants that a very specific effort be made to understand the disease introduction pathways as well as risk mitigation strategies.

2. Canada's actions in collaboration with stakeholders

2.1. Prior to PED confirmation in Canada

The Canadian Food Inspection Agency (CFIA) was notified by the United States Department of Agriculture (USDA) about the outbreak of PED in the United States of America (USA) on 22 May 2013. While making decisions on the level and extent of CFIA's engagement in the PED situation, the following were the key considerations:

- not zoonotic
- not a food safety concern
- not a listed disease of the OIE
- not a federally reportable disease in Canada.

2.1.1. Federal, Provincial and Territorial (FPT) and Industry engagement

Given the need for clear roles and responsibilities at the federal, provincial and industry levels, a common platform was required for a collaborative approach to prepare and respond to such diseases. The office of the Chief Veterinary Officer (CVO) of Canada provided leadership in this respect.

Immediately after the outbreak was confirmed in the USA in May 2013, CFIA through the Office of the CVO of Canada initiated regular teleconference calls with stakeholders as part of CFIA's preparation to facilitate an approach to deal with this emerging disease. The first such engagement happened on 27 May 2013, just five days following the notification to CFIA by the USDA.

2.1.2. Border controls

Canada ensured that the existing import policy was able to mitigate the risk of introduction of communicable swine diseases, such as PED, into Canada. The Canada Border Services Agency (CBSA) was advised concerning the risk of contaminated livestock trucks returning to Canada and the need for heightened awareness as they are responsible for ensuring CFIA's requirements as per the *Health of Animals Regulations* are met at the border. The first reminder was sent to CBSA as early as 27 May 2013.

2.1.3. Building testing capability and capacity

The National Centre for Foreign Animal Diseases (NCFAD) started liaising with their counterparts in USA federal and state laboratories and coordinating diagnostic approaches with Canadian laboratories. As a result, diagnostic testing of any suspect PED case in Canada was available at these laboratories within Canada.

On 12 June 2013, a communique was issued by CFIA on behalf of the Canadian Animal Health Laboratory Network, informing all stakeholders about the availability of the diagnostic test for PED in Canada. This opportunity was also used to encourage veterinarians to communicate with their respective animal health laboratories and submit samples for testing if PED was suspected.

2.1.4. Engaging public for disease awareness and biosecurity

At the confirmation of the outbreaks in the USA, numerous interviews were given by CFIA officials to answer media questions and to proactively ensure the public was provided with the best available information. Also, the CFIA, provinces and the pork industry started implementing extensive education programmes to increase awareness of the disease and promote biosecurity protocols among producers as per the National Swine Farm-Level Biosecurity Standard developed by the Canadian Swine Health Board (CSHB) and reviewed by CFIA. This was achieved through websites as well as interacting via webinars and town hall meetings.

The result of the collective efforts as described above is evident from the fact that Canada was able to prevent the introduction of this disease for almost eight months despite its widespread presence in the USA and significant movement of pigs and trucks between the two countries.

2.1.5. Overview of the National Swine Farm-Level Biosecurity Standard

Funded by the Ministry of Agriculture and Agri-Food Canada, the Canadian Swine Health Board (CSHB) was formed in 2008 as a national organisation with the mission 'to provide leadership and coordination in support of the management of the health of the Canadian swine herd'.

One pillar of improving swine health in Canada is to improve the biosecurity of the national swine herd. The CSHB developed the National Swine Farm-Level Biosecurity Standard [1], which has been reviewed by the CFIA as meeting the criteria for a National Agri-Commodity Biosecurity Standard.

This standard is a comprehensive voluntary standard designed to provide biosecurity guidance for veterinarians, producers, owners or managers, and service providers in all swine sectors in Canada. It has been developed in a way that has enabled stakeholders to develop biosecurity best management practices specific to each type of farm and production system for all disease hazards.

The standard is organised in three sections: direct route of contamination; indirect route of contamination; on-farm health management and regional considerations. Within each section, major target outcomes are identified with a statement, a rationale describing the associated risks, and examples of best management practices (BMPs) that could be implemented at the farm to control the identified risks.

An accompanying user guide along with training tools has also been developed as an implementation tool for this standard. It contains a comprehensive description of the BMPs and the actions needed to create a farm-specific biosecurity plan.

2.2. After the confirmation of PED in Canada

2.2.1. Current status

The first case of PED in Canada (Ontario) in a swine farm was confirmed by the CFIA on 24 January 2014.

As of July 2014, there are 67 confirmed cases of PED in Canada. These cases have been detected in only four Canadian provinces, which include Ontario (n=63), Manitoba (n=2), Prince Edward Island (n=1) and Quebec (n=1). There have been no cases reported in the other six provinces and three territories.

There was only one PED case reported in May, four new cases in June (from 4 to 13 June) and after a long intervening period another case was reported in July (21 July). This clearly shows that the number of new cases being reported per month has diminished significantly after April 2014 ([Appendix 1](#)). All the confirmed new cases in June and July have been in the province of Ontario.

Most of the affected farms in the four provinces are working their way through elimination strategies while undergoing significant management and biosecurity changes with the support of their veterinarians, industry and provincial governments.

The provincial governments, along with the pork industry, have been leading the response to PED in each of the affected provinces.

The CFIA has engaged and worked collaboratively with provincial and industry stakeholders to provide technical, diagnostic and scientific support. The CFIA will continue to engage and facilitate the management of the disease, based on the platform built on Federal, Provincial and Territorial (FPT) and Industry collaboration.

2.2.2. The following steps are the main components of PED disease control

a. Disease surveillance and monitoring

The disease has been made reportable/notifiable in the provinces of Ontario, Alberta, Saskatchewan, Manitoba and Quebec. Consequently, any suspect cases in these provinces have been and would be reported to their respective provincial governments.

There are also industry surveillance initiatives such as the Canadian Swine Health Intelligence Network (CSHIN) within Canada that will assist detecting and reporting the disease. The CSHIN is a surveillance network of veterinarians and producers reporting on changes to pig health in real time. It was established through an initiative of the Canadian Swine Health Board (CSHB).

The provincial authorities along with the swine industry are also conducting environmental sampling at assembly yards; truck wash stations, slaughter plants, etc., and the virus does not seem to be widely distributed.

b. Herd management

PED cases are being managed on an individual basis depending on the risk assessment conducted by provincial authorities. Case management is a collaborative effort between the producer, the herd veterinarian, provincial authorities and industry as required.

No positive farms in the affected provinces have been put under official quarantine though movement restrictions are considered by producers voluntarily, if needed, as a part of the case management approach. Upon confirmation of a PED case, the provincial authorities contact the referring veterinarian to discuss the specific details of the case and to gather the information required to perform the risk assessment and trace-outs. The herd veterinarian continues to work with the producer to manage the disease and to ensure appropriate biosecurity measures are in place.

c. Biosecurity

The provincial authorities, along with the swine industry, are also taking steps such as heightened emphasis on cleansing and disinfection of trucks to mitigate the spread of the virus.

Proper biosecurity measures remain the first and best line of defense for pork producers to prevent introduction and spread of PEDV. The CFIA along with the provinces continue to recommend that producers maintain high vigilance and follow strict biosecurity protocols.

d. Border controls

The CFIA continues to work with the CBSA to be vigilant at the border in assessing vehicles that have been used to transport pigs in the United States, to ensure that proper cleaning and disinfection procedures have been followed under the Health of Animals regulations.

e. Vaccine availability

The CFIA is also facilitating access to PED vaccines for emergency use under veterinary supervision to help the swine industry respond to the threat posed by PED.

3. Feed as a potential pathway for PED introduction

While sampling for PED during the course of the disease investigation in Ontario, feed testing done by the Ontario Ministry of Agriculture and Food (OMAF) revealed that a particular lot of US-origin spray-dried porcine blood plasma (plasma) used in feed pellets distributed by one particular company contained PEDV genetic material.

This triggered a feed investigation to address the concerns that feed could cause the transmission of the virus. The CFIA activated its National Emergency Operations Centre (NEOC) on 18 February 2014 in order to provide national leadership to the feed investigation. The National Emergency Response Team (NERT) carried out the required tracing, sampling and testing of implicated feed and feed ingredients. The involved company voluntarily withdrew all suspected feed on 9 February 2014. Upon removal of this feed from the marketplace, and once all other lines of investigation were closed, the NEOC was deactivated on 17 March 2014.

The weight of the epidemiological evidence was assessed using a framework based on Hill's criteria for causality [4]. Factors considered include, but are not limited to:

- temporal and/or spatial clustering of cases consistent with the availability/distribution of the feed;
- strength of the statistical association between the feed (and amount consumed) and the disease; and
- consistency of the laboratory results with the epidemiological evidence.

For further information on the epidemiological investigation, see the executive summary of the feed epidemiology report ([Appendix 2](#)).

The attack rate amongst the farms which received the feed was 21.4% (18/84). During the same period, only 16 other cases were reported amongst the approximately 7,000 hog farms in Canada. The risk of disease was significantly higher on farms that received feed with higher plasma inclusion rate. In addition, 17/27 (63%) of the early case farms in Ontario had received the feed containing the specific plasma lot, which is much more than expected from the 15% market share of the feed in Ontario.

The CFIA confirmed by reverse transcription polymerase chain reaction (RT-PCR) that both the plasma and the feed pellets contained PEDV genetic material. Bioassay studies conducted at the NCFAD demonstrated that the implicated porcine blood plasma did contain PEDV capable of infecting and causing disease in pigs. The bioassay studies with the feed containing the infected plasma showed that inoculation with the feed samples did not produce any significant excretion of PEDV but genetic material could be detected in the feed. Thus, as the tested feed did contain the plasma capable of infecting and causing disease and did contain the PEDV genome, CFIA consider the tested feed as inconclusive or not possible to determine whether it was infectious or not by bioassay. It is very much possible that the limited bioassay studies carried out by CFIA are likely much less sensitive than what might occur under field conditions where other variables can play a contributing role. For details, refer to the recent publication based on this bioassay study by Pasick *et al.* [7].

CFIA has reached to the conclusion that the weight of the epidemiological evidence supports that the source for most of the early cases in Ontario and for the single case in Prince Edward Island in January 2014, was pelleted swine feed containing a specific lot of spray-dried porcine plasma imported from the USA.

It remains uncertain whether spray-dried porcine plasma or pelleted swine feed in general are important in the epidemiology of PEDV. It is also not clear at which point in the production or the distribution chain did the contamination of the spray-dried porcine plasma with PEDV occur.

4. PED Forum: further engagement with stakeholders

Subsequent to the extensive feed and related epidemiological investigation as well as feed testing and bioassay studies, it was apparent that there was a need to further streamline the efforts to address this emerging issue by continuing the collaborative approach taken so far. Keeping this in mind, the CFIA, through the Office of the CVO for Canada, facilitated a PED forum on 12 March 2014 to bring overall leadership in addressing PED-related issues. The meeting served as a platform for the stakeholder community to engage in an all-day, face-to-face open dialogue on the Canadian and USA experience with PED. Representatives from USDA, the USA pork industry, the Canadian pork industry and the federal, provincial and territorial governments were invited as guest speakers. The presentations focussed on lessons learned and future directions for the management of PED. Representatives from the swine industry (producers, producer organisations, and processors), the Canadian Swine Health Board (CSHB), swine veterinary practitioners, the Canadian Veterinary Medical Association (CVMA), academia (Veterinary Colleges) and the federal, provincial and territorial governments participated in the forum.

The following topics were discussed and identified as major points of focus for managing PED and for moving forward:

- *Biosecurity* – Continued and sustained biosecurity at all levels.
- *Feed and PED* – Completion of the epidemiological investigation on linkages of feed and PED in Canada as well as exploration of future policy directions to maintain effectiveness of control measures as a follow-up to the feed investigation.
- *Border vigilance* – Review of existing regulations in regards to requirements for cleansing and disinfection (C&D) of conveyances returning to Canada from the USA as well as raise awareness regarding C&D and implement interim measures.
- *PED research* – PEDV pathogenesis, routes of infection, disease characteristics, vaccines, disinfectants, diagnostics and sharing of information on research efforts and finding.
- *National surveillance* – Planning, coordinating, and executing surveillance at a national level and information sharing with partners.
- *Governance for emerging issues* – Clarifying roles for FPT governments and Industry.
- *Funding* – Determination of mechanisms to leverage funding to address needs, matching funding.
- *Response* – Rapid response team as well as biosecurity and management strategies.
- *Communications* – Providing a mechanism to communicate among stakeholders.
- *Regulations* – Notification status for PED.
- *Market access* – Updating trading partners to ensure that there are no disruptions in trade.

A list of proposed action items based on above-listed topics and ranked by priority as well as proposed responsible party/parties was distributed to participants for their input and comments as a part of the report after the meeting. The timelines and status have been included as a part of an action plan to assist with mapping out project objectives and activities.

5. PED: global spread and possible threat for the European Union

There has been a recent global spread of PEDV with its emergence in North and South America for the first time. It has been reported to the OIE, as a first time occurrence, by USA, Canada, Mexico, the Dominican Republic and Colombia. Japan has also recently notified the OIE of re-emergence of the disease after a gap of seven years [6].

However, PED is not a new disease as it was first recognised in England in 1971 as an enteric disease affecting feeder and fattening pigs [10]. Since then, PED outbreaks have been documented in many European and Asian countries, the outbreaks being more acute and severe in Asian countries as compared to Europe [8]. Since 2010, variant strains associated with high

mortality in suckling piglets have emerged in China. The genetic and phylogenetic analysis of the PEDV strains isolated from the outbreaks in USA have revealed a close relationship with Chinese PEDV strains and suggests a likely Chinese origin [5]. However, the route of introduction into the USA has not been adequately identified yet [9]. In Canada there is only one PEDV strain which is identical to the initial USA strain found in April–May 2013.

PED is not a notifiable disease in the European Union (EU) and there is no routine surveillance in place [2]. It is difficult to assess if there is any risk to the animal health status of the EU from the recent global spread. The exact prevalence, virulence and the level of immune cross protection needs to be assessed within the EU to reach such a conclusion.

As far as the risk from Canada is concerned, CFIA is regularly updating and answering queries from trade partners, including EU, with respect to PED in order to ensure minimum disruption to the trade. As elaborated in this report, the collaborative approach to PED amongst the Canadian federal, provincial governments and the swine industry, as well as the proactive education/awareness programmes have allowed the development of heightened diligence to assist in the detection of PED on Canadian farms. Understanding where the disease exists in the country and exercising high levels of biosecurity on swine farms throughout the country is beneficial for both the control of this disease within Canada's borders and the prevention of transmission of the disease to international trading partners.

At the request of some countries, and based on the health status of that country, Canada has modified some sanitary export health certificates for live swine, requiring additional risk mitigating measures for PEDV. Modifications such as these have permitted Canada to continue to export pigs free from this disease.

The EU has already reviewed the animal health requirements for the import of porcine animals into the EU and published the new implementing regulation on protection measures concerning veterinary certification of porcine animals from certain third countries due to PED [3]. Canada has taken notice of this and will meet the specific guarantees as per the new certificate.

Canada is also satisfied that the EU has committed to reviewing its measures in six months taking into consideration the findings of the European Food Safety Authority and any new science which may shed more light on the disease. We also request the EU share with us at the earliest opportunity the results of surveillance that may be taking place in the EU.

6. Conclusion

Given the nature of the PED virus, the fact that it is circulating widely in the USA, the extensive land border and the integrated nature of the pork industry in Canada and the USA, it was a significant achievement to keep PEDV out of Canada for almost eight months.

Also noteworthy is the fact that even after the entry of the virus in Canada, the magnitude of the spread has been contained due to the collective efforts and actions taken. The bulk of cases in Canada are confined to a few counties in only one province. The lessons learned with respect to biosecurity, laboratory capacity and control measures have allowed Canada to manage this infection in a controlled manner. While sporadic cases may continue to occur, CFIA does not feel that PED is continuing to affect the greater pig population in Canada.

As far as the possible threat to Europe is concerned, the recent global emergence and re-emergence of PED warrants that a specific effort be made to understand the disease introduction pathways as well as risk mitigation strategies.

Canada understands the concerns and protection measures the EU has taken with regards to PED. Canada has already undertaken steps and taken extra mitigation measures as per the requests of its trading partners. These have effectively proven that Canada can still export pigs of high sanitary health therefore minimizing any trade interruptions due to the PEDV intrusion into this country.

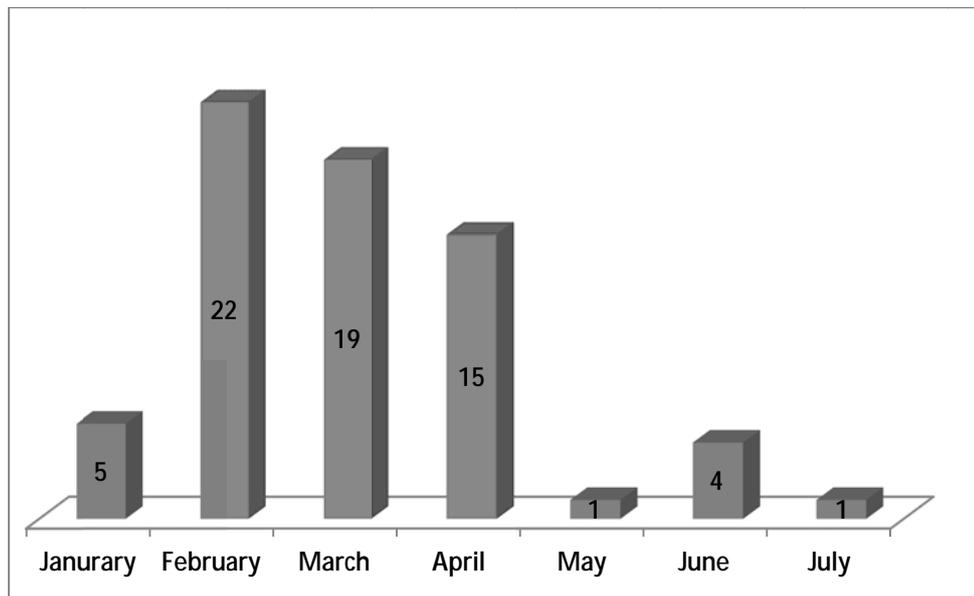
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.../Appendices

Appendix 1

Number of confirmed PED cases in swine farms in Canada
from January to July 2014



Appendix 2

Investigation into pelleted swine feed containing spray-dried porcine plasma as a possible source of Porcine Epidemic Diarrhea (PED) in Canadian swine herds

Assessment of the epidemiological evidence available as of 7 March 2014

Porcine epidemic diarrhea virus (PEDV) was first confirmed in Canada (Ontario) on 22 January 2014. A feed investigation was triggered on 9 February 2014, after testing from the Ontario Ministry of Agriculture and Food (OMAF) revealed that a particular lot of US-origin spray-dried porcine blood plasma (plasma) used in feed pellets distributed by a Canadian livestock nutrition company contained PEDV genetic material. As a precautionary measure, the distributor voluntarily withdrew the potentially affected feed pellets from the marketplace on 9 February 2014.

The CFIA conducted traceback and traceout activities, and OMAF led the epidemiological investigation. The methodology used for this epidemiological assessment was based on *Weight of Evidence: Factors to Consider for Appropriate and Timely Action in a Foodborne Illness Outbreak Investigation*, available on Health Canada's website¹.

Factors considered were whether it was plausible that the feed pellets containing plasma were the vehicle of infection, whether the temporal and/or spatial clustering of cases was consistent with the availability/distribution of the feed, and whether a single specific feed appeared to be the vehicle of infection. The strength of the statistical association between the feed and the illness, and whether the strength of the association increased with increasing consumption of the feed were also considered, as well as the temporal association between feed consumption and illness. The consistency of the laboratory results with the epidemiological evidence was assessed. Finally, alternate explanations were considered.

PEDV had not been reported in Canada prior to the current outbreak. The date of onset of clinical signs at the index farm was 20 January 2014, one week after they received feed containing the implicated plasma. Prior to the market withdrawal of the feed, 11/12 primary cases (i.e. no epidemiological links between them), all located in Ontario, reported consuming feed containing the implicated plasma. After the date of the voluntary market withdrawal, only 7/18 otherwise unrelated cases (up until 7 March 2014) had received feed containing the implicated plasma.

The attack rate amongst the farms which received piglet feed containing the implicated lot of plasma was 21.4% (18/84). During the same period, only 16 other cases (including 4 secondary cases having an epidemiological link with case farms) were reported amongst the approximately 7,000 hog farms in Canada. The feed did not contain any other ingredient of porcine origin. Additional lines of inquiry related to various swine by-products used as ingredients in swine nursery feeds were also followed by the CFIA. All ingredients were negative for PEDV when tested at the National Centre for Foreign Animal Disease (NCFAD) using RT-PCR.

Feeding porcine blood plasma to piglets is very common and is used as part of the first phases of a pig starter nutrition programme. Prior to the voluntarily market withdrawal of the potentially affected feed pellets, the livestock nutrition company which was the distributor of the feed had an approximate market share of 10-15% for pelleted piglet starters with plasma inclusion in Ontario. Yet, as of 7 March 2014, 17/27 (63%) primary case farms in Ontario had received the feed containing the specific plasma lot. It is extremely unlikely that this could have occurred by chance alone (exact binomial probability test p-value [one-tailed] = 1.81:10⁻⁸, assuming a 15% market share).

The attack rate was higher on farms that received feed containing higher concentration of plasma. Moreover, the risk of disease was significantly higher on farms that received feed containing higher plasma concentrations (3–6%) compared to farms that received only feed containing lower plasma concentrations (1–1.5%). However, it is unclear whether the higher attack rates represent a dose–response relationship, an increased susceptibility of younger piglets (the plasma concentration used in nursery feed usually decreases as the piglets get older), or perhaps a combination of both.

1 www.hc-sc.gc.ca/fn-an/pubs/securit/2011-food-illness-outbreak-ecllosion-malad-ailments/index-eng.php

It was confirmed by RT-PCR that both the plasma and the feed pellets contained PEDV genetic material similar to the strain seen in the USA since April–May 2013 and seen in the initial Canadian field cases. Bioassay studies conducted at the NCFAD demonstrated that the implicated porcine blood plasma did contain PEDV capable of infecting and causing disease in pigs. On the other hand, the bioassay studies could not demonstrate that the feed pellets containing the plasma were capable of infecting and causing disease in pigs. This could indicate that infectious PEDV was present at very low concentration in the feed. At such very low dose, the probability that at least one piglet becomes infected during a bioassay was very low compared to field use of the feed where hundreds to thousands of pigs are exposed.

The scientific literature to date has suggested that PEDV is very unlikely to survive the plasma spray-drying process; however, there is a potential for cross contamination of the spray-dried porcine plasma with PEDV to occur at any point during the manufacturing, packaging, storage and/or transportation of the product, due to a breach in good manufacturing practices and/or biosecurity.

Alternate explanations for the origin of the outbreak, such as feed delivery trucks, service providers, dead stock removal, assembly yards and transportation were also considered. Testing at one of the assembly yards revealed significant environmental contamination with PEDV, and 8 of the initial 20 farms have had contact with this assembly yard via inbound transport of culled animals. It is difficult to determine the significance of the role of the assembly yard in the dissemination of PEDV in Ontario as the length of time that the yard was positive for PEDV is unknown.

Based on the afore-mentioned information, the weight of the epidemiological evidence, which was considered to be 'moderate' to 'strong', suggested that the source for most of the early cases in the outbreak of PEDV that started in Ontario in January 2014 was pelleted swine feed containing a specific lot of spray-dried porcine plasma imported from the USA and distributed by a Canadian livestock nutrition company between 3 January and 7 February 2014. It remains uncertain whether spray-dried porcine plasma or pelleted swine feed in general are important in the epidemiology of PEDV. It is also not clear at which point in the production or distribution chain did the contamination of the spray-dried porcine plasma with PEDV occur.
