Annex to:

EFSA (European Food Safety Authority), 2016. Scientific Report on the collection and review of updated epidemiological data on porcine epidemic diarrhoea (PED). EFSA Journal 2016;14(1):4375, 9 pp. doi:10.2903/j.efsa.2016.4375

Annex A – Porcine Epidemic Diarrhoea (PED) data reporting guidelines

In the last decade, many porcine epidemic diarrhoea (PED) outbreaks have been reported by several countries in Asia. In Europe, only a few Member States reported PED clinical cases and/or PEDV-seropositive animals within the last 10 years. In 2014, some outbreaks have been reported in Germany and Italy. EFSA published in 2014 a Scientific Opinion of the EFSA Panel on Animal Health and Welfare, on porcine epidemic diarrhoea and emerging porcine deltacoronavirus (http://www.efsa.europa.eu/en/efsajournal/doc/3877.pdf). PED is not an OIE listed disease neither it is notifiable in the EU. EFSA has received a new mandate 'Request for scientific and technical assistance on the collection and review of updated scientific epidemiological data on porcine epidemic diarrhoea (PED)'. In the mandate it is indicated that '…Member States are concerned by the limited and scattered epidemiological data available on PED and expressed the need for more efficient sharing of information on this disease…' and that '…The current epidemiological situation requires risk managers to obtain up-to-date consolidated information on the distribution and consequences of PED in the EU and worldwide…'. The current guidelines have the purpose of harmonising and facilitating data collection in order to elucidate the epidemiological situation and assess the impact of the disease in pig production. Member States (MS) affected by PED are kindly requested to submit data as described in this document.

1. PED dataset – Herd level

Reporting deadlines

1) MS should provide the dataset for all herds affected between **1 January 2013 and March 31, 2015**. This will be used to provide an overview of the PED situation during the last 2.5 years. Dataset should be submitted by **29 May, 2015**.
2) MS should provide an updated dataset for the current situation, with a focus on newly affected herds and previously affected herds with new PED cases between 1 April and September 30, 2015. Updated dataset should be submitted by **10 November 2015.**

2. Objectives

Two Scientific Reports of EFSA will be prepared and published, detailing the epidemiological findings from this work. It is expected that the first one will be issued on July, 1st and the second one on December 15th, 2015. The dataset will be used to obtain information on the presence and epidemiological picture of PED in Europe, including both a temporal (Date of first suspicious report) and a spatial (Country/Region of holding) description of infection with different PED virus strains/types. Whenever possible, the dataset will be complemented with virus sequence data. The impact of the disease on pig production will be quantified based on morbidity and mortality rates as well as the severity of clinical disease.

3. Plan of analysis

Descriptive statistics will be provided on the number of herds with confirmed PED cases, by country, farm system and virus strain. Temporal evaluation of possible epidemiologic trends by virus strain based on date of sampling and spatial evaluation of occurrence by country and/or NUTS region. Within-herd impact analysis considering reported PED morbidity and mortality rates, by farm system. Analysis of results for herd size or production system will only be presented at country or European level to ensure anonymity of affected holdings.

Population: Data should be reported for farmed populations of pigs.

Epidemiological unit: is the herd, all pigs on a holding are considered to represent a herd.

4. Case definition

Confirmed cases:

Following suspicion based on clinical signs (described below), a confirmation of viral infection is necessary, by any of the following tests: RT-PCR, antigen ELISA, immunohistochemistry (IHC), electron microscopy, immunoelectron microscopy or virus isolation. Sample materials: fresh faeces, oral fluids, intestine.

Herd case definition

Any herd with one or more confirmed cases.

5. Required information

- Unique herd identifier – Provide a code to uniquely identify the herd within the reporting country. The code should be designed to ensure the individual holding remains anonymous and should be retained in each data submission (e.g. IT000001, IT000002).
- Location – report the geographical location of the holding

  Countries should be encoded using the standard ISO-3166-1-alpha-2 coding system, described in the COUNTRY catalogue.

  Additional geographical detail about the region where the holding is located can be specified using the Nomenclature of Territorial Units for Statistics (NUTS) code (http://ec.europa.eu/eurostat/web/nuts/overview).
- Date of sample – report the year, month and day when the first confirmed sample was taken for testing at the holding.
- Date when the first clinical signs were observed at the holding - report the year, month and day when the first clinical signs were observed at the holding.
- Clinical signs: clinical presentation can be quite variable, ranging from mild to severe symptoms and mortality. Example clinical signs include
- Suckling piglets (newborn to weaning):

  Very high morbidity (up to 100%), watery, non-mucous-haemorrhagic, fetid diarrhoea containing flocculent undigested milk, vomiting (not in all affected animals). Dehydration and emaciation.
- Weaned pigs (from weaning up to 60-80 days of age):

  Very high morbidity, watery, non-mucous-haemorrhagic diarrhoea, vomiting, anorexia, lethargy, reduction in average daily gain.
- Fatteners (from 70-90 days of age) approx.. 30-40 kg. to slaughter

  and

  Adults (breeding pigs: includes both sows and boars).

  Morbidity up to 90%, watery diarrhoea and vomiting.

  Systemic clinical signs, such as fever, anorexia and lethargy, may also be present.

  Mortality: 0-4%
- Production type
  - Weaner-producer: breeding herd where piglets leave as weaners around 7kg
  - Grower-producer: breeding herd where piglets leave as growers around 30-40kg
  - Breeder-finisher: breeding herd where pigs finish (fatten) on site
  - Nursery: post-weaned pigs kept from weaning around 4 weeks old to 10-12 weeks old

  - Nursery-Finisher: post-weaned pigs kept for the whole rearing period from weaning to finishing (slaughter)
  - Finisher: post-weaned pigs kept for finishing from 10-12 weeks old
  - Gilt unit: post-weaned gilts destined for breeding
  - Boar stud: for AI
  - Sow pool central unit: a breeding unit for sows where they are housed from after weaning until 3-4 weeks before farrowing, when they are transported to satellite herds.
  - Smallholder: includes pet pigs and backyard pigs

- Housing – it should be reported whether animals are kept exclusively in an indoor controlled environment, whether they also have outdoor access or whether they are reared exclusively outdoors.
- Laboratory results – Describe the type of sample, the laboratory test performed and the result of the test. If sequencing of the virus genome has been performed, indicate the database where the sequence can be found. Where samples are pooled for laboratory testing provide the number of samples included in the laboratory sample.
- Herd statistics – the reporting of herd statistics includes information by age group for the number of pigs on the holding, the proportion of pigs with clinical signs, the number of dead pigs, the number of pigs tested and the number of pigs positive for viral detection. For each of the numerical elements where information has been collected and there are no animals within that category report 0, where no information has been collected report -9999.

Element name	Definition	Data type	Mandatory	Catalogue
herdID	Unique identifier for herd	String(50)	Y	
country	Country where the holding is located	String(2)	Y	COUNTRY
NUTScode	Code for region where holding is located using Nomenclature for Territorial Units for Statistics	String(5)	Y	NUTS
NUTSregion	Text for region where holding is located using Nomenclature for Territorial Units for Statistics	String(250)	Y	
productionType	Type of production at the holding	string (50)	Y	weaner-producer/grower-producer/breeder-finisher/nursery/nursery-finisher/finisher/gilt unit/boar stud/smallholder/sow pool central unit/unknown
housing	Type of pig housing	string (50)	Y	indoor controlled environment/indoors with outdoor access/exclusively outdoors/unknown
labID	Identifier for laboratory performing test	string (50)		
anMatText	Material sampled for laboratory testing (if more than one materials were sampled, list them all)	string (250)	Y	faeces/oral fluids /intestine/rectal swabs/ unknown

Element name	Definition	Data type	Mandatory	Catalogue
testType	Test used to confirm PEDV viral infection	string (250)	Y	RT-PCR-Pan-coronavirus RT-PCR-PEDV/TEGV RT-PCR-M-PEDV/TEGV RT-PCR-S1-PEDV RT-PCR-N-PEDV MAb-based sandwich ELISA OtherAntigenELISA Immunohistochemistry Virus isolation Electron microscopy Immunoelectron microscopy
pooled	If samples from multiple animals are pooled for laboratory testing report the number of animals	integer (2)		
sampY	Year when the confirmed sample was taken at the holding	integer (4)	Y	
sampM	Month when the confirmed sample was taken at the holding	integer (2)	Y	
sampD	Day when the confirmed sample was taken at the holding	integer (2)		
signsY	Year when the first clinical signs were observed at the holding	integer (4)		
signsM	Month when the first clinical signs were observed at the holding	integer (2)		
signsD	Day when the first clinical signs were observed at the holding	integer (2)		
suckling	Number of suckling piglets in the herd (newborn to weaning)	Integer(10)	Y	
symptSuckling	Proportion of symptomatic suckling animals in the herd (watery, non-mucous-haemorrhagic, fetid diarrhoea containing flocculent undigested milk, vomiting, dehydration and emaciation) in the 8 weeks after date of first suspicious report	Integer(10)	Y	
deadSuckling	Number of suckling animals in the herd that died (suspected death due to PED) in the 8 weeks after date of first suspicious report	Integer(10)	Y	
sucklingTestPD	Number of suckling animals (or pools) tested for PED by pathogen detection methods in the herd related to the suspicion of disease presence	Integer(10)	Y	
sucklingTestPD Pos	Number of suckling animals (or pools) positive for PED by pathogen detection methods in the herd in testing related to the suspicion of disease presence	Integer(10)	Y	
weaned	Number of weaned pigs in the herd (from weaning up to 60-80 days of age)	Integer(10)	Y	

Element name	Definition	Data type	Mandatory	Catalogue
symptWeaned	Proportion of symptomatic weaned animals in the herd (watery, non-mucous-haemorrhagic diarrhoea, vomiting, anorexia, lethargy, reduction in average daily gain) in the 8 weeks after date of first suspicious report	Integer(10)	Y	
deadWeaned	Number of weaned animals in the herd that died (suspected death due to PED) in the 8 weeks after date of first suspicious report	Integer(10)	Y	
weanedTestPD	Number of weaned animals (or pools) tested for PED by pathogen detection methods in the herd related to the suspicion of disease presence	Integer(10)	Y	
weanedTest PDPos	Number of weaned animals (or pools) positive for PED by pathogen detection methods in the herd in testing related to the suspicion of disease presence	Integer(10)	Y	
adult	Number of sows and boars in the herd, including animals for AI	Integer(10)	Y	
symptAdult	Proportion of symptomatic sows and boars in the herd (fever, watery diarrhoea, anorexia, lethargy, vomiting) in the 8 weeks after date of first suspicious report	Integer(10)	Y	
deadAdult	Number of sows and boars in the herd that died (suspected death due to PED) in the 8 weeks after date of first suspicious report	Integer(10)	Y	
adultTestPD	Number of sows and boars (or pools) tested for PED by pathogen detection methods in the herd related to the suspicion of disease presence	Integer(10)	Y	
adultTestPDPos	Number of sows and boars (or pools) positive for PED by pathogen detection methods in the herd in testing related to the suspicion of disease presence	Integer(10)	Y	
fatteners	Number of fatteners and breeding gilts in the herd	Integer(10)	Y	
symptFatteners	Proportion of symptomatic fatteners and breeding gilts in the herd (fever, watery diarrhoea, anorexia, lethargy, vomiting) in the 8 weeks after date of first suspicious report	Integer(10)	Y	
deadFatteners	Number of fatteners and breeding gilts in the herd that died (suspected death due to PED) in the 8 weeks after date of first suspicious report	Integer(10)	Y	
fattenersTestPD	Number of fatteners and gilts (or pools) tested for PED by pathogen detection methods in the herd related to the suspicion of disease presence	Integer(10)	Y	

Element name	Definition	Data type	Mandatory	Catalogue
fattenersTest PDPos	Number of fatteners and gilts (or pools) positive for PED by pathogen detection methods in the herd in testing related to the suspicion of disease presence	Integer(10)	Y	
durationClinical Signs	Number of days clinical signs were observed within the herd	Integer(10)	Y	
sequenced	Sequence from the virus detected on the holding is available	String (50)	Y	Full length/Partial/Not sequenced/Not available
sequenceID	Id of the sequence in the database	String (250)		
database	Name of database where the sequence is stored	String (250)		
Suspected Source	Free text to describe the possible source of PED infection in the farm (for example incoming animals, connections with other holdings, transporters or slaughter houses)?	String (250)		
diseaseControl	Specific disease control methods applied in the herd and/or relating to transportation of the animals (e.g. cleaning/disinfection of transportation trucks etc.)	String (250)		no specific measures/exposure of sows to piglet faeces/cleaning and disinfection after affected batch is slaughtered/specific measures related to transportation of animals
strain	Information about the strain of PEDV that was confirmed	String (250)		Colorado/2013-like/ Ohio851-like/other

6. Reporting of serological surveys and other testing

This data model is designed to facilitate the reporting and exchange of the results of serological surveys and other PEDV testing not covered by the case definition above (for example negative results or testing of healthy pigs for monitoring or trade purposes). Results can be reported for any time period of testing and for testing of previously stored sera. Outbreaks already included in the Scientific Opinion of the EFSA Panel on Animal Health and Welfare, on porcine epidemic diarrhoea and emerging porcine deltacoronavirus do not need to be reported.

Reporting serological survey: Complete as many of the fields as possible in order to describe fully the study performed, this would include details of the sampling method, the characteristics for the laboratory test and the estimate of the prevalence including confidence intervals. If the study has been published the title of the publication should be reported in progID. Additional rows can be completed to record region, age group or production sector specific prevalence results.

Reporting negative results: Ensure the country and year, the number of herds or animals or samples tested (in the fields sampUnitType and sampUnitSize) and the type of laboratory test are reported. In this case resVal=0.

Other testing results: The results of other laboratory tests for PEDV can be reported at an aggregated level (for example per country, region, monitoring programme or reporting organisation) or alternatively individual laboratory results can be reported (in this case complete resQualValue to indicate a positive or negative result).

For each of the test results described above resInfo must be complete to indicate the reason for performing PEDV testing.

Definitions

progType

Monitoring-active: Active monitoring programme of pathogens based on random sampling strategies of the population of interest, stratified according to the relevant subcategories of the population.

Monitoring-passive: Passive monitoring programme of pathogens results are typically derived from testing of diseased animals.

Surveillance-active: Targeted surveillance involves planned collection of precise field data on the presence of a specific disease or pathogen within a defined population. This kind of surveillance can provide the data required to prove that the specified populations are free of a specific disease. In order to maximize the value of targeted surveillance, it should be based on survey techniques which provide representative samples of the susceptible population of interest.

Surveillance-passive: Passive surveillance is the secondary use of data routinely collected for some other purpose. This would include the retrospective testing of stored sera.

Survey: A study involving a sample of units selected from a larger, well - delineated population. This (target) population is the entire set of units to which findings of the survey are to be extrapolated. The units to examine are to be selected randomly.

Clinical investigations: Results obtained as a result of outbreak investigation for pathogens where no national monitoring or surveillance programme exists.

SampStrategy:

Random sample (Objective sampling): Strategy based on the selection of a random sample from a population on which the data are reported. Random sample is a sample which is taken under statistical consideration to provide representative data.

Risk-based sample (selective sampling): Strategy based on the selection of a random sample from a subpopulation (or more frequently from subpopulations) of a population on which the data are reported. The sampling from each subpopulation may not be proportional: the sample size is proportionally bigger for instance in subpopulations considered at high risk.

Linked to clinical signs (suspect sampling): Selection of an individual product or establishment in order to confirm or reject a suspicion of non-conformity or presence of disease.

Convenience sample (convenient sampling): Strategy based on the selection of a sample for which units are selected only on the basis of feasibility or ease of data collection.

Element Name	Description	Datatype	Mandatory	Catalogue
progId	Study name or code to identify all results from the same study	xs:string (250)	*Y*	
sampStrategy	Strategy used to select sample units for laboratory analysis	xs:string (5)		ST10A-Random sample ST20A-Risk-based sample ST30A-Linked to clinical signs ST40A-Convenience sample
progType	Type of survey	xs:string (5)		K020A-Clinical investigations K023A-Monitoring – active K024A-Monitoring – passive K030A-Surveillance active K031A-Surveillance passive K028A-Survey
sampPoint	Point in the food chain, where the samples were taken.	xs:string (5)		E101A Farm E311A Slaughterhouse
sampUnitType	Type of sampling unit	xs:string (5)	*Y*	G199A animal G200A slaughter batch G202A herd G204A pooled

Element Name	Description	Datatype	Mandatory	Catalogue
sampUnitSize	Number of sampling units tested (sample size)	xs:double	*Y*	
sampCountry	Country where the sample was taken	xs:string (2)	*Y*	COUNTRY
sampArea	Area where the sample was collected	xs:string (5)		NUTS
sampY	Year of sampling.	xs:integer (4)	*Y*	
sampM	Month of sampling. In case the sampling has been performed over a period of time the start date (as month) of sampling should be reported.	xs:integer (2)		
sampMatType	Type of sample taken	xs:string (5)	*Y*	S000A Animal sample S026A Feed sample S027A Environmental sample
sampMatCode	Description of the sample. Where result relates to environmental samples this field can be left blank but sampMatText should be completed	xs:string (50)		A0C9X Breeding pigs A0C9Y Fattening pigs A0C9Z Mixed pig herds A0CAA Breeding piglets A0CAE Fattening piglets A07VC Pig feed A0C74 Boot swabs A0C71 Dust A0F7L Freshwater for animal farming A020P Animal slaughtering products
sampMatText	Text description of the matrix analysed	xs:string (250)		
analysisY	Year when the analysis was completed.	xs:integer (4)	*Y*	
anMatText	Matrix tested	xs:string (250)		faeces/oral fluids/intestine /serum/unknown
labId	Identification code of the laboratory (National laboratory code if available).	xs:string (50)		
paramType	Class of analysis	xs:string (5)	*Y*	P001A Individual
paramCode	Virus tested	xs:string (250)	*Y*	PEDV

Element Name	Description	Datatype	Mandatory	Catalogue
anMethCode	Analytical method	xs:string (5)	*Y*	F080A Enzyme-linked immunosorbent assay (ELISA) F152A Indirect ELISA (I-ELISA) F190A IgG ELISA F191A IgM-capture ELISA (MAC-ELISA) F530A ELISA, Competitive ELISA (C-ELISA) F531A ELISA, Blocking ELISA (B-ELISA) F527A Immunoperoxidase monolayer assay (IPMA) F189A Reverse-transcription PCR (RT-PCR) F537A Immunofluorescence method F155A Immuno Histo Chemistry (ICH) F529A Virus neutralisation test (VN) F193A Seroneutralisation test
anMethText	If available provide details of method performance (specificity, sensitivity)	xs:string (250)		
anMethInfo	If available provide URL or reference for analytical method used	xs:string (250)		
resId	Identification code of an analytical result (a row of the data table) in the transmitted file. This may be used in communications if additional information is needed	xs:string (100)	*Y*	
resVal	Number of samples testing positive or prevalence value	xs:double		
resQualValue	Positive / Negative if individual sample results are reported	xs:string (3)		POS Positive/Present NEG Negative/Absent
resType	Type of result reported	xs:string (250)		Prevalence / N positive
resValUncert	For prevalence values, report confidence intervals if available	xs:string (250)		
resInfo	Free text to describe the reason for performing PED testing (e.g. serological survey, trade purposes)	xs:string (250)	*Y*	