

Terrestrial Animal Health Standards Commission
Report

September 2007

USA Comments

CHAPTER 2.7.13.

NEWCASTLE DISEASE

General Comment and concerns: If this chapter addresses virulent Newcastle disease, then it must be clear that other strains of ND (those with an ICPI less than or equal to 0.7 or which do not have the multiple sequence of basic amino acids) should not be a basis for restricting trade. The United States would like to see this stated upfront because many countries are claiming to be free of *all* strains of ND and thus are refusing to take poultry products from exporting countries that are vND virus free although non-pathogenic ND virus may occur.

In addition, the United States would like the Code chapter on Newcastle disease to be very clear that it refers to virulent ND (as defined in the chapter) when referring to Newcastle disease and that no unjustified trade restrictions should be applied for other forms of ND (those whose ICPI is less than 0.7). Currently as written, some Articles of the Code chapter refer to ND while other Articles refer the vND, and still others refer to both in the same article. While the intent is understood by some, the apparent inconsistency in use of ND and vND is already a source of confusion and is being utilized to restrict or even prohibit trade in poultry and poultry products.

The United States also requests the OIE to draft a short appendix – similar to the appendix on AI inactivation guidelines – specifying the time/temperature parameters for inactivating vND.

Article 2.7.13.1.

1. For the purposes of the international trade, An outbreak of Newcastle Disease (ND) for the purpose of the Terrestrial Code is defined in the Terrestrial Manual is defined as an infection of birds poultry caused by a virus of avian paramyxovirus serotype 1 (APMV-1), termed virulent Newcastle disease virus (vNDV), that meets one of the following criteria for virulence:
 - a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallus gallus*) of 0.7 or greater; or
 - b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term ‘multiple basic amino acids’ refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the

characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.’

~~Viruses classified as APMV-1 are synonymous with Newcastle disease virus (NDV). Those viruses that meet the criteria of virulence to be the cause of ND are termed virulent Newcastle disease virus (vNDV). All other APMV-1s that do not meet the criteria for vNDV are termed low virulent NDV (lvNDV).~~

2. Poultry is defined as ‘all domesticated birds, including backyard poultry, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose’. ~~All backyard and game fowl regardless of use will be defined as poultry.~~

Birds that are kept in captivity for any reason other than those ~~defined as poultry reasons referred to in the preceding paragraph~~, including those that are kept for shows, races, exhibitions, competitions, ~~or sale breeding or selling these categories of birds as well as pet birds~~, are not considered to be poultry.

3. This chapter ~~only~~ deals with vNDV *infection* of ~~birds poultry as defined in point 1 above~~, in the presence or absence of clinical signs. For the purposes of *international trade*, a country should ~~interpret as not impose immediate trade bans in response to reports occurrence of infection with vNDV in birds other than poultry according to the Terrestrial Code and should not impose immediate trade bans, although such infections should be notified.~~
4. ~~The following defines~~ ‘The occurrence of infection with vNDV is defined as the isolation and identification of:
 - a) ~~vNDV has been isolated and identified as such or the detection of viral RNA specific for vNDV has been detected.~~
 - b) 5. For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.
 - c) 6. Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.

Article 2.7.13.2.

The **ND status** of a country, a *zone* or a *compartment* can ~~only~~ be determined ~~and certified~~ on the basis of the following criteria:

Observation: based on the principles of this chapter, the United States understands this to mean the “virulent” ND status of a country; however, other countries may (and are) interpreting this as “any” ND virus. The United States recommends that vND be used throughout the text except in those very specific instances where you may only need to use ND, otherwise, using ND in some places and vND in others generates confusion.

1. **ND is notifiable** in the whole country, an on-going ND awareness programme is in place, and all

notified suspect occurrences of ND are subjected to field and, where applicable, laboratory investigations;

Observations: Again, to highlight the potential confusion, does this mean that any ND virus is reportable or is it the virulent ND? Since the intent is vND, then the text should state vND.

2. appropriate surveillance is in place to demonstrate the presence of vNDV *infection* in the absence of clinical signs in poultry, this may be achieved through an ND surveillance programme in accordance with Appendix 3.8.x.;
3. consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 2.7.13.3.

ND free country, zone or compartment

A country, *zone* or *compartment* may be considered free from ND when it has been shown that vNDV *infection* has not been present in the country, *zone* or *compartment* for the past 12 months, based on surveillance in accordance with Appendix x.x.x. ~~The surveillance may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent outbreaks.~~

If *infection* has occurred in a previously free country, *zone* or *compartment*, ND free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that surveillance in accordance with Appendix x.x.x. has been carried out during that three-month period.

Article 2.7.13.4.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., ~~Veterinary Administrations~~ Authorities should require:

for live poultry (other than day-old poultry)

the presentation of an *international veterinary certificate* attesting that:

1. the poultry showed no clinical sign suggestive of ND on the day of shipment;
2. the poultry were kept in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
3. **the poultry have not been vaccinated against ND;** if the birds were vaccinated against ND, the nature of the vaccine used and the date of vaccination shall be attached to the certificate;

Observation: Many importing countries take action against exporting countries for vaccinating against ND, or require that the birds have not been vaccinated against ND. This phrase should be deleted, or changed to say that the birds were not vaccinated against vND

4. the ~~birds~~ poultry are transported in new or appropriately sanitized containers.

Article 2.7.13.5.

Regardless of the ND status of the country, ~~zone~~ or *compartment* of origin, *Veterinary Administrations Authorities* should require:

for live birds other than poultry

the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical sign suggestive of ND on the day of shipment;
2. the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of *infection with a virus which would be considered ND in poultry* during the isolation period;
3. the birds other than day-old birds were subjected to a diagnostic test ~~7 to~~ within 14 days prior to shipment to demonstrate freedom from *infection with vNDV*, or in the case of day-old birds, a representative sample of birds in the parent flock was subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from infection with vNDV;

Comment/rationale: The United States assumes that the intent of deleting Article 2.7.13.7 below (related to day-old birds other than live poultry) is that Article 2.7.13.5 (regarding importation of all live birds other than poultry) should apply to importation of day-old birds other than poultry as well, thus eliminating the need for a separate Article for day-old birds other than poultry. In the case of *poultry*, separate Articles are provided for live *poultry* other than day-old *poultry* and for day-old *poultry* because the requirements are slightly different. However, the net effect of deleting Article 2.7.13.7 is to require testing of the day-old birds other than *poultry* themselves and to eliminate the requirement for testing of the parent flock at the time of egg collection. Testing day old birds presents challenges that would include animal welfare concerns. One way to remove Article 2.7.13.7 while still retaining the original requirement for testing the parents would be to reword item 3 as shown above.

Also, we are recommending the re-wording of the testing time frame from “test 7 to 14 days prior to shipment” to “test within 14 days prior to shipment” because the current wording would appear the rule out the option of testing within 7 days prior to shipment. When and if feasible, testing as close to shipment as possible is desirable and provides greater assurance on the health status of the birds.

Finally, and as stated in our previous comments we submitted to the Code Commission, the United States strongly urges the OIE to adopt language which clearly states that when testing of “flocks” or “shipments” is being recommended, that such testing be based on a representative sample of that population. Many countries are prone to misinterpret this testing recommendation as a requirement to test *all* birds in the flock or shipment, which is clearly neither the intent of this Article, nor feasible.

4. ~~the birds are transported in new or appropriately sanitized containers~~ the birds have not been vaccinated against ND; if the birds were vaccinated against ND, the nature of the vaccine used and the date of vaccination shall also be attached to the certificate;

5. ~~the birds have not been vaccinated against ND or if the birds were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate~~ the birds are transported in new or appropriately sanitized containers.

Article 2.7.13.6.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., ~~Veterinary Administrations~~ Authorities should require:

for day-old live poultry

the presentation of an *international veterinary certificate* attesting that:

1. the poultry were hatched and kept in an ND free country, *zone* or *compartment*;
2. the poultry were derived from parent flocks which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the poultry have not been vaccinated against ND; if poultry or parent flocks were vaccinated against ND, the nature of the vaccine used and the date of vaccination shall also be attached to the certificate;
4. the ~~birds~~ poultry are transported in new or appropriately sanitized containers.

~~Article 2.7.13.7.~~

~~Regardless of the ND status of the country, zone or compartment, Veterinary Administrations~~ Authorities should require:

for day-old live birds other than poultry

the presentation of an *international veterinary certificate* attesting that:

1. the birds showed no clinical sign suggestive of ND on the day of shipment;
2. the birds were hatched and kept in isolation approved by the *Veterinary Services*;
3. the parent flock birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from infection with vNDV;
4. the birds are transported in new or appropriately sanitized containers;
5. ~~the birds have not been vaccinated against ND or if the birds or parent flocks were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate.~~

Article 2.7.13.~~8~~7.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., ~~Veterinary Administrations~~ Authorities should require:

for hatching eggs from poultry

the presentation of an *international veterinary certificate* attesting that:

1. the eggs came from an ND free country, *zone* or *compartment*;
2. the eggs were derived from parent flocks which had been kept in an ND free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
3. the parent flocks have not been vaccinated against ND; or if parent flocks were vaccinated against ND the nature of the vaccine used and the date of vaccination shall also be attached to the certificate;
4. the eggs are transported in new or appropriately sanitized containers.

Article 2.7.13.98.

Regardless of the ND status of the country, *zone* or *compartment* origin, *Veterinary Administrations Authorities* should require:

for hatching eggs from birds other than poultry

the presentation of an *international veterinary certificate* attesting that:

1. a representative sample of birds of the parent flock birds were subjected to a diagnostic test 7 days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with vNDV;

Comment/rationale: The United States strongly urges the OIE to adopt language which clearly states that when testing of “flocks” or “shipments” is being recommended, that such testing be based on a representative sample of that population. Many countries are prone to misinterpret this testing recommendation as a requirement to test *all* birds in the flock or shipment, which is clearly neither the intent of this Article, nor feasible.

2. the ~~birds~~ eggs are transported in new or appropriately sanitized containers;
3. the parent flocks have not been vaccinated against ND; if parent flocks were vaccinated against ND, the nature of the vaccine used and the date of vaccination shall also be attached to the certificate.

Article 2.7.13.109.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., *Veterinary Administrations Authorities* should require:

for poultry eggs for human consumption

the presentation of an *international veterinary certificate* attesting that:

1. the eggs were produced and packed in an ND free country, *zone* or *compartment*;
2. the eggs are transported in new or appropriately sanitized packing material.

Article 2.7.13.110.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., ~~Veterinary Administrations~~ Authorities should require:

for poultry egg products

the presentation of an *international veterinary certificate* attesting that:

1. the egg products come from, and were processed in, an ND free country, *zone* or *compartment*;
2. the egg products are transported in new or appropriately sanitized containers.

Article 2.7.13.111.

~~Regardless of the ND status of the country, *zone* or *compartment* of origin~~ When importing from a country, *zone* or *compartment* not considered free from ND, ~~Veterinary Administrations~~ Authorities should require:

for poultry egg products

the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* is processed to ensure the destruction of vNDV([under study](#));
2. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of vNDV;
3. the egg products are transported in new or appropriately sanitized containers.

Comment/rationale: Studies are now available to demonstrate the inactivation of NDV in egg products (see Swayne, David E. and Beck, Joan R., Heat inactivation of avian influenza and Newcastle disease viruses in egg products; *Avian Pathology*, October 2004; **33(5)**, 512-518).

Article 2.7.13.112.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., ~~Veterinary Administrations~~ Authorities should require:

for poultry semen

the presentation of an *international veterinary certificate* attesting that the donor poultry:

1. showed no clinical sign suggestive of ND on the day of semen collection;
2. were kept in an ND free country, *zone* or *compartment* for at least the 21 days prior to and at the time of semen collection.

Article 2.7.13.1413.

Regardless of the ND status of the country, *zone* or *compartment* of origin, *Veterinary Administrations Authorities* should require:

for semen of birds other than poultry

the presentation of an *international veterinary certificate* attesting that the donor birds:

1. were kept in isolation approved by the *Veterinary Services* for at least the 21 days prior to and on the day of semen collection;
2. showed no clinical sign suggestive of *infection with vNDV* during the isolation period and on the day of semen collection;
3. were subjected to a diagnostic test ~~7 to~~ within 14 days prior to semen collection to demonstrate freedom from *infection* with vNDV.

Comment/rationale: we are recommending the re-wording of the testing time frame from “test 7 to 14 days prior to collection” to “test within 14 days prior to collection” because the current wording would appear the rule out the option of testing within 7 days prior to shipment. When feasible, testing as close to collection as possible is desirable and provides greater assurance on the health status of the birds.

Article 2.7.13.1514.

When importing from an ND free country, *zone* or *compartment* as defined in Article 2.7.13.3., *Veterinary Administrations Authorities* should require:

for fresh meat of poultry

the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from birds:

1. which have been kept and slaughtered in an ND free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
2. which have been slaughtered in an *approved abattoir* and have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1. and have been found free of any sign suggestive of ND.

Article 2.7.13.1615.

When importing from an ND free country, *zone* or *compartment*, *Veterinary Authorities* should require:

for meat products of poultry

the presentation of an *international veterinary certificate* attesting that:

1. the commodity is derived from fresh meat which meets the requirements of Article 2.7.13.14 and has been processed in an ND free country, zone or compartment;

Comment/rationale: Renumbering of the Articles due to deletion of Article 2.7.13.7 needs to carry through the document –

2. the necessary precautions were taken to avoid contact of the commodity with any source of vNDV.

Article 2.7.13.16.

When importing from a country, zone or compartment not considered free from ND. Regardless of the ND status of the country, zone or compartment of origin, Veterinary Administrations Authorities should require:

for meat products of poultry

the presentation of an *international veterinary certificate* attesting that:

1. the entire consignment of meat comes from animals which have been slaughtered in an approved abattoir and have been subjected to ante-mortem and post-mortem inspections in accordance with Appendix 3.10.1, and have been found free of any signs suggestive of ND;

Comment/rationale: Added the wording “in accordance with Appendix 3.10.1” for consistency with Article 2.7.13.14.

2. the commodity is derived from fresh meat which meet the requirements of Article 2.7.13.15 (fresh meat) and has been processed in an ND free country, zone or compartment; or the commodity has been processed to ensure the destruction of vNDV (under study);

Comment/rationale: previous data submitted should allow the “under study” note to be removed.

23. the necessary precautions were taken to avoid contact of the commodity with any source of vNDV.

Article 2.7.13.17.

When importing from a ND free country, zone or compartment, Veterinary Authorities should require:

for products of poultry origin intended for use in animal feeding, or for agricultural or industrial use

the presentation of an international veterinary certificate attesting that:

1. the commodities come from poultry which have been kept and processed in an ND free country, zone or compartment since they were hatched or for at least the past 21 days;

2. the necessary precautions were taken to avoid contact of the commodity with any source of vNDV;

Article 2.7.13.17.bis

When importing from a country, zone or compartment not considered free from ND **Regardless of the ND status of the country, zone or compartment of origin,** *Veterinary Administrations Authorities* should require:

for products of poultry origin intended for use in animal feeding, or for agricultural or industrial use

the presentation of an *international veterinary certificate* attesting that:

1. **these commodities come from poultry which have been kept and processed in an ND free country, zone or compartment since they were hatched or for at least the past 21 days; or** these *commodities* have been processed to ensure the destruction of vNDV (~~under study~~);
2. the necessary precautions were taken to avoid contact of the *commodity* with any source of vNDV.

Comment/rationale: The OIE is proposing Article 2.7.13.17 as a new proposed article and Article 2.7.13.17 bis as an altered article. The United States believes that the original Article 2.7.13.17 should be retained unchanged because regardless of whether an exporting country is free of vNDV or not, importing countries must be assured of the absolute safety of by-products such as rendered offal. Such poultry by-products should come from compartments or establishments that are free from ND and the by-products should be processed (rendered, or otherwise thermally treated) sufficiently to remove all pathogens (including, but not limited to vNDV, NAI, Salmonella, and so forth) prior to entering international commerce. Retaining the original language makes Chapter 2.7.13 consistent with Code Chapter 2.7.12 on Avian Influenza.

We also request that the term “under study” be removed because there is enough data, experimental and circumstantial, to support removing the term (please refer to attached supporting manuscript by Swayne, *et al* accepted January 30, 2008 for publication in the *Journal of Food Protection*).

Article 2.7.13.18.

Regardless of the ND status of the country, ~~zone~~ or *compartment* of origin, *Veterinary Administrations Authorities* should require:

for feathers and down

the presentation of an *international veterinary certificate* attesting that:

1. these *commodities* come from poultry which have been kept and processed in an ND free country, ~~zone~~ or *compartment* since they were hatched or for at least the past 21 days; or these *commodities* have been processed to ensure the destruction of vNDV (under study);
2. the necessary precautions were taken to avoid contact of the *commodity* with any source of vNDV.

Article 2.7.13.19.

Regardless of the ND status of the country, ~~zone~~ or *compartment*, *Veterinary Administrations* *Authorities* should require for the importation of:

meat or other products from birds other than poultry

the presentation of an *international veterinary certificate* attesting that:

1. the *commodity* has been processed to ensure the destruction of vNDV (under study);
2. the necessary precautions were taken after processing to avoid contact of the *commodity* with any source of vNDV.