PART 1 (COUNCIL DECISION 2002/813/EC)

SUMMARY NOTIFICATION INFORMATION FORMAT FOR THE RELEASE OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS IN ACCORDANCE WITH ARTICLE 11 OF DIRECTIVE 2001/18/EC

In order to tick one or several possibilities, please use crosses (meaning x or X) into the space provided as (.)

A. General information

1. Details of notification

(a)	Member State of notification	NL
(b)	Notification number	B/NL/15/011
(c)	Date of acknowledgement of notification	23/11/2015
(d)	Title of the project	Vaccination of chickens with a herpes virus of turkey vaccine with inserted the F-gene of Newcastle Disease Virus and the VP2 gene of Infectious Bursal Disease Virus.
(e)	Proposed period of release	From 01/Jan/2016 until 31/Dec/2018

2. Notifier

Name of institution or company: Intervet International bv.

3. GMO characterization

(a) Indicate whether the GMO is a:

viroid	(.)
RNA virus	(.)
DNA virus	(X)
bacterium	(.)
fungus	(.)
animal	
- mammals	(.)
- insect	(.)
- fish	(.)
- other animal	(.)

specify phylum, class …

(b) Identity of the GMO (genus and species)
The Innovax-ND-IBD vaccine contains the live cell-associated Herpesvirus of Turkey (HVT) strain HVP360 in a cell-associated form. This is a vector vaccine: the HVP360 virus strain was generated by inserting the F-gene of Newcastle Disease Virus (NDV) and the VP2 gene of Infectious Bursal Disease Virus (IBDV) into the HVT strain FC-126 genome.

HVT belongs to the virus family *Herpesviridae*, subfamily *Alphaherpesvirinae*, genus "Marek's disease-like viruses" (also known as the genus Mardivirus).

(c) Genetic stability – according to Annex IIIa, II, A(10)
The recipient organism, HVT FC-126 strain, has been isolated from a commercial turkey flock and found to be non-pathogenic for both turkeys and chickens.
Genetic stability of the GMO (strain HVP360) was confirmed after five passages in chickens.

4. Is the same GMO release planned elsewhere in the Community (in conformity with Article 6(1)), by the same notifier?

Yes (.) No (X)

If yes, insert the country code(s)

5. Has the same GMO been notified for release elsewhere in the Community by the same notifier?

Yes (.) No (X)

If yes:
- Member State of notification …
- Notification number B/../../…

Please use the following country codes:
Austria AT; Belgium BE; Germany DE; Denmark DK; Spain ES; Finland FI; France FR; United Kingdom GB; Greece GR; Ireland IE; Iceland IS; Italy IT; Luxembourg LU; Netherlands NL; Norway NO; Portugal PT; Sweden SE

6. Has the same GMO been notified for release or placing on the market outside the Community by the same or other notifier?

Yes (.) No (X)

If yes:
- Member State of notification …
- Notification number B/../../…

7. Summary of the potential environmental impact of the release of the GMOs.
No environmental impact is expected.
The environmental risk assessment concerns the vaccine Innovax-ND-IBD containing live HVT virus strain HVP360.
- HVT is a non-pathogenic virus. Its natural host is the turkey but the virus can also replicate in chickens. Replication in other avian species is very unlikely and only occasionally observed. HVT causes no clinical disease in turkeys, chickens and other avian species. The virus can spread via inhalation of dust particles shed from the skin from infected (or vaccinated) birds to turkeys, but spreading to chickens is highly unlikely. Shedding from vaccinated chickens is limited and transient in nature.
- Genetic modifications made by introducing the NDV and IBDV genes, resulted in reduced shedding from the feather follicles, and did otherwise not change the phenotype of the parent virus and the recombinant is therefore still non-pathogenic.
- The vaccine virus was shown to be genetically stable.
- HVP360 or HVT are not capable of replicating in mammalian cells.

As the virus is non-pathogenic, the level of risk for both humans and the environment for Innovax-ND-IBD can be considered as effectively zero.

B. **Information relating to the recipient or parental organism from which the GMO is derived**

1. Recipient or parental organism characterisation:

(a) Indicate whether the recipient or parental organism is a:

(select one only)

viroid	(.)
RNA virus	(.)
DNA virus	(X)
bacterium	(.)
fungus	(.)
animal	
- mammals	(.)
- insect	(.)
- fish	(.)
- other animal	(.)
(specify phylum, class)	…

other, specify …

2. Name

(i)	order and/or higher taxon (for animals)	Herpesvirales
(ii)	genus	Mardivirus ("Marek's disease like viruses")
(iii)	species	Meleagrid herpesvirus 1 (Herpes virus of turkeys)
(iv)	subspecies	…
(v)	strain	Herpes virus of Turkeys (HVT) strain FC-126
(vi)	pathovar (biotype, ecotype, race, etc.)	…
(vii)	common name	HVT

3. Geographical distribution of the organism

(a) Indigenous to, or otherwise established in, the country where the notification is made:
Yes (X) No (.) Not known (.)

(b) Indigenous to, or otherwise established in, other EC countries:
(i) Yes (X)

If yes, indicate the type of ecosystem in which it is found:
HVT is not found in one particular ecosystem by is widely spread (through vaccination) in chickens

Atlantic ..
Mediteranean ..

	Boreal	..
	Alpine	..
	Continental	..
	Macaronesian	..
(ii)	No	(.)
(iii)	Not known	(.)

(c) Is it frequently used in the country where the notification is made?
Yes (X) No (.)

HVT is a ubiquitous non-pathogenic virus and the natural habitat is turkeys. It has been used worldwide for more than 35 years in the poultry industry for the vaccination of chickens against Marek's disease. Vaccines containing the HVT FC-126 strain are also registered in The Netherlands (Nobilis Marexine CA126 and Nobilis Rismavac+CA126).

(d) Is it frequently kept in the country where the notification is made?
Yes (X) No (.)

4. Natural habitat of the organism

(a) If the organism is a microorganism

water	(.)
soil, free-living	(.)
soil in association with plant-root systems	(.)
in association with plant leaf/stem systems	(.)
other, specify …	

HVT is a ubiquitous non-pathogenic virus and the natural habitat is turkeys.

(b) If the organism is an animal: natural habitat or usual agroecosystem:
Not applicable

5. (a) Detection techniques
The virus can be grown in primary or secondary cultures of chicken cells such as embryonic fibroblasts, and causes a typical cytopathic effect (CPE). These plaques can be seen macroscopically or visualized by Giemsa-, Naphtalene black- or serospecific-staining. HVT in blood samples from infected chickens can be identified by plating lymphocytes on monolayers of primary or secondary chicken cells. Detection can also be performed on DNA extracted from the virus using the polymerase chain reaction (PCR).

(b) Identification techniques
HVT virus can be identified by labeling viral foci with the aid of the immuno-fluorescence method using specific anti-HVT antibodies. Alternatively, detection can be performed on DNA extracted from the infected cells/virus using the polymerase chain reaction (PCR). A primer set composed of HVT genome specific primers can be used to specifically detect HVT.

6. Is the recipient organism classified under existing Community rules relating to the protection of human health and/or the environment?

Yes (.) No (X)

If yes, specify

7. Is the recipient organism significantly pathogenic or harmful in any other way (including its extracellular products), either living or dead?

Yes (.) No (X) Not known (.)

If yes:

(a) to which of the following organisms:

humans (.)
animals (.)
plants (.)
other (.)

(b) give the relevant information specified under Annex III A, point II. (A)(11)(d) of Directive 2001/18/EC

…

8. Information concerning reproduction

(a) Generation time in natural ecosystems:
The natural host is turkey. The generation time in the natural host and in chickens is not exactly known, but can be estimated between 12 and 48 hours. HVT causes a persistent infection in turkey and can be detected during the whole life of the animal. Spreading of the virus between turkeys occurs through the release of dust particles from feather follicles.

(b) Generation time in the ecosystem where the release will take place:
The generation time in chickens is not exactly known, but can be estimated between 12 and 48 hours. HVT causes a persistent infection in chickens and can be detected during the whole life of the animal. Spreading of the virus between chickens is highly unlikely.

(c) Way of reproduction: Sexual .. Asexual X..

(c) Factors affecting reproduction:
Host dependent replication.

9. Survivability

(a) ability to form structures enhancing survival or dormancy:

(i) endospores (.)
(ii) cysts (.)
(iii) sclerotia (.)

(iv)	asexual spores (fungi)	(.)
(v)	sexual spores (funghi)	(.)
(vi)	eggs	(.)
(vii)	pupae	(.)
(viii)	larvae	(.)
(ix)	other, specify …	

None

(b) relevant factors affecting survivability:
HVT vaccine viruses are being produced in chicken embryo fibroblast (CEF) cells and stored in liquid nitrogen. The virus can only survive in viable CEF cells. Factors that influence the survival of CEF cells (high temperatures, desiccation, pH, etc.) also affect the stability of the virus.
After vaccination of chickens the virus could spread via dust from the feather follicles. These dust particles can be relatively stable and may retain infectious virus for longer periods of time.

10. (a) Ways of dissemination
Even though highly unlikely, after vaccination of chickens the virus could spread to other chickens via dust from the feather follicles. Infection through inhalation of dust is the natural way of infection but this was not experimentally demonstrated in chickens. Spread of HVT is only seen in turkeys and is normally not observed in other avian species such as chickens.

(b) Factors affecting dissemination
The dissemination is host dependent. Spread of HVT is only seen in turkeys, but normally not observed in other avian species such as chickens.

11. Previous genetic modifications of the recipient or parental organism already notified for release in the country where the notification is made (give notification numbers)
B/NL/11/006

C. **Information relating to the genetic modification**

1. Type of the genetic modification

(i)	insertion of genetic material	(X)
(ii)	deletion of genetic material	(.)
(iii)	base substitution	(.)
(iv)	cell fusion	(.)
(v)	others, specify …	

2. Intended outcome of the genetic modification
The inserted F-gene of NDV and VP2 gene of IBDV will be transcribed and express the F-protein and VP-2 protein after vaccination with HVP360 which will induce an immune response against Newcastle disease (ND) and Infectious Bursal Disease (IBD).

3. (a) Has a vector been used in the process of modification?

Yes (X) No (.)

If no, go straight to question 5.

(b) If yes, is the vector wholly or partially present in the modified organism?
Yes (.) No (X)

If no, go straight to question 5.

4. If the answer to 3(b) is yes, supply the following information

(a) Type of vector

plasmid (.)
bacteriophage (.)
virus (.)
cosmid (.)
transposable element (.)
other, specify …

(b) Identity of the vector
…

(c) Host range of the vector
…

(d) Presence in the vector of sequences giving a selectable or identifiable phenotype
Yes (.) No (.)

antibiotic resistance (.)
other, specify …

Indication of which antibiotic resistance gene is inserted
…

(e) Constituent fragments of the vector
…

(f) Method for introducing the vector into the recipient organism

(i) transformation (.)
(ii) electroporation (.)
(iii) macroinjection (.)
(iv) microinjection (.)
(v) infection (.)
(vi) other, specify …

5. If the answer to question B.3(a) and (b) is no, what was the method used in the process of modification?

(i) transformation (.)
(ii) microinjection (.)
(iii) microencapsulation (.)
(iv) macroinjection (.)
(v) other, specify:
Homologous recombination

6. Composition of the insert

(a) Composition of the insert
Genomic/DNA fragment of the F-gene of NDV and a DNA/genomic fragment of the VP2-gene of IBDV with regulatory (promotor and terminator) sequences, respectively.

(b) Source of each constituent part of the insert
The inserted cassette is composed of NDV, IBDV, cytomegalovirus (CMV) and simian virus 40 (SV40) sequences.

(c) Intended function of each constituent part of the insert in the GMO
The inserted region contains the F-gene of NDV, the VP2-gene of IBDV and promoter and terminator sequences.
The inserted F- and VP2-gene are transcribed and express proteins which induce an immune response against ND and IBD in vaccinated chickens.
The function of the promoter sequences is to facilitate the transcription of the F-gene and VP2-gene and the function of the terminator sequences is to facilitate termination of transcription.

(d) Location of the insert in the host organism

- on a free plasmid (.)
- integrated in the chromosome (.)
- other, specify …

Integrated in the viral genome.

(e) Does the insert contain parts whose product or functions are not known?
Yes (.) No (X)
If yes, specify …

D. Information on the organism(s) from which the insert is derived

Insert 1: F-gene of NDV
1. Indicate whether it is a:

viroid (.)
RNA virus (X)
DNA virus ()
bacterium (.)
fungus (.)
animal

- mammals (.)
- insect (.)
- fish (.)
- other animal (.)
(specify phylum, class) …

other, specify …

2. Complete name

(i)	order and/or higher taxon (for animals)	Mononegavirales
(ii)	family	Paramyxoviridae
(iii)	genus	Avulavirus
(iv)	species	Newcastle disease virus/Avian paramyxovirus 1
(v)	subspecies	…
(vi)	strain	Clone 30
(vii)	cultivar/breeding line	…
(viii)	pathovar	…
(ix)	common name	Newcastle disease virus

3. Is the organism significantly pathogenic or harmful in any other way (including its extracellular products), either living or dead?

Yes (.) No (X) Not known (.)

The organism from which the insert is derived is a NDV vaccine strain.

If yes, specify the following:

+

+6

(a) to which of the following organisms:

humans (.)
animals (.)
plants (.)
other ..

(b) are the donated sequences involved in any way to the pathogenic or harmful properties of the organism

Yes (.) No (.) Not known (.)

If yes, give the relevant information under Annex III A, point II(A)(11)(d):

…

4. Is the donor organism classified under existing Community rules relating to the protection of human health and the environment, such as Directive 90/679/EEC on the protection of workers from risks to exposure to biological agents at work?

Yes (X) No (.)

If yes, specify …

According to EU Directive 2000/54/EC, NDV is considered as a class 2 organism. Exposure of humans to infected birds can cause mild conjunctivitis, but NDV otherwise poses no hazard to human health.

5. Do the donor and recipient organism exchange genetic material naturally?
Yes (.) No (X) Not known (.)

Insert 2: VP2-gene of IBDV

1. Indicate whether it is a:

viroid	(.)	
RNA virus	(X)	
DNA virus	()	
bacterium	(.)	
fungus	(.)	
animal		
- mammals	(.)	
- insect	(.)	
- fish	(.)	
- other animal	(.)	
(specify phylum, class)		…
other, specify	…	

2. Complete name

(a)	order and/or higher taxon (for animals)	…
(ii)	family	Birnaviridae
(iii)	genus	Avibirnavirus
(iv)	species	Infectious bursal disease virus
(v)	subspecies	…
(vi)	strain	52/70 Faragher strain
(vii)	cultivar/breeding line	…
(viii)	pathovar	…
(ix)	common name	…

3. Is the organism significantly pathogenic or harmful in any other way (including its extracellular products), either living or dead?
Yes (.) No (X) Not known (.)
The organism from which the insert is derived is an IBDV vaccine strain.

If yes, specify the following:

(b) to which of the following organisms:

humans	(.)
animals	(.)
plants	(.)
other	..

(b) are the donated sequences involved in any way to the pathogenic or harmful properties of the organism

Yes (.) No (X) Not known (.)

If yes, give the relevant information under Annex III A, point II(A)(11)(d):
…

4. Is the donor organism classified under existing Community rules relating to the protection of human health and the environment, such as Directive 90/679/EEC on the protection of workers from risks to exposure to biological agents at work?

Yes (.) No (X)

If yes, specify …

5. Do the donor and recipient organism exchange genetic material naturally?

Yes (.) No (X) Not known (.)

E. Information relating to the genetically modified organism

1. Genetic traits and phenotypic characteristics of the recipient or parental organism which have been changed as a result of the genetic modification

(a) is the GMO different from the recipient as far as survivability is concerned?

Yes (.) No (X) Not known (.)

Specify …

The amount of virus shedding is reduced as the amount of virus particles in the feather follicles are reduced. Other than that, there is no difference in survivability of the GMO compared to the recipient HVT: the virus has the same properties as described under B.9.b.

(b) is the GMO in any way different from the recipient as far as mode and/or rate of reproduction is concerned?

Yes (.) No (X) Unknown (.)

Specify …

The in-vitro growth characteristics of HVP360 are not different from the recipient HVT FC-126. The GMO is propagated like the recipient in chicken embryo fibroblasts (CEF) and no differences are observed concerning infectivity rate and growth (plaque formation).

For in-vivo growth characteristics see also (c).

(c) is the GMO in any way different from the recipient as far as dissemination is concerned?

Yes (.) No (X) Not known (.)

Specify …

Dissemination of HVP360 in chickens was studied in comparison to the recipient HVT FC-126 strain; there were no apparent qualitative differences between HVP360 and HVT FC-126 in terms of virus localization and chronology of virus appearance in tissues tested in this study except for a lower viral content in feather follicles.

Therefore, the dissemination rate of the GMO form vaccinated chickens is decreased compared to the parent virus.

(d) is the GMO in any way different from the recipient as far as pathogenicity is concerned?
Yes (.) No (X) Not known (.)
Specify …
HVP360 is still non-pathogenic when inoculated at a high dose into chickens. Studies on the effect of HVP360 (in comparison to HVT FC-126) after subcutaneous inoculation of a high dose in non-target avian species such as quail, pheasants, and turkeys showed that the GMO, similar to HVT, is non-pathogenic in non-target species.

2. Genetic stability of the genetically modified organism
Studies have been performed to demonstrate the genetic stability of HVP360. The virus is genetically stable during passage on cells and through chickens.

3. Is the GMO significantly pathogenic or harmful in any way (including its extracellular products), either living or dead?
Yes (.) No (X) Unknown (.)

(a) to which of the following organisms?

humans (.)
animals (.)
plants (.)
other …

(b) give the relevant information specified under Annex III A, point II(A)(11)(d) and II(C)(2)(i)
…

4. Description of identification and detection methods

(a) Techniques used to detect the GMO in the environment
The virus can be grown in primary or secondary cultures of chicken cells such as embryonic fibroblasts, and causes a typical cytopathic effect (CPE). These plaques can be seen macroscopically or visualized by Giemsa-, Naphtalene black- or serospecific-staining. HVP360 in blood samples from infected chickens can be identified by plating lymphocytes on monolayers of primary chicken cells. Detection can also be performed on DNA extracted from the virus using the polymerase chain reaction (PCR).

(b) Techniques used to identify the GMO
HVP360 virus can be visualized by labeling viral foci with the aid of the immuno-fluorescence method using specific HVT antibodies or antibodies raised against the F-protein or VP2-protein. Alternatively, detection can be performed on DNA extracted

from the virus using the polymerase chain reaction (PCR). Specific primers in the HVT genome and F-gene/VP2 gene regions can be selected for this purpose.

F. Information relating to the release

1. Purpose of the release (including any significant potential environmental benefits that may be expected)
The vaccine Innovax-ND-IBD will be used in the Netherlands for the active immunization of chickens against ND, IBD and Marek's disease. The purpose of the release applied for is to perform a field trial to support the application for registration of the vaccine in the EU.

2. Is the site of the release different from the natural habitat or from the ecosystem in which the recipient or parental organism is regularly used, kept or found?
Yes (.) No (X)
If yes, specify …

3. Information concerning the release and the surrounding area

Site 1:

(a) Geographical location (administrative region and where appropriate grid reference):
Oeffelt, Boxmeer, The Netherlands

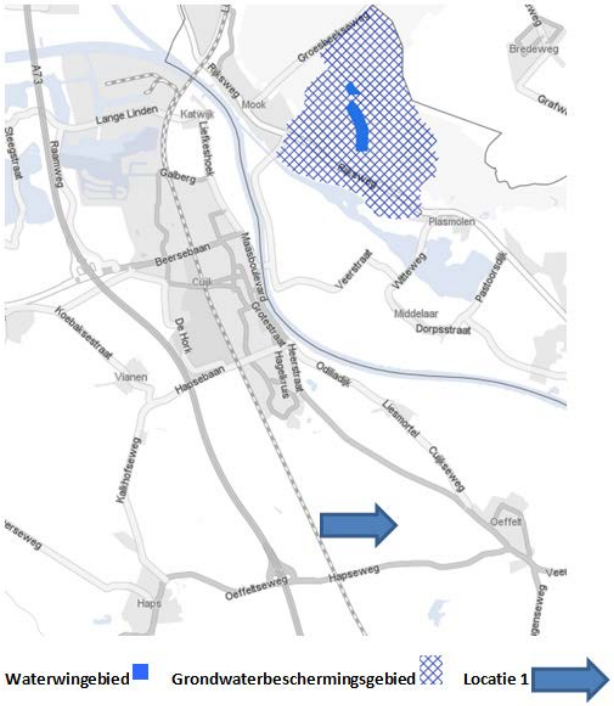
(b) Size of the site (m^2): 9000 m^2
(i) actual release site (m^2): 769 m^2
(ii) wider release site (m^2): 8231 m^2

(e) Proximity to internationally recognised biotopes or protected areas (including drinking water reservoirs), which could be affected:
Approx. 2.4 km (from border "Oeffelter Meent" (Habitatrichtlijngebied), see map I below).
Approx. 4 km from border "Waterwin- en/of grondwaterbeschermingsgebied" at the other side of the river Maas, see map II below).

Map I


A77
Habitatrichtlijngebied
Vogel en habitatrichtlijngebied
Locatie 1

Map II


Bredeweg
Lange Linden
Katwijk
Mook
Plasmolen
Beersebaan
Cuijk
Middelaar
Dorpsstraat
Vianen
Haps
Oeffelseweg
Hapseweg
Oeffet
Waterwingebied
Grondwaterbeschermingsgebied
Locatie 1

(f) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO

Broilers are kept in 2 other houses on the site. No turkey farm is located within a radius of ± 5 km from the location. Interaction of the GMO with migratory species will be very unlikely to occur.

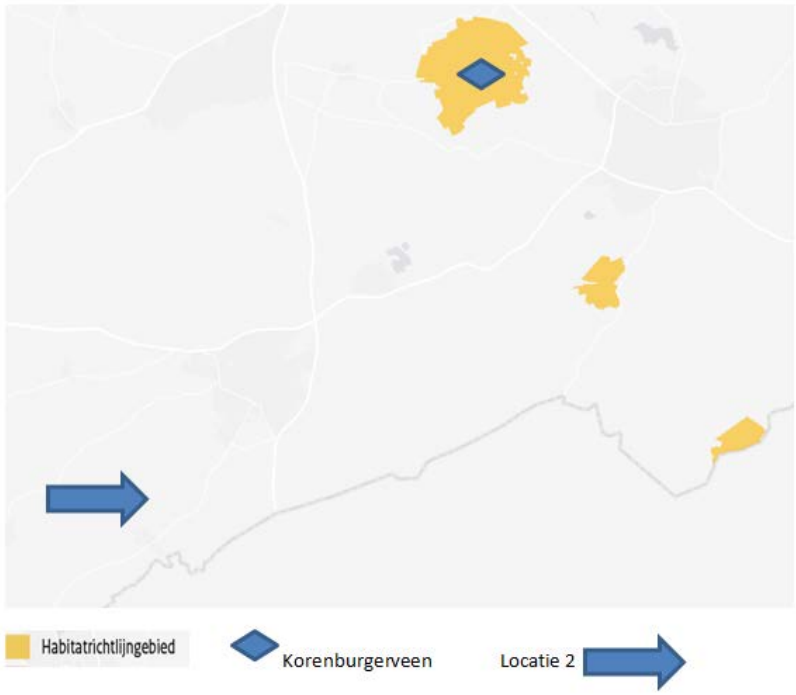
Site 2:

(a) Geographical location (administrative region and where appropriate grid reference): Aalten, Aalten, The Netherlands

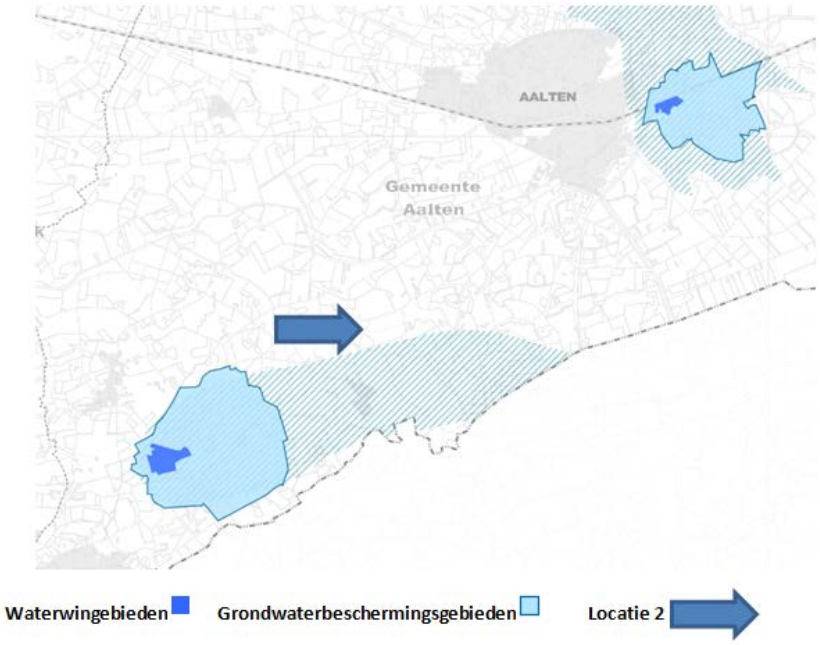
(b) Size of the site (m^2): 26200 m^2
(i) actual release site (m^2): 565 m^2
(ii) wider release site (m^2): 25635 m^2

(g) Proximity to internationally recognised biotopes or protected areas (including drinking water reservoirs), which could be affected:
Approx. 9 km (from border “Korenburgerveen” (Habitatrichtlijngebied), see map I below).
Approx. 1.6 km (from border “Waterwin- en/of grondwaterbeschermingsgebied”, see map II below).

Map I



Map II



(h) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO
Broilers are kept in 3 other houses on the site. No turkey farm is located within a radius of ± 20 km from the location. Interaction of the GMO with migratory species will be very unlikely to occur.

4. Method and amount of release

(a) Quantities of GMOs to be released:
A maximum of 60.000 chickens will be vaccinated that is 60.000 doses (~5000 pfu/dose)

(b) Duration of the operation:
Birds will be vaccinated once and kept for maximum 10 weeks

(c) Methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of the release
Standard business operations will be applied.

5. Short description of average environmental conditions (weather, temperature, etc.)
The start of the trail is planned for Q1/Q2 2016. This is the winter/spring period in the Netherlands which has a European or maritime climate (gematigd zeeklimaat) with average temperatures of 5-9.5°C, average precipitation of 30-90 mm per month and an average of 110-200 sun hours per month in March/April.

6. Relevant data regarding previous releases carried out with the same GMO, if any, specially related to the potential environmental and human health impacts from the release.
Not applicable.

G. Interactions of the GMO with the environment and potential impact on the environment, if significantly different from the recipient or parent organism

The interaction of the GMO with the environment is not different from the recipient organism HVT FC-126. The HVT FC-126 vaccine strain has been safely used worldwide for more than 35 years in the poultry industry for the vaccination of chickens against Marek's disease.

1. Name of target organism (if applicable)

(i)	order and/or higher taxon (for animals)	Galliformes
(ii)	family name	Phasianidae
(iii)	genus	Gallus
(iv)	species	Gallus Gallus
(v)	subspecies	G. Gallus domesticus
(vi)	strain	na
(vii)	cultivar/breeding line	na
(viii)	pathovar	na
(ix)	common name	na

2. Anticipated mechanism and result of interaction between the released GMOs and the target organism (if applicable)
Vaccination of chickens with Innovax-ND-IBD will induce active immunity against Newcastle Disease, Infectious Bursal Disease and Marek's Disease.

3. Any other potentially significant interactions with other organisms in the environment
The GMO is non-pathogenic and spreading of the GMO between chickens is highly unlikely to occur.

4. Is post-release selection such as increased competitiveness, increased invasiveness for the GMO likely to occur?
Yes (.) No (X) Not known (.)
Give details
Back passage studies in chicken have demonstrated the GMO does not become virulent upon passaging.

5. Types of ecosystems to which the GMO could be disseminated from the site of release and in which it could become established
The natural host of HVT is the turkey. This means that HVT or the GMO can infect turkeys via the natural route (via inhalation of feather follicle dust). The GMO is non-pathogenic for turkeys. If spreading to turkey would occur, this would not cause harm to the turkey. Spreading to turkeys is very unlikely to occur as no turkey farm is located with a radius of 5 km of the location.

6. Complete name of non-target organisms which (taking into account the nature of the receiving environment) may be unintentionally significantly harmed by the release of the GMO.

Not applicable

(i) order and/or higher taxon (for animals) …
(ii) family name for plants …
(iii) genus …
(iv) species …
(v) subspecies …
(vi) strain …
(vii) cultivar/breeding line …
(viii) pathovar …
(ix) common name …

7. Likelihood of genetic exchange in vivo

(a) from the GMO to other organisms in the release ecosystem:
Transfer or exchange of genetic material from other organisms has never been observed for HVT.
The HVT backbone of HVP360 has been modified by the insertion of a fragment containing the F-gene of NDV and the VP2-gene of IBDV. There have been no gene deletions. The phenotype of this vaccine strain is the same as that of the HVT FC-126 backbone. The potential for recombination of HVP360 with a wild type HVT could only result in the virus reverting to the wild state (i.e. losing the inserted F- and VP2 genes), which would result in the wild type HVT which is also non-pathogenic.
The potential for recombination of the HVP360 with virulent Marek's Disease virus would be no greater than can occur with current vaccines containing HVT. HVT is commonly present in vaccinated chickens that may become "double-infected" with virulent MDV. Further, serotype 3 (HVT) is often given with serotype 2 and/or serotype 1 strains as a polyvalent vaccine. As there have never been reports on the recombination of HVT with either the virulent MDV or the serotype 2, this possibility can be considered extremely small.

(b) from other organisms to the GMO:
Transfer or exchange of genetic material with other organisms has never been observed for HVT.

(c) likely consequences of gene transfer:
See answer under a.

8. Give references to relevant results (if available) from studies of the behaviour and characteristics of the GMO and its ecological impact carried out in stimulated natural environments (e.g. microcosms, etc.):
Animal studies have been done in containment. The results indicated that the GMO will not have any impact on chickens or other avian species living in close contact with vaccinated chickens.

9. Possible environmentally significant interactions with biogeochemical processes (if different from the recipient or parental organism)
There are no known or predicted involvements in biogeochemical processes.

H. Information relating to monitoring

1. Methods for monitoring the GMOs
No specific monitoring will occur.

2. Methods for monitoring ecosystem effects
No specific monitoring will occur.

3. Methods for detecting transfer of the donated genetic material from the GMO to other organisms
Not applicable since transfer is highly unlikely.

4. Size of the monitoring area (m^2)
Not applicable

5. Duration of the monitoring
Not applicable

6. Frequency of the monitoring
Not applicable

I. Information on post-release and waste treatment

1. Post-release treatment of the site
After removal of bedding material and faeces at the end of the experiment, the site will be cleaned according to standard business operations (as usual) and disinfected.

2. Post-release treatment of the GMOs

3. (a) Type and amount of waste generated
The nature and amount of waste like faeces, bedding material, waste water, in-ovo vaccination related waste and euthanized birds will be as usual.

3. (b) Treatment of waste
All waste will be collected and destroyed.

J. Information on emergency response plans

1. Methods and procedures for controlling the dissemination of the GMO(s) in case of unexpected spread
Not applicable

2. Methods for removal of the GMO(s) of the areas potentially affected
Not applicable

3. Methods for disposal or sanitation of plants, animals, soils, etc. that could be exposed during or after the spread
Not applicable

4. Plans for protecting human health and the environment in the event of an undesirable effect

Not applicable