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/11/006
(c) Date of acknowledgement of notification: 05/10/2012
(d) Title of the project: 'Vaccination of chickens with a combination vaccine against infectious laryngotracheitis (ILT) and Marek's disease (MD)'.
(e) Proposed period of release From (c) until 31 Dec 2016

2. Notifier

Name of institution or company: Intervet International bv.

3. GMO characterisation

(a) Indicate whether the GMO is a:

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

other, specify (kingdom, phylum and class)

(b) Identity of the GMO (genus and species)
The Innovax-ILT vaccine contains the live cell-associated Herpesvirus of Turkey (HVT) strain HVT/ILT-138 in a cell-associated form. This is a vector vaccine: the HVT/ILT-138 virus strain was generated by inserting glycoprotein genes of Infectious Laryngotracheitis virus (ILTV) into the HVT strain FC-126 genome.
HVT belongs to the virus family *Herpesviridae*, subfamily *Alphaherpesvirinae*, genus "Marek's disease-like viruses" (also knows 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 apathogenic for both turkeys and chickens. Hence, the vaccine strain was not obtained by attenuation of a pathogenic field isolate or genetic modifications by recombinant DNA techniques.
Genetic stability of the GMO (strain HVT/ILT-138) 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 (X) No (.)

If yes, insert the country code(s)
ES

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

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 (X) No (.)

If yes:
- Member State of notification
- Notification number

The GMO (vaccine Innovax-ILT) has been registered:

Country	*Registration number*
USA	16J1.R1
Argentina	136/09
Brazil	002/2011
Bolivia	003805/09
Canada	800VV/F10.0.16.2
Colombia	8283-BV
Costa Rica	USs14-98-03-4482
Kazakhstan	1-7.0/03440
Mexico	B-0273-250
Nepal	396/066-67
Peru	B.01.8.01.I.0956
Philippines	VBPR No. R-2017
Russian Federation	1-7.0/03440
Thailand	1F 15/54(B)

7. Summary of the potential environmental impact of the release of the GMOs.

This environmental risk assessment concerns the vaccine Innovax-ILT containing live HVT virus strain HVT/ILT-138 as active ingredient. Since 2007, Innovax-ILT has been safely used in the field in several countries where it has been registered: over 2,000 million doses have been used.

HVT is a fully apathogenic 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 and chickens. In turkeys the virus can spread via inhalation of dust particles shed from the skin from infected (or vaccinated) birds. Spreading of the virus to chickens via the natural route (inhalation of dust particles) is highly unlikely. Shedding however is observed in (vaccinated) chickens although limited and transient in nature.

Genetic modifications made by introducing the ILTV genes did not change the phenotype of the parent virus and the recombinant is therefore still fully apathogenic. The vaccine virus was shown to be genetically stable and is administered to chickens by injection.

The GMO could potentially spread through dust particles released from the skin of vaccinated chickens. Although unlikely, it is possible that they infect turkeys that live in close proximity of the trial but it is highly unlikely that they infect chickens that live in close proximity of the trial.

As the virus is fully apathogenic, the level of risk for both humans and the environment for Innovax-ILT 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*
	Family:	*Herpesviridae*
	Subfamily:	*Alphaherpesvirinae*
(ii)	genus:	Mardivirus (“Marek's disease-like viruses")

(iii)	species:	*Meleagrid herpesvirus 1* (Herpesvirus of Turkeys)
(iv)	subspecies:	…
(v)	strain:	Herpesvirus 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 but is widely spread (through vaccination).

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 apathogenic virus and the natural habitat is turkeys. It has been used worldwide for more then 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 (Marexine CA126 and 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 apathogenic 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 HVT antibodies. Alternatively, detection can be performed on DNA extracted from the 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
HVT is not indicated in the EU Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work, and is not considered as a zoönosis. No other species than avian are known to be susceptible to HVT infection.

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)
None.

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 Infectious Laryngotracheitis virus (ILTV) genes will be expressed in the chicken after vaccination with HVT/ILT-138 generating immunity against Infectious Laryngotracheitis (ILT).

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	(X)

Homologous recombination.

6. Composition of the insert

(a) Composition of the insert
Genomic fragment of ILTV containing glycoprotein genes and their regulatory elements.

(b) Source of each constituent part of the insert
The inserted region is from ILTV; no other sequences have been inserted.

(c) Intended function of each constituent part of the insert in the GMO
The inserted region contains only ILTV sequences: ILTV promoter regions, ILTV glycoproteins and polyA signal sequence.
The ILTV glycoprotein genes (including termination codons) are inserted; upon expression in the vaccinated chickens, the expressed proteins induce an immune response against ILT.

The function of the endogenous ILTV promoters is to facilitate the transcription of the glycoprotein genes. The function of the polyadenylation signal is the polyadenylation of the glycoprotein mRNAs.

(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 function are not known?

Yes (.) No (X)

If yes, specify

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

1. Indicate whether it is a:

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

other, specify

2. Complete name

(i)	order and/or higher taxon (for animals):	*Herpesvirales*
(ii)	family name for plants	…
	Family:	*Herpesviridae*
	Subfamily:	*Alphaherpesvirinae*
(iii)	genus	Iltovirus
(iv)	species	*Gallid herpesvirus 1* (Infectious laryngotracheitis virus, ILTV)
(v)	subspecies	…
(vi)	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 (X) No (.) Not known (.)

If yes, specify the following:

(b) to which of the following organisms:

humans (.)
animals (X)
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
ILTV is not indicated in the EU Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work, and is not considered as a zoönosis. No other species than avian are known to be susceptible to ILTV infection.

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
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 HVT/ILT-138 are not different from the recipient 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). In addition the GMO was not able to infect (and grow) in other cells than CEFs. Mammalian cell lines (Vero, MDBK and BHK-21) were not susceptible for infection with the GMO.

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 HVT/ILT-138 in chickens was studied in comparison to the recipient HVT FC-126 strain after subcutaneous inoculation of one day old chickens. At several points in time post-inoculation, several tissues of the chickens were examined for the presence of virus. There were no apparent qualitative differences between HVT/ILT-138 and HVT FC-126 in terms of virus localization and chronology of virus appearance in tissues tested in this study. Therefore, these results indicate that the biological features of HVT/ILT-138 are not different from the parent virus, in terms of dissemination of the virus and tissue tropism.

(d) is the GMO in any way different from the recipient as far as pathogenicity is concerned?

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

Specify

HVT/ILT-138 is still fully apathogenic when inoculated subcutaneously at a high dose into susceptible one-day-old chickens. Studies on the effect of HVT/ILT-138 (in comparison to HVT FC-126) after subcutaneous inoculation of a high dose on non-target avian species such as pigeon, quail, pheasants, and turkeys showed that the GMO, similar to HVT, is fully apathogenic in non-target species. Replication in non-target species was only demonstrated in turkeys and pheasants (limited).

2. Genetic stability of the genetically modified organism

Studies have been performed to demonstrate the genetic stability of HVT/ILT-138. The virus is genetically stable during passage 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. HVT/ILT-138 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
HVT/ILT-138 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 ILTV glycoproteins. Alternatively, detection can be performed on DNA extracted from the virus using the polymerase chain reaction (PCR). Specific primers in the HVT genome or ILTV insert region 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-ILT will be used in the Netherlands for the active immunization of chickens against ILT 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.

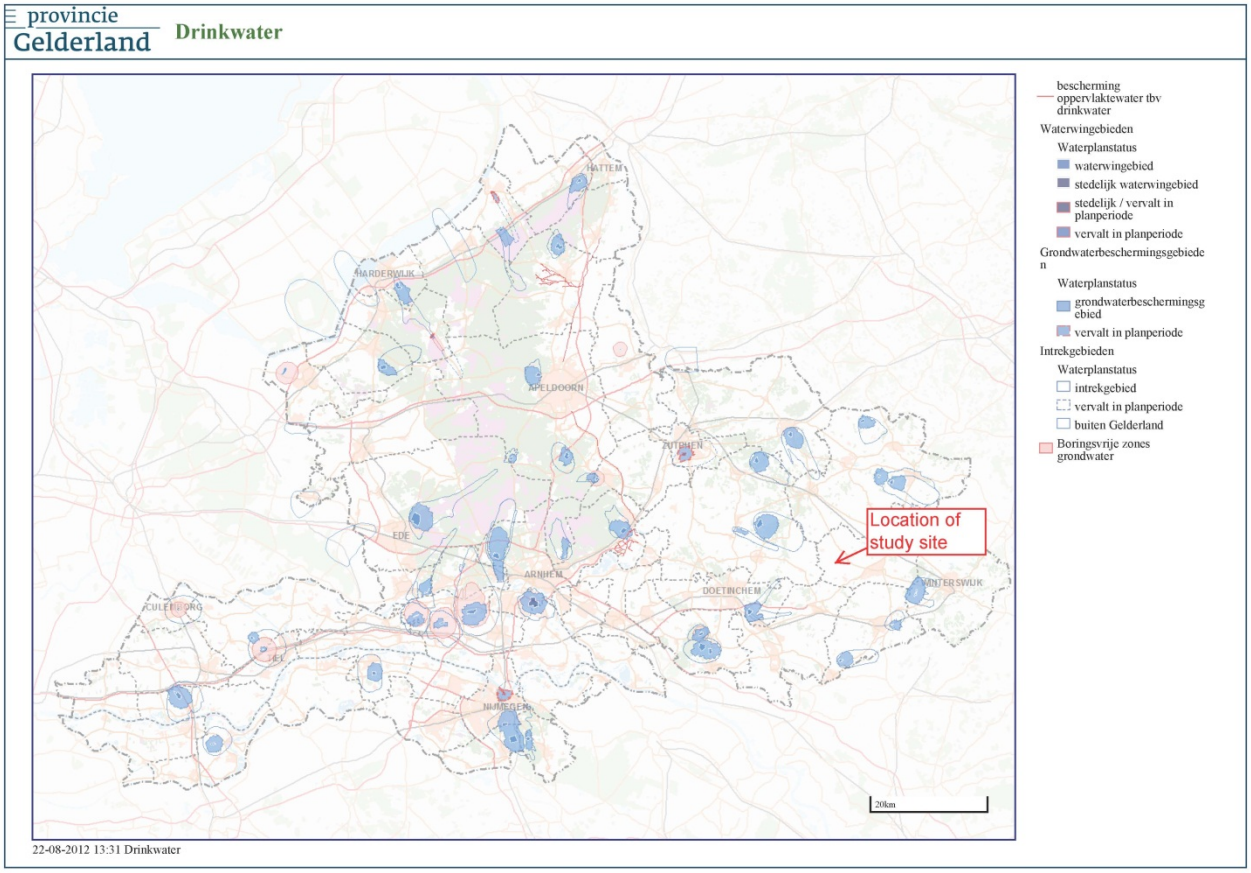
2. Is the site of the release different from the natural habitat or from the ecosystem in which the recipient or parental organism is regularly used, kept or found?
Yes (.) No (X)
If yes, specify

3. Information concerning the release and the surrounding area

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

(b) Size of the site (m^2):
(i) actual release site (m^2): 700
(ii) wider release site (m^2): ±1500

(c) Proximity to internationally recognized biotopes or protected areas (including drinking water reservoirs), which could be affected: At least 6 km (from border "intrekgebied" between Zelhem and Ruurlo, see map below).



(d) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO:
The nearest commercial poultry farm (broiler chickens) was located at approximately 1.5 km (has been closed now). No turkey farm is located with a radius of 2 km of 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 20.000 chickens will be vaccinated that is 20.000 doses (1000-3000 pfu/dose)

(b) Duration of the operation: Maximum 20 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 Q4 2012 or Q1 2013. This is the winter period in the Netherlands which has a European or maritime climate (gematigd zeeklimaat) with low temperatures (average temperatures of 2.5-3.5°C, average precipitation of 80 mm and an average of 50-60 sun hours per month in December and January).

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.
Innovax-ILT has been registered in USA, Argentina, Brazil, Bolivia, Canada, Colombia, Costa Rica, Kazakhstan, Mexico, Nepal, Peru, Philippines, Russian Federation and Thailand. Since 2007 more than 2,000 million doses have been sold worldwide. No reports have been received on adverse reaction caused by the vaccine.

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 then 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 for plants	na
(iii)	genus	Gallus
(iv)	species	G. Gallus
(v)	subspecies	Gallus Domesticus
(vi)	strain	na
(vii)	cultivar/breeding line	na
(viii)	pathovar	na
(ix)	common name	na

The vaccine is for use in chickens (different strains, breeds)

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

3. Any other potentially significant interactions with other organisms in the environment.
The GMO is fully apathogenic 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 fully apathogenic 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 2 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 HVT/ILT-138 has been modified by the insertion of a fragment containing the ILTV glycoprotein genes. 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 HVT/ILT-138 with a wild type HVT could only result in the virus reverting to the wild state (i.e. loosing the inserted ILTV genes), which would result in the wild type HVT which is also avirulent.
The potential for recombination of the HVT/ILT-138 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 become "superinfected" 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.

(d) 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 isolators or floor pens. The results indicated that the GMO will not have any impact on chickens or other avian species living in close contact with vaccinated chickens. Furthermore, the GMO has been used in the field to vaccinate chickens since 2007 and there are no reports of impact on 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 as monitoring is not considered necessary.

2. Methods for monitoring ecosystem effects
No specific monitoring will occur as monitoring is not considered necessary.

3. Methods for detecting transfer of the donated genetic material from the GMO to other organisms
Not applicable. Since transfer is highly unlikely this is not considered necessary.

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 with faeces, the site will be cleaned according to standard business operations (as usual) and disinfected.

2. Post-release treatment of the GMOs
All experimental birds will be euthanized and destroyed at the end of the experiment.

3. (a) Type and amount of waste generated
The nature and amount of waste like faeces, bedding material and waste water will be as usual.

3. (b) Treatment of waste
All waste, like bedding material with faeces, will be collected at the end of the experiment and incinerated.

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
   The GMO (HVT/ILT-138) is not pathogenic to humans. No adverse effects are expected.