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	***Hungary***
(b)	Notification number	B/HU/12/01
(c)	Date of acknowledgement of notification	2012.09.03.
(d)	Title of the project	***Field safety and efficacy study for Vectormune ND applied subcutaneously or in ovo to broiler chickens.***
(e)	Proposed period of release	***Within 3 months from the obtainment of the authorization for release. Planned date: between 2012 November-2013 January.***

2. Notifier

Name of institution or company: ***Ceva Phylaxia Co Ltd, Szállás utca 5, Budapest, Hungary, 1107***

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 GMO is a modified turkey herpes virus expressing the F gene of Newcastle disease virus. It belongs to the Mardivirus genus; current species name is Meleagrid herpesvirus 1, previously called Turkey herpes virus or HVT. It is the active ingredient of Vectormune ND, a live vaccine for chickens.

(c) Genetic stability – according to Annex IIIa, II, A(10)
According to the studies performed the GMO constructed is stable. The inserted sequences are well characterized and they are expressed in all studied passages of the strain.

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 /../../…

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

A vaccine containing the same GMO strain is currently authorized and marketed in the USA, Bolivia, Brazil, Colombia, Lebanon, Mexico, Peru, Russia, Thailand Turkey and Ukraine.

7. Summary of the potential environmental impact of the release of the GMOs.
None expected
The Vectormune ND vaccine does not represent a risk to humans or to the environment for the following reasons:
- ***The parent strain of the active ingredient (of the GMO) is the HVT virus which is a naturally nonpathogenic virus. It is not listed in Annex III to Directive 2000/54/EC of the European Parliament.***
- ***The genetic modification did not result in the change of the major biological properties of the strain (host range, spreading capability, shed and tissue tropism).***
- ***The safety of the GMO was tested in the most susceptible non target animals and it was found safe.***
- ***The genetic stability of the GMO was demonstrated***

- ***The GMO does not contain any harmful genes that could result in increase of virulence if transmitted to other organisms or antibiotic resistance genes***
- ***the GMO is well characterized and can be identified by the specific detection of the inserted gene sequence.***
- ***HVT or the GMO is not capable of replication in mammalian cells, does not produce any toxins and is not a known allergen.***

For these reasons it is considered that the risk of the use of the GMO to human health or to the environment is effectively zero.

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

1. Recipient or parental organism characterization:

(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)	***Turkey herpes virus (HVT)***

other, specify …

2. Name

(i)	order and/or higher taxon (for animals)	***Herpesviridae family***
(ii)	genus	***Mardivirus***
(iii)	species	***Meleagrid herpes virus 1***
(iv)	subspecies	…
(v)	strain	***Modified FC 126 strain designated rHVT NDV***
(vi)	pathovar (biotype, ecotype, race, etc.)	…
(vii)	common name	***HVT (= Turkey herpes virus)***

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:

Atlantic	..
Mediterranean	..
Boreal	..
Alpine	..
Continental	(X)
Macaronesian	..

(ii) No (.)
(iii) Not known (.)
(iv) Other (**X**)

The strain is present in poultry production environments all over the world and probably in wild turkey populations in continental climate regions

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

(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	

The FC 126 strain was originally isolated from turkeys by R.L Witter. It is naturally present in turkeys.

HVT is present in turkey and chicken producing environments worldwide due to the practice that it is used to vaccinate chickens against Marek's disease.

(b) If the organism is an animal: natural habitat or usual agroecosystem:
N/A

5. (a) Detection techniques
Immunostaining in culture on chicken embryo fibroblasts (black plaque assay) or PCR.

(b) Identification techniques
Immunostaining in culture on chicken embryo fibroblasts (black plaque assay) or PCR.

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

Yes (X) No (.)

If yes, specify

Related to vaccines strains against Marek's disease (BSL 2) ref: http://www.lgcstandards-atcc.org/LGCAdvancedCatalogueSearch/ProductDescription/tabid/1068/Default.aspx?ATCCNum=VR-584B&Template=animalVirology

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

The recipient organism does not represent any hazard for domestic or wild animals.

8. Information concerning reproduction

(a) Generation time in natural ecosystems:

Not applicable , the GMO is a virus, it is capable of replication only in live permissive cells. After inoculation of chickens the virus may spread to SPF turkeys after 35 days of contact exposure.

(b) Generation time in the ecosystem where the release will take place:

The same as in section 8.a)

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

(d) Factors affecting reproduction:

N/A

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	

Marek's disease viruses (MDV) do not form survival structures. The parent HVT and the rHVT NDV are both cell associated viruses, they lose infectivity when the cells that harbour them die. Survival in the environment is very short: it is 2 hours in wood shavings on 25°C (mimicking the environment of a poultry house).

Serotype 1 and 2 Marek disease viruses are able to replicate in the feather follicle epithelium of birds that are susceptible to the virus. MDVs shed by the feather dander may remain viable for a few months. However, the replication of HVT in the feather follicle epithelium is only limited and transient in chickens. No vertical or airborne infection with HVT is known. In turkeys the spread happens probably by contact exposure.

(b) relevant factors affecting survivability:
Cell associated virus cannot survive in the environment after drying. In wet environment it loses infectivity within 2 hours.

10. (a) Ways of dissemination
HVT is capable of replication only in live permissive cells of susceptible birds. Turkeys are the most susceptible to HVT. The virus may infect some other bird species, but according to the knowledge of the applicant only by contact exposure or by the parenteral route. According to literature data infection of chickens quail, pheasants is possible with HVT. However, it does not spread between chickens due to the replication of the virus in chicken feather follicle epithelium is only transient and the quantity of cell free virus shed by the vaccinated birds is very low, not sufficient to infect other bird except SPF turkeys. Spread from chickens to susceptible turkeys by contact exposure is possible due to the higher susceptibility of turkeys to the virus.
HVT may spread from turkey to turkey, also by contact exposure. No dissemination is known between wild birds.

(b) Factors affecting dissemination
The parent, or the GMO is cell associated, the cell associated virus is not able to survive in the environment after the cells die. Horizontal spread of HVT is known only in turkeys by contact exposure.

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

It is to note that there is a currently authorized vaccine in the country where the notification is made which contains a modified virus of the same parent strain the FC 126 (Authorization holder : Merial SAS , Vaxxitek HVT+IBD)

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
Expression of the F surface glycoproteins of Newcastle disease virus to act as antigens for immunization against Newcastle disease

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 (X) No (.)

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

(b) Identity of the vector
p45/46PecF2

(c) Host range of the vector
E. coli

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

The LacZ gene was used to give an electable phenotype to the plasmid, but it is not present in the final construct. No antibiotic resistance gene was used.

antibiotic resistance (.)
other, specify ***LacZ***

Indication of which antibiotic resistance gene is inserted

Not applicable.

(e) Constituent fragments of the vector
The vector or homology plasmid consist of the followings: homologous non-essential region of the HVT genome; NDV F-gene cDNA; PEC promoter at the 5' terminus and polyadenylation signal at the 3' terminus.

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

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

Transfection of the plasmid into chicken embryo fibroblast (CEF) cell culture infected with HVT. The sequences of interest were recombined by homologous recombination into the HVT genome.

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 …

6. Composition of the insert

(a) Composition of the insert

Gene insertion was characterized by genetic detection: The NDV F product was detected by Western blotting of CEF expressing F gene product of 60-kilodaltons (kd), using a mono-specific antibody to the F protein of NDV.

In addition two Southern blotting schemes are available as well as three PCR schemes to amplify three regions. The 378-bp PCR product contains sequence from HVT UL 46 to Pec. The 425-bp PCR product contains sequence from Pec to the 5' end of the F gene. The 619-bp PCR product contains sequence from the 3' end of the F gene to HVT UL 45. The sequence of these PCR products was analyzed and it was found that it is identical with the sequence of the plasmid.

A 3.6-kb SfuI-XbaI fragment and a 1.2-kb XbaI-XhoI fragment define the insert and HVT sequences flanking the insertion. In one Southern blot, a probe designed to bind to

the F gene anneals to the 3.6-kb SfuI-XbaI fragment. In the second Southern blot, a probe designed to bind to sequences flanking the insertion site, referred to as the insertion site probe, anneals to both the 3.6-kb SfuI-XbaI and the 1.2-kb XbaI-XhoI fragments.

The two Southern blots and the three PCR schemes described in Figure 6 were used to test the presence of the insert in the MSV and MSV+5.

Recombinant rHVT NDV virus plaques were identified by immunostaining against the F protein.

(b) Source of each constituent part of the insert

The used genetic motifs are the Pec promoter and the SV40 poly A addition sites. The Pec promoter was constructed by combining the core sequence of the chicken beta-actin promoter) and the enhancer region of the CMV IE promoter (Stratagene). Bacterial plasmid components are derived from well-defined pUC-based vectors. Vectors, such as pUC and the used host strains: E. coli JM109 and TG1 are considered to be Biosafety Level 1 pathogens.

(c) Intended function of each constituent part of the insert in the GMO

Immunization against Newcastle disease virus by the surface glycoproteins proteins

(e) Location of the insert in the host organism

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

Inserted into the HVT genome between two open reading frames.

(f) 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

The insert sequence was derived from Newcastle disease virus D26 strain. The nucleotide sequences of the HN, P, M and F genes have been reported in the literature. The donor gene is the F gene of the D26 strain. The gene was isolated from double-stranded DNA (cDNA) by converting the single-stranded RNA, negative sense genome of NDV to a double-stranded cDNA.

)

1. Indicate whether it is a:

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

- mammals (.)
- insect (.)
- fish (.)
- other animal (.)

(specify phylum, class) ***Paramyxoviridae,***

other, specify …

2. Complete name

(i) order and/or higher taxon (for animals) …
(ii) family name for plants …
(iii) genus …***Avulavirus***
(iv) species …
(v) subspecies …
(vi) strain …***D26***
(vii) cultivar/breeding line …
(viii) pathovar …***lentogenic***
(ix) common name ***Newcastle disease virus or Avian paramyxovirus serotype 1***

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 (X)
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 (X) No (.)

If yes, specify

Newcastle disease virus: Risk class BSL 2 according to 61/1999(XII.') EÜM.

NDV is not a human pathogen, however NDV may infect humans. The most common sign of infection in humans is conjunctivitis that develops within 24 hours of NDV exposure to the eye. Reported infections lasted for not more than a day or two.

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 …

(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 …

(c) is the GMO in any way different from the recipient as far as dissemination is concerned?
Yes (X) No (.) Not known (.)
Specify ***Dissemination rate of the GMO from vaccinated chickens is the same or decreased compared to the parent HVT.***

(d) is the GMO in any way different from the recipient as far as pathogenicity is concerned?
Yes (.) No (X) Not known (.)
Specify …

2. Genetic stability of the genetically modified organism

The F gene is expressed in visibly all of the plaques after in each of at least five passages of the virus.

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 GMO may be detected using PCR or by specific immunostaining using monoclonal antibodies (black plaque assay).

(b) Techniques used to identify the GMO

The identity of the GMO may be checked using PCR probes specific for the insert or by specific immunostaining using monoclonal antibodies (black plaque assay).

F. Information relating to the release

1. Purpose of the release (including any significant potential environmental benefits that may be expected)

Veterinary clinical field trial to assess the safety and efficacy of the vaccine strain in chickens under field circumstances to generate information for the future registration of the vaccine in accordance with Directive 2009/9/EC.

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):

Address of cooperating partner: Baromfi-Coop Kft. Petneházi keltetőüzem, 4561 Baktalórántháza, Hrsz. 039/1. The vaccination will be done on two different dates, three days apart, because the vaccine is indicated for in ovo and subcutaneous application. One half of the birds will be inoculated in ovo on the 18th day of incubation and the other half will be vaccinated 3 days later subcutaneously on the day of hatching.
The birds will be placed to the following farms:
Farm 1: Baktalórántháza
Address: 4561 Baktalórántháza, Hrsz. 039/1
Farm 2: Rohod
Address: 4563 Rohod, Jókai u. 35.

(b) Size of the site (m^2):

The poultry farms territory is: approximately 25 acres (Baktalórántháza) and, Rohod: 7 acres, having 800-1780 m2 sized closed animal houses.

(i) actual release site (m^2): …800-1780 m^2

(ii) wider release site (m^2): Not applicable

(c) Proximity to internationally recognized biotopes or protected areas (including drinking water reservoirs), which could be affected:

There are no such areas in the proximity.

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

Flora is not affected by HVT or the GMO. On the farm only chickens are kept. Spread from chickens is only possible to susceptible turkeys. There is no wild or domestic turkey population in the proximity of the farm. The environment of the poultry house is closed, no exposure to any wild birds is expected.

4. Method and amount of release

(a) Quantities of GMOs to be released:

95 000 doses of the vaccine is planned to be used (1 dose/ chick).

(b) Duration of the operation:

Approximately 42 days (full production period for broilers)

(c) Methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of the release

In house protocols are available to: store, transport and administer the vaccine. Additional protocols to adequately destruct all materials that have been in contact with the GMO are available. All these protocols and the zootechnical practices used in the animal producing facility contain the appropriate measures to avoid spread of the GMO in the environment. The territory of the farm is surrounded by physical barriers , the animal houses are closed.Trafic is restricted to authorized personnel .

5. Short description of average environmental conditions (weather, temperature, etc.)

The weather in Hungary is characterized by four well defined seasons, including at least one month with average temperatures below zero centigrade.

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.

The GMO is incapable of replication in humans or mammalians .
The cell associated GMO is not able to survive, disseminate in other organisms than some Galliform birds and is not pathogenic to animals or plants.

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

1. Name of target organism (if applicable) ***chicken***
   (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 …
2. Anticipated mechanism and result of interaction between the released GMOs and the target organism (if applicable)

   By vaccinating the chickens with the GMO a protective immune-response is anticipated to develop against Newcastle disease and Marek's disease.

3. Any other potentially significant interactions with other organisms in the environment

   None.

4. Is post-release selection such as increased competitiveness, increased invasiveness for the GMO likely to occur?
   Yes (.) No (**X**) Not known (.)
   Give details
   …

5. Types of ecosystems to which the GMO could be disseminated from the site of release and in which it could become established

   The GMO can replicate in turkeys, and some other Galliform birds. Spread is only known from turkeys, however no notable wild turkey population exists in the proximity of the release site.. In clinical studies it has been shown that the virus is safe in turkey and in other wild birds that may harbor the virus: safety study was done in in pheasants, quails, turkey and pigeons.

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 ***None***

   (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:

The exchange of genetic material from the GMO or to the GMO may be possible only between other HVT or MDV viruses infecting the same host cells.
In poultry production it is a common practice to use vaccines containing two different MDV strains (for example HVT +SB1). In the USA the compatibility of the use of Vectormune ND and SB1 vaccine was authorized by the USDA APHIS. No evidence of recombination of the virus strains or emergence of viruses having unexpected traits have been revealed, yet. Based on this it is highly unlikely that any harmful trait would emerge in other MDVs originating from the GMO if used on the field.

(b) from other organisms to the GMO:

The exchange of genetic material from the GMO or to the GMO may be possible only between other HVT or MDV viruses infecting the same host cells. Likelihood of postrelease selection leading to the expression of unexpected and/or undesirable traits in the GMO is highly unlikely.

(c) likely consequences of gene transfer:

The consequence of a gene transfer to other MDVs in the case it would happen, could be the expression of the NDV F gene. This could induce antibodies against NDV in the birds that would harbor the resulted virus.

8. Give references to relevant results (if available) from studies of the behavior and characteristics of the GMO and its ecological impact carried out in stimulated natural environments (e.g. microcosms, etc.):

A vaccine containing the same GMO is currently authorized and marketed in the USA, Bolivia, Brazil, Colombia, Lebanon, Mexico, Peru, Russia, Thailand Turkey and Ukraine. A vaccine containing the same parent strain –the FC 126- is authorized in Europe since 2002 (Vaxxitech IBD; Merial) No detectable environmental impact was reported so far.

9. Possible environmentally significant interactions with biogeochemical processes (if different from the recipient or parental organism)

Not applicable.

H. Information relating to monitoring

1. Methods for monitoring the GMOs

The vaccine strain can be detected by PCR or specific immunostaining method (black plaque assay).

2. Methods for monitoring ecosystem effects

HVT is incapable of replication in humans or in mammals and infective virions are not shed by the vaccinated chickens in a rate that allows spread between chickens, thus there should be no virus spreading from the vaccinated flocks. The GMO is not able to survive, spread and is not pathogenic to animals or plants. No susceptible wild fauna is present in the surroundings of the area. No effect in the ecosystem is expected.

3. Methods for detecting transfer of the donated genetic material from the GMO to other organisms

Genetic material from the GMO may be transferred only to MDVs. In case this event the only consequence may be the emergence of MD viruses expressing the F gene of NDV, no impact is expected.
The presence of the inserted sequence could be detected by PCR.

4. Size of the monitoring area (m^2)

Monitoring will be done on the poultry farm. The chickens will be placed into 4 closed animal houses each having the size of 800-1780m2.

5. Duration of the monitoring

The monitoring on the farm will be done from the starting date of the release, until the end of the production period in the vaccinated flock (aproximately42 days).

6. Frequency of the monitoring

Daily.

I. Information on post-release and waste treatment

1. Post-release treatment of the site

Surfaces that have been used during vaccination will be cleaned using the usual practice in the vaccination area after poultry vaccination. It has been showed that the vaccine strain does not survive after drying due to its cell associated nature.All materials used during vaccination will be put in special containers and destructed according to procedures for infectious waste.
The animal houses will be cleaned and disinfectedaccordingto the procedure in force on the farm. This includes sweeping, cleaning with water, with detergent, rinsing and disinfection with formaldehyde gas twice.
Any dead birds will be transpored by Szatev for decontamination. The litter from the poultry house where the animals were kept will be handled according to usual protocols on the farm, as no cell free virus is shed by the faeces and the cell associated virus is not able to survive in the litter or manure.

2. Post-release treatment of the GMOs

Used vaccine vials and other exposed materialswill be transported back to the applicants laboratories. pharmacy using closed, unbreakable leakage-free container and will be will be destroyed according to procedures for infectious waste. Unused vaccine will be returned to the sponsor by the study director.

3. (a) Type and amount of waste generated

During vaccination: Vaccine vials, needles, syringes, disposable aprons.

3. (b) Treatment of waste

Destruction according to procedures for infectious waste

J. Information on emergency response plans

1. Methods and procedures for controlling the dissemination of the GMO(s) in case of unexpected spread

Vaccine that may be spilled during the vaccination procedures will be cleaned using absorbent material and by disinfectants usually used on the farm. All materials used during the cleaning procedures will be destructed according to procedures meant for the destruction of infectious waste.

Poultry houses where the animals were kept will be disinfected using the usual disinfection and cleaning methods in force on the farm.

2. Methods for removal of the GMO(s) of the areas potentially affected

Vaccine that has been spilled during any of the vaccination procedures will be cleaned using absorbent material and by disinfectants usually used on the farm. All materials used during the cleaning procedures will be destructed according to procedures meant for the destruction of infectious waste. The litter from the poultry house where the animals were kept will be handled according to usual protocols on the farm, as the virus is not able to survive in the litter or manure.

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.