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: Spain
(b) Notification number: B/ES/05/01
(c) Date of acknowledgement of notification: 16/12/2004
(d) Title of the project: Field trial of a vaccinie against canine Leishmaniasis
(e) Proposed period of release: April 2005-Dec. 2006

2. Notifier

Name of institution or company: Consejo Superior de Investigaciones Científicas

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)

+ plasmid pORT

(b) Identity of the GMO (genus and species): Ankara strain of vaccinia virus + plasmid pORT

(c) Genetic stability – according to Annex IIIa, II, A(10): Stability verified on pervious laboratory experiences

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 (.) No (X)

If yes:

- Member State of notification
- Notification number

7. Summary of the potential environmental impact of the release of the GMOs. The GMOs will be inoculated into dogs. Environmental impact is not expected.

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

(specify phylum, class)

other, specify

2. Name
   (i) order and/or higher taxon (for animals)
   (ii) genus: ortopoxvirus
   (iii) species: vaccinia
   (iv) subspecies
   (v) strain: Ankara
   (vi) pathovar (biotype, ecotype, race, etc.): non aplicable
   (vii) common name: vaccine virus

3. Geographical distribution of the organism

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

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

   If yes, indicate the type of ecosystem in which it is found:

   Atlantic ..
   Mediteranean ..
   Boreal ..
   Alpine ..
   Continental ..
   Macaronesian ..

   (ii) No X)
   (iii) Not known (.)

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

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

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: in association with animals

   (b) If the organism is an animal: natural habitat or usual agroecosystem:
   non aplicable

5. (a) Detection techniques : Immunostrain
Western blot

(c) Identification techniques : Western blot

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: MVA is not pathogenic according to the CDC report on vaccination recommendations.

8. Information concerning reproduction

(a) Generation time in natural ecosystems: non aplicable

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

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

(c) Factors affecting reproduction: non aplicable

9. Survivability

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

(i) endospores (.)

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

(b) relevant factors affecting survivability:

10. (a) Ways of dissemination

non aplicable

(b) Factors affecting dissemination

non applicable

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)

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

In vivo expression of specific proteins.

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: plasmid pORT and MVA virus

(c) Host range of the vector: Mammalian cells

(d) Presence in the vector of sequences giving a selectable or identifiable phenotype

Yes (X) No (.)

antibiotic resistance (.)
other, specify: sequences of MVA

Indication of which antibiotic resistance gene is inserted: none

(e) Constituent fragments of the vector
CMV, T3, T7, pM31, SV40, latepA, lacO, LACK

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

(i)	transformation	(X)
(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	(.)

6. Composition of the insert

(a) Composition of the insert: LACK sequence

(b) Source of each constituent part of the insert: L infantum genome

(c) Intended function of each constituent part of the insert in the GMO: Insertion in the host antigen presenting cells to be presented to the I.S.

(d) Location of the insert in the host organism

- on a free plasmid (.)
- integrated in the chromosome (.)
- other, specify: is not known

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

other, specify: protozoo

2. Complete name

(i) order and/or higher taxon (for animals): kynetoplastid
(ii) family name for plants: trypanosomatid
(iii) genus: Leishmania …
(iv) species: infantum …
(v) subspecies: n.a. …
(vi) strain: MON-1 …
(vii) cultivar/breeding line: n.a. …
(viii) pathovar : n.a. …
(ix) common name: Leishmania …

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: in animals

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

Specify: has no pathogenic ability. Does not survive out of the host.

(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: Does duplicate very poorly.

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

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

Specify: The MVA is not pathogenic.

2. Genetic stability of the genetically modified organism: Acoording to “in vitro” experiments is stable.

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): n.a.

4. Description of identification and detection methods

(a) Techniques used to detect the GMO in the environment: Immunostain, Western blot

(b) Techniques used to identify the GMO: Western blot

F. Information relating to the release

1. Purpose of the release (including any significant potential environmental benefits that may be expected): Vaccination trial against canine leishmaniosis.

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 : MVA does not have natural habitat.

3. Information concerning the release and the surrounding area

(a) Geographical location (administrative region and where appropriate grid reference): Three Aragon zones

(b) Size of the site (m^2): n.a.
(i) actual release site (m^2): n.a.
(ii) wider release site (m^2): n.a.

(c) Proximity to internationally recognised biotopes or protected areas (including drinking water reservoirs), which could be affected: no

(d) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO: none

4. Method and amount of release

(a) Quantities of GMOs to be released: Port (100 ug/dog)
MVA ($5X10^8$ puf/dog)

(b) Duration of the operation: One year and a half.

(c) Methods and procedures to avoid and/or minimise the spread of the GMOs beyond the site of the release: The GMOs will be confined

5. Short description of average environmental conditions (weather, temperature, etc.): Continental conditions in Spain.

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: n.a.

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)

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

2. Anticipated mechanism and result of interaction between the released GMOs and the target organism (if applicable): protection against natural leishmania infection.

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

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: none

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

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

7. Likelihood of genetic exchange in vivo

(a) from the GMO to other organisms in the release ecosystem: n.a.

(b) from other organisms to the GMO: n.a.

(d) likely consequences of gene transfer: n.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.):

Gonzalo, R. et al. Vaccine 20, 1226-31 (2002)
Gonzalo, R et al Microb.Infect. 3, 701-11 (2001)
Ramiro, M.J. et al. Vaccine, 21, 2474-84 (2003)

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

H. Information relating to monitoring

1. Methods for monitoring the GMOs

Elisa with α-LACK serum in vaccinated dogs.

2. Methods for monitoring ecosystem effects: n.a.

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

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

5. Duration of the monitoring: Two years.

6. Frequency of the monitoring: monthly

I. Information on post-release and waste treatment

1. Post-release treatment of the site: n.a.

2. Post-release treatment of the GMOs: n.a.

3. (a) Type and amount of waste generated: n.a.

3. (b) Treatment of waste: n.a.

J. Information on emergency response plans

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

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

3. Methods for disposal or sanitation of plants, animals, soils, etc. that could be exposed during or after the spread: n.a.

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